

PHARMA R&D PRODUCTIVITY: DISCOVERING NEW MEDICINES

CEO OF MEDICINES DISCOVERY
CATAPULT, CHRIS MOLLOY
PROVIDES A COMPELLING
ANALYSIS OF PHARMA R&D
PRODUCTIVITY AND THE
DISCOVERY OF NEW MEDICINES
AND THE ROLE THAT THE SME
SECTOR CAN PLAY IN THIS

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FOREWORD

Milena Angelova

EESC member

European Economic and Social Committee (EESC)

Small and medium-sized enterprises (SMEs) are the driving force of the European economy and have huge potential to contribute to its development. Unlike in other parts of the world, SMEs in Europe also have to comply with extensive regulations at both national and supra-national level, which significantly increases the difficulty and cost of doing business. At the same time, SMEs are currently facing more challenges than ever: harsh competition, a shortage of skilled labour, new forms of work and consumption, increasingly complex and intense flows of information, limited resources for innovation, and complicated access to finance. Therefore, the European Economic and Social Committee (EESC) insists that the Small Business Act, and the two principles it establishes – “think small first” and “once only” – be made legally binding with no further delay. This should ensure that new regulations do not add to the burdens faced by businesses.

SMEs in Europe are a fairly diverse group. They can be differentiated on the basis of their size, lifecycle stage, location, type of ownership and sector of activity. Using a “one-size-fits-all” approach to developing SME policies has been a major shortcoming in the EU so far –

SME policies should explore the specific needs of all subgroups such as micro-enterprises, family and “traditional” businesses, social enterprises, liberal professions, and self-employed people, which often have very different legal forms and ways of operation. The EESC considers it essential to have a definition for each one of them.

“SMEs face serious challenges when it comes to accessing skilled labour, especially workers equipped with digital skills. One of the many reasons for this is the deteriorating situation in many regions in terms of population and ageing trends. Even in regions where the population is growing, it is difficult for SMEs to hire and keep highly skilled workers. SMEs need help to identify, attract and train human resources.”

The EESC sees the SME definition not as the answer to all SME problems, but as an instrument to provide for better access to support measures. The EC should assess whether the current definition of SMEs corresponds to their heterogeneity, sectoral dynamics, specific features and diversity during the last decade. The update must take into consideration the key recommendation based on the results of the consultations

and the decision of the EU Court of Justice. Should the SME definition be revised, the European Commission must do so in close cooperation with the SME organisations at European, national and regional level.

EU SME support tools should be translated into the language of business to be fit for their purpose of promoting growth and employment. To cope with the over-complexity of support mechanisms that have been identified and to bridge the wide communication gap between policy-makers and SMEs, it is important to seek out the help and advice of SME organisations that are most closely attuned to SMEs' needs, to make EU SME policies speak the language of business. In this regard, SMEs currently count on the national social partners as a significant positive factor in conveying their views on how to improve SME promotion policies. Their role, together with that of SME associations, chambers of commerce and industry and other SME intermediary organisations, should be strengthened.

“Small and medium-sized enterprises (SMEs) are the driving force of the European economy and have huge potential to contribute to its development. Unlike in other parts of the world, SMEs in Europe also have to comply with extensive regulations at both national and supra-national level, which significantly increases the difficulty and cost of doing business.”

The monitoring of the progress of EU SME policies remains fragmented. While SMEs' business activities are comprehensively recorded, the impact of EU support measures on these activities and the extent to which changes in SMEs' development can be attributed to these measures are not recorded. The EESC recommends that the Bulgarian, Austrian and Romanian rotating Presidencies of the EU Council establish and operate a joint permanent inter-institutional “SME Advisory Group” with the SMEs' representative organisations. It should start its work by following up and reporting on specific 2014-2020 work plans concerning horizontal and cross-sector SME policies and programmes.

SMEs face serious challenges when it comes to accessing skilled labour, especially workers equipped with digital skills. One of the many reasons for this is the deteriorating situation in many regions in terms of population and ageing trends. Even in regions where the population is growing, it is difficult for SMEs to hire and keep highly skilled workers. SMEs need help to identify, attract and train human resources.

Another challenge that has to be addressed is the need to encourage a stronger culture of entrepreneurship in Europe. The EESC has always stressed the crucial role of entrepreneurship in creating employment and growth – entrepreneurship should be better promoted, including by devising a special Pillar of Entrepreneurs' Rights, which should cover all special forms of entrepreneurship, and by announcing a Year of Entrepreneurs. The European Commission and the Member States should improve access to finance for entrepreneurs, the regulatory framework and entrepreneurial education.

SMEs have considerable potential to create sustainable jobs and lever growth. But in order to do so, they need an inclusive, coherent, effective, horizontal European SME policy, based on a multiannual action plan, which also takes into account the needs of all the different SME sub-groups and better marketing of SME policies. ■



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INTRODUCTION

Welcome to the marvellous May 2018 edition of Open Access Government. I'm delighted that this crammed edition is introduced by Milena Angelova, EESC member of the European Economic and Social Committee (EESC), who discusses how small and medium-sized enterprises (SMEs) are the driving force of the European economy.

Heading up the health & social care overview section is an excellent piece by Iceland's Minister of Health, Svandís Svavarsdóttir, who sheds light on her ambition to increase equality in the country's healthcare system. Another highlight of this section is an in-depth piece by Dr Paul De Raeve, Secretary-General of the European Federation of Nurses Associations (EFN) who provides an in-depth perspective on the extent to which nurses in Europe are code-signing an EU value-based health and social care ecosystem.

In the research and innovation section, we are honoured to feature an interview with the President of the National Research Council of the Swiss National Science Foundation (SNSF), Matthias Egger, who reveals the organisation's exciting new open access policy. Also, Denise Caldwell, Director of the Division of Physics at the U.S. National Science Foundation (NSF) provides a fascinating perspective on how the organisation is pursuing physics to the forefront of knowledge.

One special focus is space policy, which includes comment from Sebastien Moranta at the European Space Policy Institute (ESPI), who details Europe's potential to explore the Moon in co-operation with other great world powers.

Amongst the array of superb articles on blockchain innovation, one worth highlighting is from Antanas Guoga MEP, who shares his views on why 2018 an important period for rediscovering blockchain and bitcoin. Also, Crypto Valley Association's Tom Lyons says that after a stunning rally at the end of 2017, cryptocurrencies have lost almost two-thirds of their value. This is not necessarily bad news for the blockchain industry, Tom argues.

In our ICT section, I must mention a brilliant piece by John Swinney, Deputy First Minister of the Scottish Government, who tells us his thoughts on the importance of cybersecurity and why it is an essential component of delivering digital public services to citizens.

In our environment section, I am pleased to include an insightful interview with Catherine Bearder MEP, who explains the many challenges around Europe's environment today, including the funding of Natura 2000 sites and the Convention on International Trade in Endangered Species.

I trust that you find plenty of thought-provoking reading in this packed edition. Do feel free to get in touch if you would like to contribute to the journal in the future. ■

Jonathan Miles
Editor



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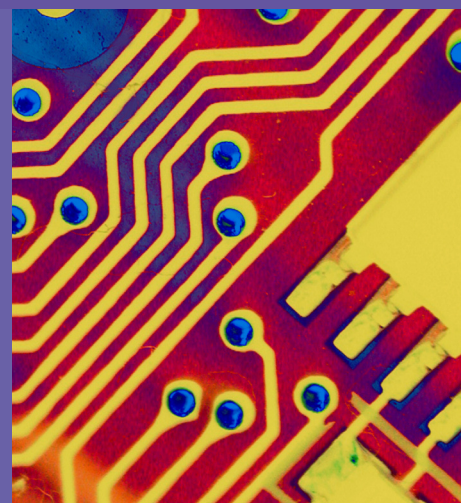
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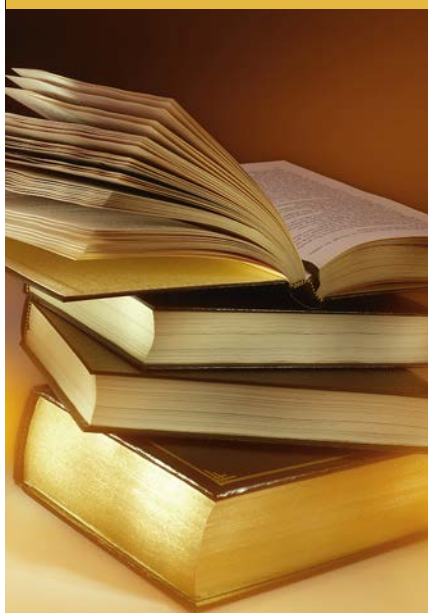
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Increasing equality in the Icelandic healthcare system

Iceland's Minister of Health, Svandís Svavarsdóttir, explains her ambition to increase equality in the country's healthcare system

Around 100 days have elapsed now since I took over as Minister of Health in Iceland's new government. I took on this cabinet post with the principal aim of increasing equality in the healthcare system. Our healthcare system should aim at offering everyone services comparable to the best available anywhere in the world and ensuring good access to healthcare services to everyone.

The new government's platform emphasises equal access to health care in a broad sense. This means that individuals' access to healthcare regardless of economic circumstances needs to be ensured. We can do this, for instance, by reducing the patients' contribution to healthcare services, to ensure that everyone can avail themselves of necessary care.

Equal access to healthcare services regardless of location is another factor. These include primary healthcare services, maternity and prenatal care and other types of care which are considered basic services. Demographic trends, the travel industry, transport and communications, varying distances from the capital area and changing age patterns result in different needs for healthcare institutions in non-urban areas. The service needs of each healthcare region have to be assessed and long-term programmes prepared aimed at providing services for all residents. Everyone in Iceland needs to be ensured suitable basic healthcare in their local area.

Action is also needed in many other areas of the healthcare system. Mental health services need to be reinforced throughout the country, aimed at providing



Svandís Svavarsdóttir, Minister of Health, Iceland

equal access to healthcare. The government will also place emphasis on prevention and public health, as well as launching a major campaign to expand care home capacity and ensure their financial operating basis. Hospital services are also a key component of a good healthcare system.

“The new government’s platform emphasises equal access to health care in a broad sense. This means that individuals’ access to healthcare regardless of economic circumstances needs to be ensured. We can do this, for instance, by reducing the patients’ contribution to healthcare services, to ensure that everyone can avail themselves of necessary care.”

A strong and well-functioning national hospital is a pre-requisite for ensuring a country-wide healthcare service which is comparable to the best anywhere in

the world. The operating basis of the National University Hospital (LSH) needs to be reinforced, as it is responsible for research and education and it is here that all more complex operations and extensive care are provided. LSH serves the entire country, complementing local healthcare and therefore provides support for the overall healthcare system.

We also need to give impetus to the construction of a new hospital in Reykjavík. One of the largest tasks we face in the coming years is to ensure better future premises for hospital services in Reykjavík.

All these aspects and plenty more, in addition, can be improved and their implementation assured by preparing a comprehensive healthcare strategy: Good healthcare services are based on a clear strategy, which is and should be part of the social contract. A strategy which prevails despite elections and changes in government focused on equal access to healthcare services regardless of economic situation, location or other factors and where public funds are utilised prudently and sensibly. Which is why it is a priority to complete work on drafting a clear and focused healthcare vision and strategy – as guidance for the ministry, all individual institutions and operators providing healthcare services. It must state clearly who is responsible for each area of service, whether they overlap and not least whether in some places services are lacking which are most definitely needed. By doing so we create a better society for everyone. ■

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Dementia research: Early diagnosis of brain disorders

Jon Snaedal, professor in Geriatric Medicine, Landspítali University Hospital in Reykjavik, Iceland shares his expertise on dementia research including the early diagnosis of brain disorders

Dementia is a syndrome not a single disease entity. The description of the syndrome is simple; “Dementia is a stage when cognitive decline has become severe enough to interfere with daily life.” Memory loss is the most prevalent symptom, but other symptoms of cognitive impairment are common as well, not least with the progression of dementia.

The most prevalent disease-causing dementia is a degenerative disorder of the brain, Alzheimer’s disease, named after the German physician Alois Alzheimer who first described the disease in a scientific journal. However, many other disorders can cause dementia, such as other degenerative disorders of the brain and vascular changes in the brain vasculature.

As Alzheimer’s disease is the most prevalent cause of dementia and as the number of cases increases constantly, it has received the most attention from the scientific community. Add to that the high cost of treatment and care and the fact that this is the only disorder of the top 10 causing death in modern society that has no effective cure, treatment or prevention and then it is easy to understand that there is an immense interest in finding a more effective treatment.

The reason for lack of effective treatment is not that no one has tried. On the contrary, there has been an



enormous effort on behalf of the pharmaceutical industry, but the sad fact is the high failure rate during the last 20 years as only one in every 30 compounds has come to the market. These treatment options are, however, of modest effect at best and the need for more effective treatment is paramount.

One reason for the failure of new treatment options might be that it is already too late by the time the person has progressed to dementia. To start treatment early has, therefore, become the holy grail. That poses extra problems as the diagnosis in these stages is not as robust as in the dementia stage. Therefore, research is currently focusing on early diagnosis at the stages preceding dementia; mild cognitive impairment (MCI) and

even in the preclinical stages, i.e. when there are no symptoms at all.

The scientists at the Memory Clinic at Landspítali University Hospital in Reykjavik, Iceland along with coworkers have been addressing this problem for the last 15 years. Iceland is a young society with only 13% of the population over the age of 65 but this will rapidly change in the coming 1-2 decades. It is also one of the smallest independent regions in the world and therefore it is fair to ask; what can such a small society bring to other populations and to the international scientific community?

The first answer is that to be small can also be advantageous. It is easier to bring messages to the population than in bigger societies and the will-

ingness to participate in research has proven to be great. It is also easier to bring about changes in the structure as it is easier in a small society to get attention from those that make decisions. Last but not least, the society seems generally foster creativity and this has borne fruit in research in Alzheimer's disease as well.

Let me give three examples of knowledge of value from research in Iceland:

Genetics

Due to the homogenous population and its isolation for centuries, there is a greater change to find genetic changes of value (i.e. the founder effect). One of the world's biggest research centre in genetics is based in Reykjavik (DeCode Genetics®) and due to the big interest among the population, more than one-third of every Icelander have participated in some project of the company.

Research into Alzheimer's disease has produced remarkable findings. The first preventive gene¹ was found for the disease, a finding that created huge interest not least as it fitted so well with the existing main ideas of the causes of the disease, the amyloid hypothesis. It is fair to say that this has had a substantial effect on the decisions of many the pharmaceutical companies to continue to look for therapeutic options based on the amyloid hypothesis. Other findings followed the most remarkable one is a new genetic risk gene, the TREM2 gene².

Diagnostic methods, electrophysiology

Researchers at the Memory Clinic have collaborated with an RDC in Reykjavik, Mentis Cura on a new method for diagnosis of Alzheimer's disease and other forms of diseases

causing dementia. The method is based on statistical methods in evaluating routine electroencephalography (EEG) creating indexes that show the likelihood of having a particular brain disorder.

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The most promising one is the Lewy index indicating the likelihood of Lewy body dementia in a person with a brain disorder, an outcome that has been verified in a multicentre Nordic study³. Another promising index indicates the prognosis of a person with mild cognitive impairment to be on the route to dementia of Alzheimer's type. Other indexes are being created.

Diagnostic methods, investigations of the eye

This is based on a new method, oximetry to measure the oxygen saturation in the small vessels in the back of the eye (in the retina). This is the only part of the central nervous system that can be directly visualised and in recent years, the retina has gained increased interest in research in Alzheimer's disease. The projects finalised until now have shown derangement in patients with mild to moderate dementia⁴, but also in individuals with mild cognitive impairment.

Modern research is not carried out in a vacuum. Collaboration with other institutions as well as over national borders is necessary. This is very clear to us in the mid-Atlantic Ocean and

therefore, research inside networks, both Nordic and European is being conducted, hopefully leading to outcomes that really matter for this patient group with so little hope today.

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The Accessibility Act: Improving life for people with disabilities

Lambert van Nistelrooij, a Dutch Member of the Internal Market and Consumer Protection Committee (IMCO) of the European Parliament reveals his thoughts on The Accessibility Act, focussing on improving life for people in Europe with disabilities

There are over 70 million people with disabilities in the European Union. With an ever-increasing ageing population, this number will go up. Due to low birth rates and rising life expectancy, the proportion of older people is also increasing rapidly. Within the coming 40 years, the number of people over the age of 65 will almost double, from 17,4% to 30%. Just like every EU citizen, elderly people and people with disabilities need full access to all aspects of life. In practice, however, this is not the case.

Elderly people and people with disabilities face hardship in accessing e-commerce services, using household appliances and accessing public transport and buildings. To address these issues and get ahead of the curve the European disability strategy 2010-2020 formulated

a specific focus on accessibility. Since this is a shared competence with the Member States, it hampered on the implementation.

In my capacity as MEP, I am both a member of the Committee Internal Market and Consumer Protection (IMCO), and President of the Parliamentary Intergroup on Active Ageing. Within the IMCO committee, we worked on the European Accessibility Act. This Directive improves the functioning of the internal market for accessible products and services by removing barriers created by divergent legislation.

Moreover, it defines the existing, but undefined, the obligation of accessibility as laid down in European law, especially when it comes to public procurement and



the structural funds. This facilitates both the work of companies and brings benefits for disabled and older people in the EU. For me, Active Ageing means helping people stay in charge of their own lives for as long as possible as they age and, where possible, to contribute to the economy and society.

“Together with the UN, we improve the accessibility of public space and participation in daily life for people with disabilities. The vote on the Accessibility Act in 2017 shows that we actually want to translate these rights into national practice. These rules mean concrete improvements for people with disabilities when it comes to mobile phones or banking services that can also be used by the blind and visually impaired.”

I also have a personal commitment to accessibility measures. In this respect, I want to be ahead of the curve in the healthcare sector. That is why from 9 to 12 July I will organise the photo exhibition “LetMEbe” in the European Parliament together with a Dutch institution for people with mental disabilities. We will also publish a booklet on the contributions from the Prisma exhibition.

Together with the UN, we improve the accessibility of public space and participation in daily life for people

with disabilities. The vote on the Accessibility Act in 2017 shows that we actually want to translate these rights into national practice. These rules mean concrete improvements for people with disabilities when it comes to mobile phones or banking services that can also be used by the blind and visually impaired. The construction of new public buildings is one of the examples in the legislation.

At the same time, we also take into account the position of small and medium-sized companies, by keeping the accessibility requirements workable and achievable for them. The directive tells them what needs to be accessible but does not impose ‘how’ they will achieve this. Thereby we leave plenty of space for innovation and dialogue with the users. This way we strike a balance between the needs of the citizens and the businesses. ■

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Nurses in Europe codesigning an EU value-based health and social care ecosystem

Dr Paul De Raeve, Secretary-General of the European Federation of Nurses Associations (EFN) provides an in-depth perspective on the extent to which nurses in Europe are codesigning an EU value-based health and social care ecosystem

In a European society where a growing number of people live with co-morbidities, non-communicable diseases and need complex care interventions, health and social care systems are expected to give greater importance to value-based outcomes. Value-based health and social care (VBHSC) is based on the patient's experience, with a focus on the quality of life, rather than the length of stay and moving away from medical diagnoses and complications systems (ICD-10 and DRG system) towards achieved outcomes from a patient perspective.

As different dimensions need to be considered in the health and social status, the promotion of healthy lifestyles is to be included in the value-based health and social care systems and as such, patients, providers and researchers should co-design the reforms needed to achieve an inclusive system for both prevention and promotion, so that they are stepping in before you get a disease. This approach refers to both self-management and co-responsibility.

In this context, the advanced role of nurses is necessary to respond to patients and citizens' unmet needs within a people-centred approach, based on the tailored continuity of care pathways which until today, has failed to turn integrated care into a reality, often financed through EU pilots.

However, to ensure a thorough implementation of an EU value-based health and social care ecosystem approach, it is key to shift from a fee-for-service payment system – which prioritises the volume of interventions over effective, efficient and even safe

people-centred care – towards bundled payments, prioritising care pathways and continuity of care thus leaving the medical DRG approach behind.

The European debate¹

The current discussion on value-based healthcare, not value-based health and social care, is often approached as a disruptive model of healthcare for Europe, hitting most of the EU policy debates, demonstrating that health is a top concern not only for EU citizens but also for politicians and health stakeholders.

However, a reflection process on disruptive innovation for health in Europe understood as 'creating new markets or add substantial value to the existing market' is too limited for investing in such a fundamental reform. We need to go beyond the market and growth discussion, focusing on improving outcomes for patients and citizens not just in the health sector, but combining health and social care, which are two interlinked sectors.

Add to the value-based equation key components as trust, user-centred innovation and data enabling technology to act, next to teamwork and health literacy, this will make the transformation of the existing models less disruptive for patients, citizens and healthcare professionals committed to their profession in the most complex and difficult working conditions they must operate in. The slogan "take care of those who care" needs to be taken more seriously when designing value-based health and social care ecosystems in the EU.

Following up on Prof. Rifat Atùn (Harvard School of Public Health and the Economist Intelligence Unit)²,

suggestions on the three key ecosystem challenges that need to be solved in the context of VBHSC – higher burden of disease (multi-morbidity) and disability; growing demand and expectation and higher costs – it is clear that concerning these elements, care team composition and advanced nurse roles need to be urgently addressed to make VBHSC ecosystems operational, implementable and most importantly, trustworthy. By assessing the needed regulatory changes, together with new business models and value networks, the current political discussion has the potential to build a holistic picture of how health and social care structures can be adapted to keep pace with innovation.

“The current discussion on value-based healthcare, not value-based health and social care, is often approached as a disruptive model of healthcare for Europe, hitting most of the EU policy debates, demonstrating that health is a top concern not only for EU citizens but also for politicians and health stakeholders.”

Despite some inspiring ideas that are circulating, most of the political debate still focuses on the medical component of healthcare, promoting the disease model and academic silo thinking which makes a real value-based discussion and regulatory co-designs based on value-based public procurement tools, difficult, unfortunately. It is time to move away from this silo value-based discussion towards an inclusive value-based approach that creates value for all EU citizens, combining the health and social care sector and empowering patients and the health and the social care professionals who are making it all happen on the frontline.

What value-based healthcare means for nurses

Value-based health and social care is a concept supported by the nursing profession if the conceptual framework goes beyond cost-control and markets³. From a nursing perspective, the creation of value for patients and citizens should be the main objective of all actors involved. Therefore, to provide a better quality and safe care outcome, such value should go beyond economics, relating more to the quality of care, life and wellbeing. As such, it is important to design a health and social care ecosystem that optimises value-



Dr Paul De Raeve

for-money and outcomes, shares accountability and liability and inevitable risks and rewards. Additionally, it is central to have a stronger focus on outcomes and more robust outcome measurements, including the patient experience and continuity of care data.

In particular, the measurement of “outcomes” needs to be designed with and for patients, bringing in the notion of the quality of life. Health and social outcomes measurements should go beyond just medical data and include continuity of care, accessibility and prevention indicators relevant for patients and citizens, crucial for improving their quality of life and their loved ones, often providing informal care, supported by nurses in advanced roles to achieve a level of integrated care. Anyhow, we need to be realistic as there is no single metric or set of indicators that will give the complete picture of health system efficiency in a country⁴.

Nowadays, the separate health and social care systems collect huge amounts of data on activity, but little information is given on the impact and results of these activities, particularly from the perspective of the patient, citizen and people. Yet people-centred care will never become a reality if systems fail to routinely and systematically collect information about experiences and outcomes of care pathways and modify these pathways, based on the data collected. Knowing that over 80% of households in ten EU member states report difficulty in covering the costs of professional home care services⁵, it is key to bring health and social care combined into the value-based ecosystem design.



The long-term trustful relationships patients have with frontline nurses can facilitate the smooth collection of outcome data. Through a regular sustained direct contact with the patient, appropriate support and coaching, nurses can make a significant contribution to measuring outcomes in a systematic way, supported by technology and being part of a culture in value-based ecosystems that empower patients, citizens and people.

However, when it comes to measuring outcomes, the main concerns relate to “who will collect the data” and what impact this will have on nurses’ direct patient time, knowing that they are already overstretched in terms of their workload. Nurses need technologies, including blockchain, at their disposal to support patients in collecting relevant outcome data, with new tools to measure patients’ outcomes over time and across their entire healthcare journey spanning hospital, ambulatory and community care, as well as mental health long-term and social care outcomes. It is impor-

tant to have standardised measures to compare these outcome data, which should be easy to interpret by all end-users. So, personalised electronic health records (PEHR) need to be available frontline through blockchain.

Likewise, privacy and standardisation of outcomes are fundamental to protect data against unjustified use. Having said that, nurses and nurse researchers need to be clear on how complex data, including qualitative data, can be deciphered and applied to support health and social system reform towards people-centred care. The industry will also need to be much clearer about how technology will bring nurses closer to patient care while collecting frontline outcome data, often on the request of patients the family themselves. How to measure the impact of care on people’s pain, function and quality of life, as well as their experience of care as key indicators of performance and how these measures can help move health and social care ecosystems for-

ward towards better value, need to be further explored with end-users in a co-creation mindset, instead of only consultations and academic expert-meetings, often in privileged meetings although the OECD PaRis project showed already huge progress. But please remember, not all EU member states are a member of the OECD!

“Nurses need technologies, including blockchain, at their disposal to support patients in collecting relevant outcome data, with new tools to measure patients’ outcomes over time and across their entire healthcare journey spanning hospital, ambulatory and community care, as well as mental health long-term and social care outcomes.”

To give deployment a real chance, as our medicine for pilotitis, key end-users in the VBHSC ecosystem need to support frontline nurses empowering patients. In the long run: ‘What is good for patients is good for nurses’. In this sense, the advanced nurse practitioner (ANP) is central to improve access and outcomes in a people-centred approach, ensuring the continuity of care across primary and secondary health and social care sectors. ANP is maintaining the continuity of care, as case managers, hold enormous potential for citizens to become active contributors and partners in the decision-making process, with ANP facilitating access, engagement and trust.

As an advanced role, nurse prescribing, supported through ICT solutions, shows already that in many member states that there are clear benefits for patients and citizens, in terms of increasing accessibility towards increased health and social literacy, facilitating a better understanding of the complexity of service delivery and reimbursement. Examples include prescribing in nurse-led warfarin clinics, community and hospital settings and national databases to enable transparent reporting of prescribing practice. End-users reported significant benefits through more accurate and effective prescribing, enabled through holistic nurse assessment, which also fosters a continuity of care. As a result, patients, citizens and people appear to be empowered with greater access to quality prescriptions and knowledge about their medications, as well as their potential side effects.

And as such, prevention comes into the equation, led by advanced nurse practitioners, creating a more refined and comprehensive view of the full value of investment in health and social care. This will sharpen the focus on disease prevention and avoidance of disease progression, incorporating the value of having citizens in good health and the benefits that this brings for the health and social ecosystem, for society and the economy.

Creating value for patients

To create a real value for patients, a shift is needed from a fragmented system in which patients struggle with access and in finding their way in the system – especially for patients suffering from multi-morbidities that need to interact multiple times with the system – towards a patient, citizen and people-centred model that empowers the individual⁶. Scaling up through end-user co-creation remains the key challenge! The evidence-based solutions often proposed by experts and EU advisors still miss the patient, citizen and people approach, resulting in recommendations being out of touch with reality. The outcome measurements currently used are not sufficiently developed by and for patients and citizens, that do not see their priorities reflected. The value of the patient and citizens perspective means something that brings concrete benefits and improvement in health and social terms, or in the quality of life. The patients’ priorities need to be reflected in terms of the outcome measurement with data that will inform the definition of EU standard sets of outcome measures that really matter to patients, with measures that should shift from individual episodes to an integrated approach.

This approach implies to include patients’ participation at all levels of the health and social care ecosystem design and to follow patients’ feedback by actions. A good example going towards this direction is the PaRis initiative⁷, based on patient-reported measures to enable better decision at clinical and policy level. PREMS and PROMS are the way forward, but more elements should be included such as life improvement. PROMS and PREMS need to be used to monitor and shape decision-making, leading to better outcomes and more value, by tailoring the continuity of care to people’s preferences. As such, personalised medicine

gets finally a higher level political dimension, moving from a medical discussion towards a health and social outcome discussion.

Consequently, there will be better management and resourcing decisions following the change in mindset. Therefore, the right methodology and structure need to be put in place to have a meaningful patient, citizen and people engagement, with financing, incentives to change and adapt the current model. To this end, patients and nurses need to be empowered through digital literacy and patient-driven technology. Nurses coaching skills in advanced roles are crucial to engage patients in this empowerment process and improve health and social literacy, as they have the capacity to explain in an easy to understand language what it is all about and how to best use these tools. This all comes back to one important component: building trust! And we all know that women play a central role in building trust!

In parallel, whereas it is widely shared that the reconfiguration of services around people, their needs, preferences and expectations is the way forward, we need to be realistic when it comes to the workforce needed to achieve person-centred and value-based ecosystems. The discussion is often very medical dominated, in terms of physicians running the systems, but we are already in 2018! So, let's change the rhetoric! People could potentially benefit the most from different care models that are more responsive to their needs and preferences and to help cut low-value and cost. However, helping them maintain health and wellbeing – and organising care around them – can be very complex if the 'continuity of care' is not fully developed and supported by technology⁸.

From DRG towards value-based reimbursements

How to anchor performance assessments and reimbursement models on patient-reported measures is not clear yet. Those member states which moved towards value-based ecosystems have used the outcome data to close hospitals (e.g. The Netherlands), units (e.g. cardiology) and often made nurses redundant. This is not the way forward to build trust!

The conditions for the organisation of the value-based health and social care in Europe are challenging, from organising services into integrated practice units, measuring outcomes and costs for every patient in the system, moving towards bundled payments for care cycles, with integrated care delivery across separate facilities and sectors, as well as to expand excellent services geographically, including remote areas. Fee for services and disease-related groups have made the system bankrupt, knowing that solidarity is questioned in the EU. So, payment needs to follow the outcomes and value achieved. This implies transparency of results and costs. However, we need to be very careful that competitive accreditation systems, mainly imported from the US, are not becoming a market trend, which needs to be paid by someone. We are wondering who that will be.

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The traditional and still widely embraced the fee-for-service system, known for producing bad incentives and being generally accepted as an obstacle to improving the quality of care, cannot be deployed in value-based health and social ecosystems, integrating preventive care services. As fee-for-service prioritises volume of care over effective and efficient people-centred care, it is key for nurses to acknowledge outcomes-oriented designs, refocussing, even giving up, the traditional data collection indicators^{9, 10, 11}.

Higher societal economic value

Adding the dimension of societal economic value to the current value-based healthcare discussions, they should be tackled within the Principle 16 “access to health care” of Chapter III of the European Pillar of Social Rights, social protection and inclusion. The right of citizens to timely access, affordable, preventive and

curative health care of good quality, becomes a key societal and economic challenge in the EU, to be addressed with an urgent re-focus on 'moving care back to the community'¹² by designing, in co-creation with advanced nurse practitioners, a more holistic and economic approach to value-based health and social care¹³.

To promote this approach, value-based health and social care need to focus on the continuity of care with health and social care teams being educated and trained together, with a strengthened teamwork to achieve better outcomes. So, there is no need for gatekeepers, dispatchers, rather a need for leadership in coordinating the care continuum in an advanced role, not being a 9 to 5 job. Therefore, political leaders need to realise and agree to bring the various end-users in health and social care – citizens, patient groups, professional bodies, service providers, insurers, industry, women representatives – together and formulate clear budgeted actions. There is often a roadmap without concrete actions, deadlines and impact measurements. Consequently, the EU should invest in policies promoting integrated and continuity of care, with end-users co-designing 'fit for purpose' health and social care ecosystems.

All EU and international institutions agree that the most important issue of the health systems is their sustainability and the need to transform volume approaches towards outcomes measurements, combining costs and outcomes to evaluate the value of the ecosystem, preferably health and social care combined. Creating positive economic value in societies by having a more holistic view on health and social care ecosystems – instead of silo views in education and work environments – will make it possible to achieve as the socio-economic value of nurses and nursing has been already researched^{14, 15}, but unfortunately not recognised enough in policy designs. ■

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Escherichia coli evolution from the lab, to the mice gut and the wild

Professor Olivier Tenaillon from IAME -INSERM outlines the evolution of *Escherichia coli* (*E. coli*) from the lab, to the mice gut and the wild

E. coli is presumably the most characterised bacteria. Since the 1940s, it has been the work-horse of molecular biology and established as a model organism. Yet, *E. coli* is not limited to the laboratory and has also a complex ecology in the wild. Being a commensal of the gut of vertebrates, it is responsible for a vast array of intra and extra intestinal diseases.

For long, the darkest side of *E. coli* was linked to the broad spectrum of diarrhoeas it was causing. Shigellas being some *E. coli* under the bad influence of a plasmid were for instance responsible to close to a million-child death per year in the 1970s. Better hygiene and treatment have led to a more than 10-fold reduction of that burden.

These hopeful signs are however contrasted by the rise of extraintestinal pathologies due to *E. coli* that are now killing close to a million person a year. Urinary tract infections, bacteraemia and some new-born meningitides are among the diverse afflictions *E. coli* may cause. These opportunistic infections were easily controlled in the past with antibiotic treatments. This is not anymore, the case: in 2017, the World Health Organization has ranked antibiotic resistant Enterobacteriaceae, that are dominated by *E. coli*, among the three most critical medical concerns linked to bacterial resistance.

The high level of resistance of *E. coli*

comes from its lifestyle as a commensal. In obligate pathogens, treatment is always associated with pathology and therefore often concentrated in the hospital. But for opportunistic pathogens such as *E. coli*, most antibiotic treatments are encountered as commensals in the gut. In this environment, both populations sizes and species diversity are high. This results in the efficient selection of resistance mutations and/or an efficient transfer of resistance genes from one clone to another or one species to another.

Moreover, this antibiotic selective pressure is not restricted to the hospital and promotes, therefore, a high prevalence of resistance in the community. *E. coli* is then the “enemy within”. It is happily carried by healthy individuals but may later invade extraintestinal compartments and launch an antibiotic-resistant infection if the patient shows any immune weakness.

These observations call for a better understanding of the dynamics of adaptation of *E. coli* in its commensal niche. In the IAME unit, Inserm U1137 in the Medical school of University Paris Diderot, we have for a long time been interested in characterising *E. coli* diversity in the gut of various vertebrates including humans. *E. coli* is divided in several phylogroups, the prevalence of which varies largely according to the host and its diet. Importantly, these phylogroups have very different contributions to extra or

intraintestinal diseases. Over the years, close to 30,000 strains have been isolated and stored. However, so far, very few studies have focused on time series within a host and as such, the dynamics of adaptation in the gut are still largely unknown.

One powerful way to study bacterial adaptation is the use of experimental evolution coupled to whole genome sequencing. With that approach, one can identify the molecular modifications that natural selection has favoured in a given environment. Most studies using this strategy have been done in vitro. They taught us global rules about microbial adaptation in both quantitative and qualitative ways.

Firstly, microbial populations are rarely mutation limited: many different beneficial mutations are occurring and competing with one another. Secondly, replicate populations tend to recruit different sets of mutations, but the repertoire of genes affected is limited such that convergence at the gene level is high. Thirdly, as the beneficial mutations invade the whole populations, they carry along some non-beneficial mutations called passengers. The fraction of the passenger to selected mutations is affected by mutation rate. Statistical analysis of the numerous passenger mutations found in high mutation rate populations revealed that these mutations are slightly deleterious on average. Finally, global regulators that control



“E. coli is then the “enemy within”. It is happily carried by healthy individuals but may later invade extra-intestinal compartments and launch an antibiotic-resistant infection if the patient shows any immune weakness.”

the expression of many genes tend to be frequent among the first targets of adaptation. While these patterns are globally true for in vitro systems their relevance in a more natural setting is unknown.

For that purpose, through the GenPhenBact ERC grant, we launched some in vivo experiments, in which a strain of *E. coli* was evolved in the mouse gut. In parallel to work performed in Isabel Gordo's laboratory in Gulbenkian Institute of Science in Lisbon, we used the simple system of streptomycin-treated mice to implant and maintain a specific strain of *E. coli* in the mouse gut. After a year of evolution, parallelism was observed at the gene level, but this time mutations affected no global regulators, but genes involved in metabolism.

Interestingly, in two completely independent experiments, we found that functional repressors were inactivated to allow a full induction of genes

involved in some sugar catabolism. These experiments constitute a step forward in the understanding of *E. coli* evolution in the wild, but they have also their limits, as the caged-mice environment homogeneity is far from natural.

To go further towards natural conditions, an alternative strategy is to sample some individuals at several time points and to sequence multiple *E. coli* strains from each sample. In a healthy individual sampled over a year, only two mutations invaded the population, including one synonymous mutation. This pattern contrasts with the observations made both in the mice and in vitro and suggests a much lower rate of evolution and potentially the lack of strong selective pressure for *E. coli* in the human gut. These results raise many new questions about the ecology of *E. coli* in the gut: what the generation time is, are their source and sink populations, how many bacteria actively contribute to

the population evolution. An ecological and evolutionary perspective is now needed to go further, with more systematic surveillance of some cohort and the developments of some genetic tools to track bacterial cells and their evolution in animal models.



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Antimicrobial resistance (AMR): Why Europe still needs to talk about a preventable crisis

Michele Calabro', European Health Management Association Policy and Communications Manager explains antimicrobial resistance (AMR), focussing on why Europe still needs to talk about a preventable crisis that could cause more deaths than cancer

Antimicrobial resistance (AMR) ⁽¹⁾ has been at the centre of the healthcare debate both in Europe and globally for an extended period. Numbers clearly illustrate the urgency of keeping a high level of attention on this topic, both at societal and economic level. AMR is estimated to be responsible for around 25,000 deaths per year in the European Union ⁽²⁾, 700,000 at the global level and projected 10 million deaths every year in 2050, ⁽³⁾ compared to, for example, eight million cancer-related deaths. Such stark numbers need also to be coupled with the healthcare and productivity loss estimated costs, which adds up to €1.5 billion annually in the EU alone, with an expected potential impact worryingly close to the financial crisis that hit global economies in 2008. ⁽⁴⁾

The European Health Management Association, located at the heart of the European dialogue and debate in Brussels, is offered numerous opportunities to participate in many of events, conferences, and research presentations on this topic, proving the buzz and commitment around it. Undoubtedly, EU institutions are trying to play a key role, in particular with the European Commission's 2017 EU One Health Action Plan against Antimicrobial Resistance ⁽⁵⁾.

The Plan is a good example of the 'health in all policies – one health' approach that the Commission is supporting and that is fundamental for AMR: the whole of society – that is a multi-sectorial approach to health hazards, in this case covering human health, environment but also agriculture, food and animal industry. Achieving its objectives revolves around three ambitious pillars: making the EU a best practice region: boosting research, development and innovation and intensifying EU efforts worldwide to shape the global agenda on AMR.



Michele Calabro'
Policy and Communications Manager

Looking at these promising interventions, it would be possible to think that the situation is largely under control and that all the key players are on the same track to tackle AMR. However, the reality is probably still far from being perfect, and it is clear that Europe still needs to talk about this issue and take further action; the key being to avoid taking the foot off the pedal. With the Plan in place, and with the future of health in the EU at risk, it is time for the Commission and DG Sante to really push, within the treaty limits, for a concrete move from policy development to policy implementation.

The involvement of all the stakeholders associated with AMR must become more than a wish list on a piece of paper. Healthcare professional associations need to take responsibility for continuing this topic; educational organisations need to ensure that AMR prevention has the right space in CPD training and education curricula; civil society organisations need to sensitise citizens about the risk of incorrect self-care and



What is AMR?

Antimicrobial resistance happens when microorganisms change when they are exposed to antimicrobial drugs (such as antibiotics, antifungals, antivirals, antimalarials, and anthelmintics). Microorganisms that develop antimicrobial resistance are sometimes referred to as “superbugs”. As a result, the medicines become ineffective and infections persist in the body, increasing the risk of spread to others.

(Source: World Health Organisation)

self-medication; the industry has to find solutions in R&D; the food and agriculture industry must understand the risk connected to AMR within their activities and implement guidelines and actions to reduce said risks ⁽⁶⁾.

And of course, institutions, both at national and supra-national levels, have the responsibility to provide the right tools, from funding to instruments and measuring, in order to create the right space to allow the main actors to take action on AMR. Antimicrobial Resistance ‘traditional’ measures and awareness raising ⁽⁷⁾ will have to be integrated with parallel preventive actions, including a necessary focus on the importance of rising vaccination rates (human and animal) and new vaccine research.

From EHMA's point of view, we will keep promoting this topic with our diverse constituency, focussing, for example, on the following four key points for health managers, one of the core components that make up our membership, together with research and policy-making: assess current situation regarding systems and infrastructure focussed on minimising the organi-

sational impact of AMR; review best practice on systems for operational response to risk of AMR; ensure boards considers problem, policies and monitoring, making links to health care-associated infection (HCAI), procurement, prescribing policies, etc.; and to assess training and information needs.

“AMR is estimated to be responsible for around 25,000 deaths per year in the European Union⁽²⁾, 700,000 at the global level and projected 10 million deaths every year in 2050,⁽³⁾ compared to, for example, eight million cancer-related deaths.”

Naturally, as mentioned, health managers are only a tiny part of the constellation of stakeholders, citizens included, that need to take full responsibility. AMR is a battle that must be won and can be won, but only by setting aside silos and taking off ‘blinkers’ can we finally move from policy to practice in a cohesive and harmonized way. ■

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A fragmented approach to child health is damaging the long-term health of the UK

A fragmented approach to child health is damaging the long-term health of the UK, warns President of The Royal College of Paediatrics and Child Health, Professor Russell Viner

The pressures on the health service are well documented – increasing demand and a workforce that’s not expanding at the same pace. Alongside this, there have been significant cuts to public health budgets which mean preventative health measures are not being prioritised. This presents a hugely worrying picture; a health service focused on dealing with acute need and a lack of resources being put into preventing ill health. It’s a viscous cycle that needs to be broken, otherwise current and future generations will face increasingly ill health and the financial burden on the NHS will continue to grow.



*Professor Russell Viner,
President of The Royal
College of Paediatrics and
Child Health*

Preventing ill health means getting health right during childhood. We know that the UK has some of the poorest child and adolescent health outcomes in Europe – in areas including mortality, diabetes hospital admissions and obesity rates. The RCPCH’s State of Child Health report, published in January 2017, set out in stark terms the fact the UK is failing its children and young people when it comes to their health – despite having one of the best health systems in the world, and some of the best trained doctors and other health professionals.

At the beginning of this year, The Royal College of Paediatrics and Child Health (RCPCH) launched its ‘State of Child Health: One year on’ scorecards for England, Scotland and Wales which describe progress made against the recommendations made in its landmark ‘State of Child Health’ report.

The scorecards for Wales and Scotland show their respective governments are making great strides in enacting policies to improve child health – and much more so than central government.

Wales is making good progress on protecting children and young people from the dangers of tobacco,

extending bans in public places to school ground, NHS sites and playgrounds and has made some exciting developments linked to child health research. It is also reforming the curriculum to provide real opportunity to improve health and wellbeing and sex and healthy relationship education – as young people consistently say they need – and is developing a strategy to help tackle obesity.

In Scotland, there has been commitments made in relation to child poverty – the passing of the Child Poverty (Scotland) Act with defined poverty reduction targets, on mental health – a strategy is in development – and there has been a commitment from Scottish Government to ensure specialist breastfeeding advice and support is delivered to women. The Scottish Government has also made commitments to expand the number of health visitors and to review statutory sex and relationships education in all schools.

For England, the very useful Childhood Obesity Plan, brave legislative action in the form of the soft drinks industry levy, the launch of a Digital Child Health Strategy, the publication of a new Tobacco Control Plan and the initiation of some specialist paediatric service

reviews, have each been welcome moves forward for child health. However, Westminster is still not giving children and young people's health the political attention it deserves in comparison to the Scottish and Welsh Governments.

In England, the scorecard revealed there had been no improvement in several fundamental areas including:

- No plans for an overarching child health strategy;
- No junk food advertising ban;
- No way of measuring UK breastfeeding prevalence and;
- No increased investment in child health research.

Of major concern are the deepening public health cuts which have worsened in the last year and are disproportionately affecting children's services. The scorecard marks this 'black', quoting latest statistics that show public health spending is over 5% lower in 2017/18 compared with 2013/14.

Take health visiting services for example. These services are vitally important for early identification and prevention of health and wellbeing issues and they are at risk of being lost entirely. Health visitors provide new mothers with breastfeeding support, health and nutrition advice and developmental advice for their baby. They also act as a tool for identifying parents who may be at risk of developing mental health problems. We need central government to give these services the attention they deserve by investing heavily in them, preventing ill health rather than trying to fix it later in life, which is often at a much greater expense.

Getting to grips with this country's obesity crisis is another example of where investment in prevention provides greater savings later in life.

Four-fifths of obese children will remain obese as adults and this will result in them losing between 10-20 years of healthy life. What's more, these adults are also more likely to have overweight or obese children. The cost of treating obesity is astronomical – in excess of £6 billion. For the sake of the nation's well-being and the financial stability of the health service, the government must get to grips with these kinds of challenges and move its

focus from the short-term and ineffective to long-term and productive.

There are many factors that lead to obesity, but one that has a significant affect is the marketing of unhealthy foods. We know that young people are hugely influenced by the adverts they see on television. They are much more likely to purchase these products or pressure their families to make the purchase and the food industry knows this. The top 18 spending crisp, confectionary and sugary drinks brands spent over £143 million advertising their products in 2016. The government must crack down on this by restricting the advertising of foods high in sugar, salt and fat before 9pm and protect those most vulnerable.

“The RCPCH's State of Child Health report published in January 2017 set out in stark terms the fact the UK is failing its children and young people when it comes to their health – despite having one of the best health systems in the world, and some of the best trained doctors and other health professionals.”

Investing in children is an investment in the entire population. A year has already passed since the RCPCH launched its flagship report on children's health. Meanwhile, the state of child health continues to stumble, and services continue to struggle under the pressure. The government must put children and young people first- and not fall victim to political short-termism. A 'child health in all policies' approach would ensure that the health implications for children are considered in whatever policy is implemented, resulting in a longer-term benefit for the population as a whole. We also need equality of priority for children's health with adult health. It is time for real parity between child and adult health because prevention is often much safer, cheaper and simpler than cure. ■

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Universal health coverage (UHC)

The World Health Organization's universal health coverage (UHC) initiative, plus the expansion of health insurance in Africa are explored here by Open Access Government

December 13th, 2017 marked the release of a report from The World Bank and The World Health Organization (WHO) regarding universal health coverage (UHC) and the “urgent upscaling” that is required to achieve new goals. The report stated with clarity, that there are currently immense problems within the current framework leading to large numbers of households being pushed into extreme poverty each year. This is because they have no choice but to pay for healthcare out of their own pockets, amounting to about 100 million people who still suffer because of health expenses.

World Bank Group President, Dr Jim Yong Kim has called it a “broken system” and one that needs to be transformed. He says: “But the system is broken: we need a fundamental shift in the way we mobilise resources for health and human capital, especially at the country level. We are working on many fronts to help countries spend more and more effectively on people and increase their progress towards universal health coverage.”

Currently, 800 million people spend at least 10% of their household budgets on health expenses for themselves, a sick child or other family members. This means that it is critical for the WHO and the World Bank to encourage and push further for countries to invest more effectively in their people and health, to build human capital and enable sustainable and inclusive economic growth.

This is all to achieve one thing, universal health coverage (UHC). It was confirmed in the report that half the world lacks access to essential health services – a fact deemed “completely unacceptable” by Dr Tedros Adhanom Ghebreyesus, Director-General of WHO.

“And it is unnecessary. A solution exists: universal health coverage (UHC) allows everyone to obtain the health services they need, when and where they need them, without facing financial hardship”, he adds.

“Currently, 800 million people spend at least 10% of their household budgets on health expenses for themselves, a sick child or other family members. This means that it is critical for the WHO and the World Bank to encourage and push further for countries to invest more effectively in their people and health, to build human capital and enable sustainable and inclusive economic growth.”

However, this is a difficult task to achieve and for it to be a success, many countries need to act. A place to do this is the global universal health coverage (UHC) forum 2017, where this report was a key point of discussion. On WHO's website, we learn that the forum is the culmination of events in over 100 countries, which started during December 2017 (Universal Health Coverage Day), to highlight the growing global momentum on UHC.” It was jointly organised by the Government of Japan, the World Bank, the World Health Organization, the United Nations Children's Fund (UNICEF), UHC2030 and JICA and seeks to showcase the strong high-level political commitment to UHC at both the global and individual country levels, highlighting the experiences of countries that have been pathfinders on UHC progress and also adding to the knowledge base on how to strengthen health systems and effectively promote UHC.

While highlighting the grave problems with the world's health services, the report also recorded some positive results. The 21st century has seen a steady increase in the number of people able to obtain some key health



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The building of the World Health Organization

services, such as immunisation and family planning, as well as antiretroviral treatment for HIV and insecticide-treated bed nets to prevent malaria due to investments and funding. This significant progress is, however, at a great imbalance.

While some areas of the world are gaining new benefits regarding healthcare, others are left with nothing at all. Each year, 6% of the world's population falls into extreme poverty for health reasons. In Africa, 60 to 70% of health expenditure is paid by households directly to healthcare providers, compared with an average of 46% worldwide. A serious accident affecting health may, therefore, involve "catastrophic" expenditure, forcing said families to sell their property, acquire debt or even take their children out of school to cover their medical expenses.

However, the recent planning to expand health insurance in Sub-Saharan Africa provides a potential solution to this problem. By spreading health costs over time using a prepayment mechanism and by mutualising the risk, insurance makes it possible to avoid the

"catastrophic" health expenses that are sending families into extreme poverty in these regions.

These figures go to show that there is still a long way to go in terms of universal health coverage (UHC). But the WHO and the Work Bank will take plenty more plans of action to fundamentally shift the ways in which they mobilise country resources and will continue to strive towards the achievement of their goals.

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Universal health coverage in Africa and the public good

Associate Professor at University of Oslo, Dr Ruth J. Prince provides an overview of universal health coverage (UHC) and why this is important in Africa when it comes to the state, citizenship, healthcare and welfare

Universal health coverage (UHC) is a World Health Organization (WHO) policy that has gained much attention since it appeared in 2010. Defined by the WHO as ensuring that all people can use the health services they need without financial hardship, UHC is a powerful concept that approaches public health as a matter of justice and obligation and is included in the Sustainable Development Goals.

UHC is particularly important in Africa, where structural-adjustment policies undermined state capacity, promoted privatisation and pushed the burden of payment onto the poor. Recent global health initiatives have done little to address the neglect of national healthcare systems and citizens' lack of trust in them. In these contexts, UHC reinserts questions of state responsibility and the public good into healthcare, appearing to turn away from neoliberal policies of fragmentation and privatisation of health services. The move towards UHC appears to offer a new approach and new ways of thinking about poverty and redistribution, the state and citizenship, health and development. In many postcolonial societies, where national systems of welfare and healthcare have historically been extremely limited, UHC suggests a progressive future.

There are, however, different models of imagining universal health coverage (UHC), which involve private as well as public sectors. Critics argue that

extending coverage often entails expanding access to private providers, which promotes medical markets at the expense of public services. In practice, UHC is thus not a universal model but a contested field surrounded by conflicting interests.

Health financing mechanisms, especially attempts to reform and extend health insurance, are a cornerstone of UHC policies. In much of Africa, insurance schemes have been limited to civil servants and people in formal employment. Extending insurance coverage means including people in the informal economy whose incomes are precarious. African governments are currently experimenting with different models of expanding health insurance, from national health insurance funds to community-based insurances to promoting the private insurance sector.

The variety of approaches towards health insurance underlines the fact that, while moves towards UHC appear to push for greater equity and inclusion, for more robust health systems and a stronger role for a state, the ways UHC addresses such issues remains unclear. While appearing to return to key post-war values concerning health for all, UHC takes shape in a very different world and it can serve very different social and political agendas.

UNIVERSAL HEALTH is a comparative anthropological project that critically

examines moves towards universal health coverage (UHC) in three African countries. Approaching UHC as a lens to explore the social contract between citizens and the state and the future of public healthcare in a context of increasing socioeconomic inequality and differentiation, it will follow the frictions that universal concepts accompanying UHC, such as obligation, solidarity and the public good, may have among policy-makers, state bureaucrats, health workers and citizens.

Moves towards UHC present interesting sites to explore issues of social justice and solidarity, as well as the social and political collectives forming around struggles for healthcare in Africa. Tracking the tensions surrounding UHC at the levels of policy-making, implementation, among beneficiaries and in public debate, the project uses ethnographic methodology through fieldwork that is multi-sited and multi-level.



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Dyspnea: Shortness of breath

Donald A. Mahler from the Geisel School of Medicine at Dartmouth and Clinical Resource Center of the Alpha-1 Foundation and Valley Regional Hospital, on behalf of the CHEST Foundation, provides an expert view on shortness of breath (dyspnea)

A healthy person breathes 12-14 times every minute without a thought. Breathing is automatic as the medulla in the brain stem sends electrical signals to the respiratory muscles to control how often and how deep to breathe. Receptors in the respiratory system provide information about how the lungs are working to the brain. Based on a neurobiological model, shortness of breath results from an imbalance or mismatch between the demand to breathe and the ability to breathe.

Dyspnea (*dys* – difficult; *pnea* – breathing) is the medical word for shortness of breath. The three major qualities are: work/effort of breathing; chest tightness; and unsatisfied inspiration. Those who experience breathing difficulty often report the feeling as, “I am short of breath,” or “I feel like I can’t get enough air in.” These experiences are a warning signal that the interaction between the respiratory system and the brain is not working properly.

Causes of shortness of breath

Shortness of breath is frequently classified by how it develops – acute (sudden onset) and chronic (over weeks to months). The most common causes of acute and/or chronic dyspnea are diseases of the heart (congestive heart failure, valve dysfunction and cardiomyopathy), of the lung [asthma, chronic obstructive pulmonary disease (COPD) and interstitial lung disease], of the pulmonary blood vessels (pulmonary embolism and pulmonary hypertension) and advanced cancer.

Other possibilities for chronic shortness of breath include anemia, deconditioning (“out of shape”) and psychological conditions, such as anxiety or depression. Although a low oxygen level in the body increases

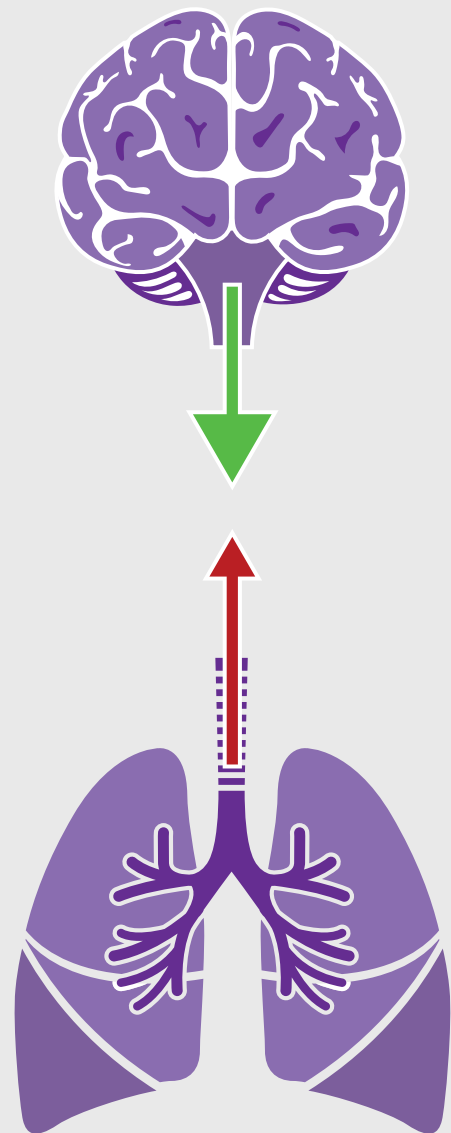


Figure A: simplified model for shortness of breath. The medulla sends an efferent signal (downward arrow) to the respiratory muscles that control breathing. Receptors in airways, lung parenchyma and respiratory muscles send afferent signals (upward arrow) to the brain about rate and depth of breathing.



ventilation and causes shortness of breath, a person may experience breathing difficulty despite a normal oxygen level.

Risk factors for heart disease include smoking, hyperlipidemia, hypertension, diabetes, obesity, physical inactivity and a family history of heart disease at an early age. Risk factors for lung disease are smoking, inhalational exposures both occupational and recreational and a family member with a specific lung condition. Deconditioning is a direct result of reduced physical activities due to a sedentary lifestyle or possibly an illness, injury, or surgery.

The diagnosis

For evaluation of acute shortness of breath, the person typically goes to an emergency department, whereas a complaint of chronic breathing difficulty is usually addressed in an out-patient facility. Assessment by a health-care professional includes a medical history, physical examination and appropriate testing that includes pulse oximetry.

For acute shortness of breath, a chest x-ray and electrocardiogram are essential. Two blood tests can be helpful. Prohormone brain natriuretic peptide (pro-BNP), secreted by the myocardium, is elevated in heart failure; and D-dimer, a product of fibrin degradation in the blood, is elevated with pulmonary embolism. Computed tomography (CT) scanning may be considered for further evaluation.

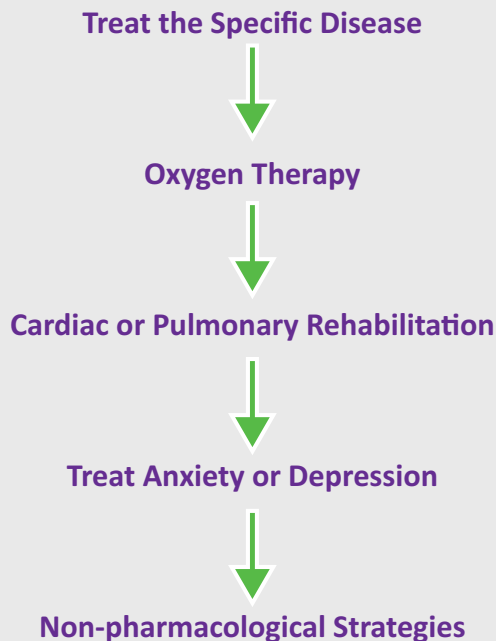
“Dyspnea (dys – difficult; pnea – breathing) is the medical word for shortness of breath. The three major qualities are: work/effort of breathing; chest tightness; and unsatisfied inspiration. Those who experience breathing difficulty often report the feeling as, “I am short of breath,” or “I feel like I can’t get enough air in.” These experiences are a warning signal that the interaction between the respiratory system and the brain is not working properly.”

For chronic shortness of breath, pulmonary function testing and a chest x-ray are typically ordered. Other

diagnostic testing may include a complete blood count, an echocardiogram and cardiopulmonary exercise depending on the individual's specific features.

Getting treatment

The following diagram provides a general approach to relieving shortness of breath.



Medications are usually prescribed as treatment for the specific disease that can relieve breathing difficulty. Oxygen therapy is provided if the individual's oxygen saturation is 88% or below. As many individuals with chronic heart or lung diseases are inactive due to their shortness of breath, referral to a cardiac or pulmonary rehabilitation program is important.

Studies show that supervised exercise training will relieve shortness of breath, improve quality of life and enhance functional ability. Anxiety and/or depression should be treated to improve an individual's mental health which may also alleviate breathing difficulty.

Non-pharmacological strategies for relief of dyspnea include a fan blowing air on the face, pursed lips-breathing (puckering the lips during exhaling in those with asthma and COPD), the leaning forward position with forearms resting on the thighs or hands on a shopping cart, listening to music, meditation, mindful breathing (an awareness of each breath so that the focus is on the present and breathing becomes relaxed) and yoga.

The priorities for future research

The following recommendations are proposed to advance the treatment of shortness of breath.

- Educate the public about the importance of shortness of breath as a symptom of heart and lung disease. It should not be considered a consequence of aging.
- Develop a new scale or instrument for individuals to rate shortness of breath related to daily and recreational activities. An ideal scale would be valid, reliable and responsive to treatments, would be used in clinical practice and would be accepted by regulatory agencies for approval of new therapies.
- Provide research support to develop new treatments. Possibilities include acupuncture, chest wall vibration and a custom engineered opioid that does not depress the respiratory drive to breathe.

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Understanding the process of intravenous access

Virginia M Stewart, MD outlines when intravenous access may be needed and how the skilful process should be undertaken

Patients coming to the Emergency Department (ED) with shortness of breath may have characteristics that impede intravenous (IV) access. Such characteristics may include hypotension, dialysis dependence, morbid obesity, history of diabetes, sickle cell disease, or IV drug use. One prospective observational study identified nearly 1 in every 9 to 10 adults coming to an urban ED had difficult venous access requiring 3 or more IV attempts.¹ If peripheral IVs are not established, patients may need a central venous catheter placed for life-saving medications administered. In addition to requiring physician skill, central venous catheter insertion carries a risk of complications including infection, arterial puncture or an aneurysm, and pneumothorax. Ultrasound-guidance for peripheral IV placement (UGPIV) has prevented the need for central venous catheter placement in 85% of patients with difficult intravenous access.² UGPIV has been performed by Emergency Medical Technicians (EMTs) in prehospital settings, as well as nurses and physicians. Patients who have been identified as having difficult access have higher patient satisfaction scores when ultrasound is used in peripheral IV access attempts.³

Frequently, the large veins of the antecubital fossa are sufficient to place large bore peripheral IVs needed for resuscitation. The brachial and basilic

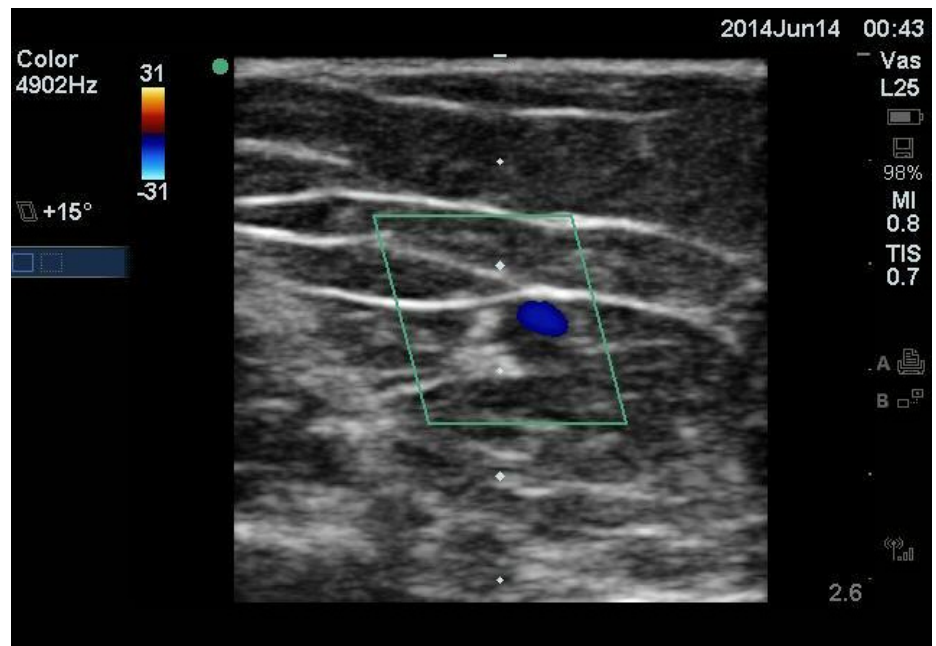


Figure 1: Short axis view of a peripheral vessel visualised with Colour Doppler (blue). The scale on the right of the screen demonstrates a total depth of 2.6 cm. A guide (white dots) in the centre of the screen marks each 0.5cm of depth. Therefore the depth of the vessel is between 1-1.5cm deep to the skin surface.

veins are easy to locate. The brachial artery is generally flanked by 2 smaller veins and the median nerve. Anatomically, these structures are medial to the insertion of the medial biceps tendon. This tendon is palpable in the antecubital fossa as the patient flexes the elbow. The basilic vein is located medial to the brachial vessels. Generally, it is more superficial, larger, and does not have an accompanying artery or nerve at the level of the antecubital fossa. As you move proximally up the arm (towards the head) the basilic vein dives deeper toward the humerus, and longer angi catheters may be required for cannulation.

When considering vascular access, there are 2 views, a short and long axis view. Cannulation from the short axis is considered 'out of plane' since the needle is perpendicular to the probe. A short axis approach 'looks' at a cross section of the vessel. Long axis uses an 'in plane' approach with the needle entering from the probe marker end, and 'looks' along the length of the vessel. Figure 1 identifies a vessel using colour Doppler in the short axis view. Figure 2 demonstrates a long axis view with a hyperechoic angiocatheter. Figure 3 is the same vessel in long axis with the angi catheter placed. While both approaches may be used for UGPIV placement, the



Figure 2: Long axis view of a peripheral vessel. The hyperechoic needle is visualized approaching from the top left of the screen into the vessel lumen.

benefit for the short axis is the ability to identify target veins as well as accompanying non-target (arteries and nerve) structures.

Identify the vein: remember the two C's

The two C's to remember for UGPIV access or for central venous cannulation are compression and colour (or Power) Doppler. Veins are thinner-walled and more easily compressed than arteries. This author advocates for finding a vessel first in the short plane, and compressing the vessel to ensure it is indeed a vein, rather than a less or non-compressible artery. Colour or Power Doppler may be utilised to determine if the pulsatile flow is consistent with an artery or vein. Colour Doppler uses red and blue to determine flow towards or away from the probe respectively. Power Doppler detects flow without concern for direction. Colour should not be relied on alone to determine arterial or venous flow due to the colour scale setting can be flipped or reversed, or aliasing can occur. Arterial flow is more pulsatile than venous. Venous flow may require distal augmentation (by squeezing the forearm distal to the probe) to appreciate the blush of colour.

Once the target vein is identified, the

depth from the skin surface should be noted. A common mistake is to use an angi catheter that is too long or too short. A general rule of thumb is to use a catheter length that is more than twice the depth of the vessel to ensure at least half the catheter lies within the vein. Sterile ultrasound gel should be used, with a covered probe to prevent infection. To prevent the risk of multiple punctures, this author advocates for first bouncing the needle on the skin over the point of entry. The tissue should deform at the top of the screen, and confirm the needle is over the target vessel. Once the skin is punctured, the needle tip is kept in view by angling the ultrasound probe until the target vessel is punctured.

To confirm placement, either a 'bubble study' with agitated saline may be performed or Colour (or Power) Doppler utilised to visualise saline flow through the cannulated vessel. A vessel that is not properly cannulated will demonstrate extravasation of saline around the vessel into the tissue before the tissue swells to a degree which is palpable on the surface of the skin. Figure 4 demonstrates confirmation of intraosseous (IO) lines utilise Power Doppler. A 10cc saline flush is rapidly pushed through the line, and flow is demonstrated beneath

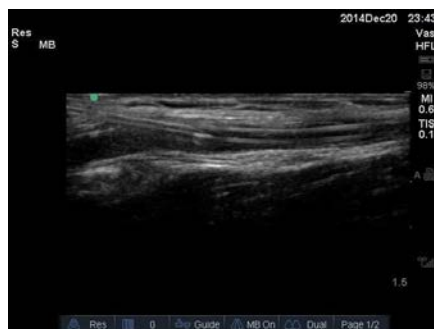


Figure 3: In this long axis view of a peripheral vessel the catheter has been threaded and is seen within the lumen of the vessel.



Figure 4: Power Doppler (orange) confirms placement of an intraosseus line within the distal tibia. The bright white line of the tibia cortex (in long axis view) is visualised at the top of the screen, with flow confirmation from a 10cc saline flush immediately distal (below) to the hyperechoic cortex.

the bony cortex in this adult tibia. If the line is improperly placed, the blush of colour using Doppler would appear in the soft tissues. For further information about UGPIV placement, visit: <http://rmgultrasound.com/piv-access/>

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Agoraphobia, associated anxiety disorders, phobias and conditions

Chief Executive of Anxiety UK, Nicky Lidbetter lifts the lid on the relief and rehabilitation of persons affected by agoraphobia and associated anxiety disorders, phobias and conditions and the extent to which these are treatable and manageable

Anxiety UK (AUK) was founded in 1970 by a gentleman called Harold Fisher. Harold was, at that time, supporting his wife Katharine who was living with agoraphobia and wanted to find ways to support others experiencing agoraphobia and phobic anxiety. In the 1970s and indeed for many years after, approaches to dealing with anxiety disorders were overly medicalised, with the standard treatment typically comprising a prescription for a benzodiazepine. Harold was an early pioneer in ensuring that anxiety was seen as just as significant a feature in mental healthcare as depression and indeed, serious mental health disorders such as psychosis.

Today, almost 50 years later, AUK is still a user-led organisation, run by people living with anxiety, stress, or anxiety-based depression. The charity works to relieve and support people with anxiety (and their carers) by providing information, help and understanding via a number of services, including 1:1 therapy. We have a high-profile medical advisory panel and work regularly with external agencies and healthcare professionals, as well as undertaking regular campaigning to raise awareness of the conditions associated with anxiety.

At the moment, it is estimated that 40% of disability worldwide is due to anxiety and depression and in the UK, there are between eight and ten million people seeking support with anxiety-related conditions at any one time and women are almost twice as likely to be diagnosed as men. Anxiety-related disorders have never had such a high profile as they do now; this change, however, has only occurred, materially, within the last five years.

Approximately 12 years ago, in 2006, AUK was lobbying the Department of Health to ensure that anxiety disorders were included in the main description as to who the national IAPT (improving access to psychological therapies programme scheme) was developed to support as the intention was to badge the scheme as being for those with depression and 'associated disorders'. Importantly, anxiety now has parity of esteem with depression and in-turn mental health disorders are increasing parity with physical health conditions.

AUK has always worked on the basis of early intervention and access to support where anxiety disorders are concerned. And we see that tackling challenges early often leads to enhanced treatment response and a greater chance of clients returning to their pre-anxiety state. Some forms of anxiety, however, are complex and require sustained interventions to alleviate symptoms. Agoraphobia for one, is one of the most challenging forms of anxiety to treat and it often occurs as the result of the lack of early intervention with panic disorder.

There is much misinformation about what agoraphobia actually is; "fear of open spaces" is an often-used expression, however, agoraphobia is often a complex collection of multiple phobias and anxiety disorders that have culminated to give the sufferer a sense of consuming fear about 'the outside world'. Fundamentally, agoraphobes can feel unsafe in situations that they cannot control, or cannot exit from easily, whether this be public transport, a movie theatre, shopping mall; fears are often both externally focussed (fear of others and situations) and internally focussed (fear of self/ internal symptoms such as vomiting, defecating etc).

Other similarly systemic forms of anxiety include GAD (generalised anxiety disorder), panic disorder and PTSD (post-traumatic stress-disorder). Having anxiety also vastly increases the likelihood of developing depression specifically related to having anxiety; in fact, mixed anxiety depressive disorder is one of the fastest growing primary care mental health difficulties.

As recognition of anxiety has progressed, so too has the availability and scope of treatment options. Previous tranquiliser-based medicines used in the 1970s and 80s, such as Valium, have given way to the use of SSRIs (selective serotonin reuptake inhibitors) as well as talking therapies, such as counselling and cognitive behavioural therapy (CBT). AUK has always been at the cutting edge of new treatments for anxiety, but we do recognise that therapies are not 'one size fits all' and that individualised approaches are key.

“At the moment, it is estimated that 40% of disability worldwide is due to anxiety and depression and in the UK, there are between eight and ten million people seeking support with anxiety-related conditions at any one time and women are almost twice as likely to be diagnosed as men. Anxiety-related disorders have never had such a high profile as they do now; this change, however, has only occurred, materially, within the last five years.”

For many years, our charity has aimed to put those living with anxiety in touch with a therapist within two weeks of their first contact with us. We offer many different forms of therapy, for example, clinical hypnotherapy and acupuncture.

We also recognise that the way people want to access therapy has changed and offer access to digital platforms for therapy; this is most welcomed by some of our clients who are house-bound because of their condition. In the last five years, our website has become the main hub for the way people access our services, whereas this used to be our telephone helpline.

At AUK we recognise that formal guidance on the treatment of anxiety disorders has not moved on significantly from the NICE guidance introduced in 2007 – despite interim updates. Next year, however,

new NICE guidelines will be introduced which we hope will expand the scope of reliable treatment options for anxiety.

We continue to invest in our own research (as funding for research into anxiety is virtually non-existent) and this has proved helpful in ensuring that our charity is continually able to best support the people who access our services because our research is so translational into direct support. In continuation of our spirit of innovative approaches to treatments we also continue to give a platform to treatment initiatives which don't have a large profile. The 'Head-Space' mindfulness App is one such success story which we helped to gain real traction in the self-accessed therapies market.

The answer to treating anxiety does not lie in one single approach and AUK have always championed the use of multiple, holistic interventions such as; improved diets, more exercise, talking therapies, medical therapies. We have a significant interest in 'nutritional psychiatry' and the links between eating certain types of foods and the effects upon mental health.

It is absolutely our mission to make sure that people who experience anxiety are given all of the information they need to improve their condition. We also recognise, perhaps most importantly, that trying to support children and young people who have anxiety, or who are at risk of developing anxiety is absolutely crucial to ensuring reduced rates of disorder occurrence, thereby lessening the potential life-long impact of the condition. ■

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A postcard showing a canopy bed: An ex-user of mental health services shares his story

In an interview, Franz-Josef Wagner tells Elena Posth from Pfalzkrankenhaus AdöR about his experiences as an ex-user of mental health services in the Rhineland-Palatinate region of Germany

Franz-Josef Wagner is the chairman of the state association of (ex-)users of mental health services in Rhineland-Palatinate (formerly LVPE, now NetzG), the regional association for self-help in mental health in Germany. From the very beginning he has been involved and in 1996, the year of its foundation, he was first vice chairman. Here, Editor at Pfalzkrankenhaus, Elena Posth talks to him about his various tasks and the messages he wants to convey.

Mr Wagner, how did the foundation of the LVPE come about?

Franz-Josef Wagner: The state law concerning mentally ill persons introduced in 1995 formed the basis of LVPE's foundation. In it, particularly,

the co-operation of mentally ill persons and the precedence of self-help over public help were pointed out. In May 1996, three chapters were merged to form the state association of (ex-) users of mental health services in Rhineland-Palatinate. The first chairman in those days was Winfried Krolla. I took over his position in 1999.

You have built up a new network organisation. What did you plan exactly?

Franz-Josef Wagner: The Federal Network Self-Help Mental Health (NetzG) was founded in November 2016. Until recently, it has not been registered, there were some formal problems. In May 2017, we had our second general meeting. In future, we want to voice our opinions regarding amending laws,

we want to have a say and represent our interests at the political level. So far, self-help groups have only offered their services. We want to change this. We want to monitor and control services by means of evaluations, for example, and to bring up a painful subject in the interests of all those concerned.

And what has changed in the state association?

Franz-Josef Wagner: Before the reorganisation, the complete work of the state association was split up between three persons. I, for myself, had more than 80 dates outside our office in Trier last year – without counting those in my surrounding area – I worked for more than 1,900 hours. To change this situation, we contacted a

business consultant for help. She advised us free of charge. Together with us, she reflected on the questions of what structure and name we should have in future, especially since we had no organisational or content-related contacts to the federal association of (ex-)users of mental health services. The new orientation of the LVPE is inspired by NetzG, the federal network of self-help in mental health. The problem is that most of our members do not want to work politically or give their name in general. This clearly shows that the stigma around mental health is still a very present one.

What forms of participation do you ask for? Are there good or bad examples?

Franz-Josef Wagner: I think, the Pfalzlinikum's initiative "The Palatinate makes itself/you strong – ways to resilience" is a very good example. It is a project with good publicity and participation. Looking at the development of this over last few years, I think that we are heading in the right direction. The World Congress of Psychiatry in October 2017 in Berlin mirrored a change in science: now an individual's subjective experience is important for objective research.

This gives meaning to psychosis. Some of my essays describe four different stages of my life: the normal phase; resignation; convalescence and the recovery phase.

In the second phase, the stage of resignation, I simply stayed in bed for 22 to 23 hours. This phase lasted for four to five years. In my case, convalescence was triggered by my daughter. One day she sent me a postcard showing a canopy bed and straight away I knew that my children were informed. However, I wanted to be a good dad and not just stay in bed.

Therefore, I decided to go cooking. In the beginning, my most difficult decision was to select a pack of rice when shopping. I said to myself: "You do not go back, you make a decision" and I trained this regularly. It can be compared to school: When you are in first class, you cannot pass your A-levels immediately. You must practice. It is the same in life.

Since when has there been a cooperation with Pfalzlinikum and how do you evaluate it?

Franz-Josef Wagner: In my opinion, the cooperation with Pfalzlinikum is very good. Prior to CEO Paul Bomke, it was zero, the medical directors did not accept us. They were simply not prepared yet. But since 2012, a very close, human and honest cooperation and communication between us has developed. Now, we have many interesting common projects, for example, EX-IN, recovery and symposiums.

What are your messages in life?

Franz-Josef Wagner: I know that I have just one life and I want to enjoy it and live in a simple way. I am grateful for every day I get up and am still alive. Previously, I found myself in a giant tunnel without any light at the beginning or the end, in the void. Today I have overcome everything. I live with a feeling of pure happiness. For me, the inner drive, the intrinsic motivation plays an important part. At first, I did not have it. I find it important that the persons concerned get more guidance from professionals. On your own, it is very hard to find a sense of direction.

What are your objectives or dreams in self-help?

Franz-Josef Wagner: My dream is to carry out quality checks by means of

evaluation and to ensure that many users and ex-users of mental health services find a job in the labour market. However, I do not want to award a TÜV stamp to organisations. Instead, I want to accept the existing system and do not want to make it exclusive.

What do you do when you have spare time?

Franz-Josef Wagner: I love hiking. For (ex-)users of mental health services, the communication with the external world is very important. For this reason, I am a member of the Trier chapter of the "Eifelverein" hiking club; I enjoy their inclusion of my deficiencies. There, I take over organisational tasks and promote interpersonal relationships. Hiking can strengthen and change one's personality.

Another hobby is cooking. Every day I prepare my meals, once a week together with another (ex-)user of mental health services. We choose a three-course meal costing approx. €6 per day, buy the food, cook, eat and do the washing up. My favourite meal is spaghetti with German caviar. I created this appetising combination myself!



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Pharma R&D productivity: Discovering new medicines

CEO of Medicines Discovery Catapult, Chris Molloy provides a compelling analysis of pharma R&D productivity and the discovery of new medicines and the role that the SME sector can play in this

Despite the greatest explosion in 'new' biology in 50 years, pharma R&D productivity has been falling for a decade. According to an annual survey by Deloitte, the top 10 global pharma companies now have a return on their R&D investment of only 3.4%¹ and spiralling R&D costs. Stand up the SME sector. Traditionally the agile, risk-taking tester of new ideas, primed to be bought, incorporated into a bigger firm or to see their product developed by others, the SME now has a new opportunity: to grow.

The Medicines Discovery Catapult has been established in Cheshire as a national collaborative R&D centre to help SMEs overcome barriers to growth. Our insightful sector analysis, *The State of the Discovery Nation*, shines a light into their world and shows how they can be helped to go beyond the next acquisition, to become the next generation of [UK] pharma.

A model in need of retooling

Discovering new medicines is hard. Every successful medicine has to do the biological equivalent of threading the eye of a moving needle from 500 miles away. It takes an average of 13 years, hundreds of skills, thousands of people, millions of pounds and countless data points to turn 1% of good scientific ideas into an approved treatment. Even then, as more diverse patients use the product the risk of failure remains. It is no wonder that for every successful drug brought to market, \$2 billion has been spent on it, and the sum of all the failures along the way.

If the blockbuster medicine is now a thing of the past what does the future look like? In short: more precise, more patient centred and more SME-led. We no longer need to develop new medicines for a mass market of medicine. Discrete groups of patients can now be selected by more advanced diagnostic tests, linked to

the medicine and measured throughout the course of their treatment. Much of this is being proven in the treatment of cancers but can be extended into many other important diseases.

Who will make these more focussed targeted medicines? The SME community. This is the agile sector of scientific risk-takers who take academic excellence and develop new, high-value products. However, despite the UK's global leadership in science and strong financial sector, we have fewer growth biotechs than we should, when compared with our global competitors. Too many of our firms are bought by a global market as soon as the green shoots show. Their ability to turn the hard-won experience into a strong growth pipeline is therefore limited, as is our ability to capture long-term value from the science we have invested in. This is a trend recognised in the UK's Life Science Industrial Strategy, published in 2017.

New approaches, tools and technologies

To find out how best to help SMEs address key barriers to growth the Medicines Discovery Catapult talked extensively to the community about what tools, techniques and support systems they needed. *The State of the Discovery Nation 2018* sets out clear calls to action for the sector, by the sector. It contains detailed responses from over 200 online surveys and 100 face-to-face interviews with senior executives from the drug discovery field.

The sector asks for two major interventions to help them reduce the risks of failure and become more efficient in translating great science into products.

1) Faster validation and release of academic disease model breakthroughs for industrial use
Biotechs need access to new models that better reflect



human disease. Many of this remains locked in academia. Biotechs find that overly complex IP negotiations and insufficient industrial validation dissuades them from using their limited time and expensive venture capital to extract these potentially game-changing approaches.

SMEs and academia need: Independent testing of potentially breakthrough models and informatics systems, driven by consented patient samples and data.

2) Easier access to national R&D capabilities that can help them

The NHS, charities and research councils have a wide range of infrastructure, insights and systems that could help biotechs develop their products without having to reinvest or reinvent. These capabilities are themselves fragmented, which, coupled to biotech's national fragmentation means they often go unknown or unused.

Biotechs and national capability owners need: greater visibility to each other and means by which industry can leverage public resources to create national wealth.

These are not simple challenges to address, but neither is medicines discovery in an SME with limited

resources. Much of the necessary infrastructure already exists across the nation. The clear call is to apply our industry skills, facilities and neutrality to bring them to bear in the right way, at the right time. With this focussed support, SMEs will themselves develop the products that will attract the investment they need to grow rather than sell, and the UK can firmly embed the next generation of this strategic industry sector. ■

1 A new future for R&D? Measuring the return from pharmaceutical innovation, Deloitte 2017.

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Acute respiratory distress syndrome

Cecilia Van Cauwenberghe, from TechVision Group, Frost & Sullivan provides a fascinating overview of acute respiratory distress syndrome, including refocusing clinical concerns and disease management, as well as the overall characteristics and health implications

Acute respiratory distress syndrome (ARDS) is an inflammatory disease characterised by a severe dysfunction of the pulmonary epithelial cells and the capillary endothelial cells. According to a recent study published by Yang et al., 2018, the process occurs along with the infiltration of alveolar macrophages and neutrophils in the respiratory track and additional biochemical adverse effects that may lead to cell apoptosis (programmed cell death), necroptosis (programmed form of necrosis or inflammatory cell death), NETosis (cell death characterised by the release of decondensed chromatin and granular contents to the extracellular space), and fibrosis (formation of excess fibrous connective tissue). The authors emphasise that inflammatory cascades also impair the regulation of vascular endothelial barrier and vascular permeability.

In fact, all stages of ARDS involve inflammatory responses, which mean that an in-depth understanding of immune signalling and regulatory pathways in the pulmonary microenvironment plays an essential role in ARDS clinical management with the development of effective therapeutic interventions. This perspective has detonated the interest in associating clinical and basic research with the critical study of the molecular regulation of inflammatory cells and cytokines in the pathogenesis of ARDS.

Statistical framework and economic burden

ARDS is a life-threatening respiratory disease that reports 10.4% of intensive care unit admissions worldwide, corresponding to more than 3 million patients with ARDS annually, according to the epidemiological studies carried out by Bellani et al., 2016. The authors remark that ARDS appears to be generally under-recognised and undertreated, thereby explaining its high mortality rate. In the United States alone, ARDS

affects approximately 200,000 patients each year, representing broadly 75,000 deaths annually. According to Frost & Sullivan's competitive pipeline analysis, Das, 2015, ARDS involves 3.6 million hospital days per year in this country. Furthermore, from patients surviving the disease only 49% can return to work, which implies an average annual loss in earnings of \$27,000 per ARDS patient. Moreover, 13% of ARDS patients on average need permanent renal replacement therapy, typically dialysis, that is, an additional annual cost of dialysis \$89,000 per ARDS patient. Summarising, the ARDS economic burden in the United States is approximately \$1.16 billion per year.

Therapeutic approach

Early recognition guidelines

The Berlin definition proposes three categories of ARDS based on the severity of hypoxemia: mild, with a ratio of arterial partial pressure of oxygen to fraction of inspired oxygen ($\text{PaO}_2/\text{FiO}_2$) between 200 and 300 millimetres of mercury (mmHg); moderate, with a $\text{PaO}_2/\text{FiO}_2$ between 100 and 200 mmHg and severe, with a $\text{PaO}_2/\text{FiO}_2$ lower than 100 mmHg. These categories are additionally supported by explicit criteria related to the timing of the syndrome's onset, the origin of oedema and the chest radiograph outcomes for early recognition.

Biochemically, ARDS is typified by three main phases: 1) an exudative phase in which antigen-presenting cells (APCs) trigger immune responses leading to the aforementioned epithelial and endothelial cell damage; 2) a proliferative phase in which the release of vascular endothelial growth factor (VEGF) increases vascular permeability and exudation of protein-rich fluid that may become chronic; and 3) a lung remodelling phase in which lungs change their architecture involving the



formation of fibrosis and honeycomb geometries thus impairing gas exchange. Therefore, an effective ARDS clinical management necessarily implies recognising first signs at early stages and once diagnosed, preventing tissue hypoperfusion and adequate gas exchange ratio.

“...from patients surviving the disease only 49% can return to work, which implies an average annual loss in earnings of \$27,000 per ARDS patient. Moreover, 13% of ARDS patients on average need permanent renal replacement therapy, typically dialysis, that is, an additional annual cost of dialysis \$89,000 per ARDS patient. Summarising, the ARDS economic burden in the United States is approximately \$1.16 billion per year.”

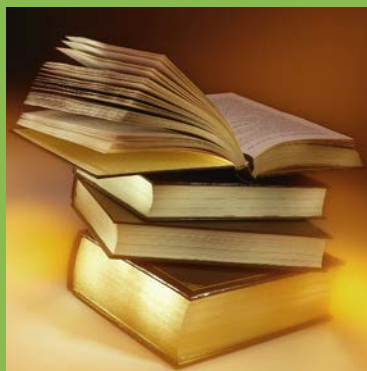
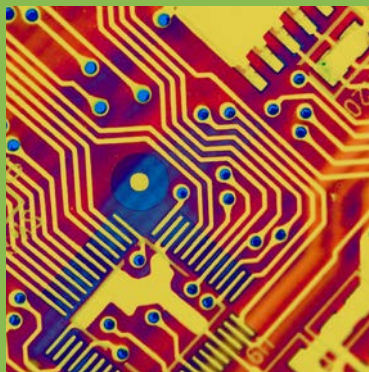
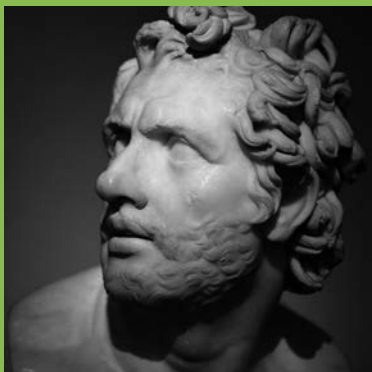
Disease management discussion

Fan et al., 2018, have reviewed the advances in diagnosis and treatment of ARDS over the last five years by

critically and systematically assessing MEDLINE, EMBASE and the Cochrane Database of Systematic Reviews dating from 2012 to 2017 and searching for randomised clinical trials, meta-analyses, systematic reviews and clinical practice guidelines for ARDS.

According to the researchers, no effective therapeutic treatments focused on the underlying biology of the disease are exhibited. Gattinoni et al., 2018, have noted that present disease management approaches are based on improved guidelines for lung-protective mechanical ventilation and symptoms relief. The authors also remark the level of uncertainty in many studies, the complexity of the disease, as well as, inappropriate enrollment criteria and imprecise deployment of the interventions, among others. Regarding this approach, Beloncle et al., 2018, have remarked that despite major enhancements in ventilation strategies, hospital mortality and morbidity associated with ARDS remain dramatically high. The authors foresee

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some potential improvements in the field by paying attention to adjacent measures to limit the risks of inflammation, infection and fluid overload, prevent ventilator-induced lung injury and patient self-inflicted lung injury and advance pharmacological treatments on the base of immune system modulation. However, according to Reiss et al., 2018, inflammation-directed therapies have yet failed to improve the outcome in ARDS patients.

“ARDS is a life-threatening respiratory disease that reports 10.4% of intensive care unit admissions worldwide, corresponding to more than 3 million patients with ARDS annually, according to the epidemiological studies carried out by Bellani et al., 2016.”

The authors highlight the underestimation of the syndrome's complexity, including its complex interrelations between inflammatory circuits. Indeed, recent gene expression analyses from patients with ARDS reveal a vast number of distinct expressed genes significantly overlapping immunologic conditions. To address this concern, the researchers propose the combination of model-driven simulations, data-driven modelling and hypothesis-driven experimental studies illustrating regulatory circuits interacting during pulmonary inflammation. Hussein et al., 2018, also claim the crucial need to introduce 'omics' approaches to assess suitable therapeutic targets and develop new strategies to reduce heterogeneity and optimise the design of clinical trials.

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Further reading

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Assessing the RAGE pathway in at-risk critically ill patients: A step towards better ARDS prediction?

Associate Professor of Medicine, Anesthesiology and Critical Care at Université Clermont Auvergne, Matthieu Jabaudon assesses the RAGE pathway in at-risk critically ill patients and asks if this is a step towards better acute respiratory distress syndrome (ARDS) prediction

In recent years, there has been growing interest in identifying and treating patients before they develop acute respiratory distress syndrome (ARDS) ([see our ebook](#)). However, little is known of the biological processes that precede overt ARDS and because ARDS does not develop in most patients with identifiable risk factors, those subgroups at highest risk of developing ARDS should be better identified.

The focus on identifying patients before they develop ARDS has increased substantially with the validation of a lung injury prevention score (LIPS) to predict the development of ARDS in 18% of patients at risk of developing the disorder. Recent data has suggested that plasma biomarkers such as angiopoietin-2 may enhance the prediction of ARDS onset among a general population of critically ill patients without ARDS on admission ([Agrawal A. et al. Am J Respir Crit Care Med 2013. doi: 10.1164/rccm.201208-1460OC](#)).

The soluble form of the receptor for advanced glycation end-products (sRAGE), which is a marker of lung epithelial injury, may better predict ARDS in selected at-risk patients, e.g. after cardiac surgery, severe trauma, or in patients at risk of postoperative

pulmonary complications after major surgery (see [New biomarkers of lung injury in ARDS](#)).

The main soluble forms of RAGE include the extracellular domain of membrane RAGE that is cleaved by proteinases and the endogenous secretory RAGE (esRAGE), which is produced after alternative splicing. Some single nucleotide polymorphisms (SNPs) within the AGER gene (e.g. rs1800625, rs1800624, rs3134940 and rs2070600) have been recently associated with modified plasma sRAGE and distinct outcomes during inflammatory diseases, such as arthritis, major trauma or lupus and the recent development of genomic applications could facilitate better prediction of ARDS. However, the predictive value of AGER gene variants for ARDS remains under-investigated.

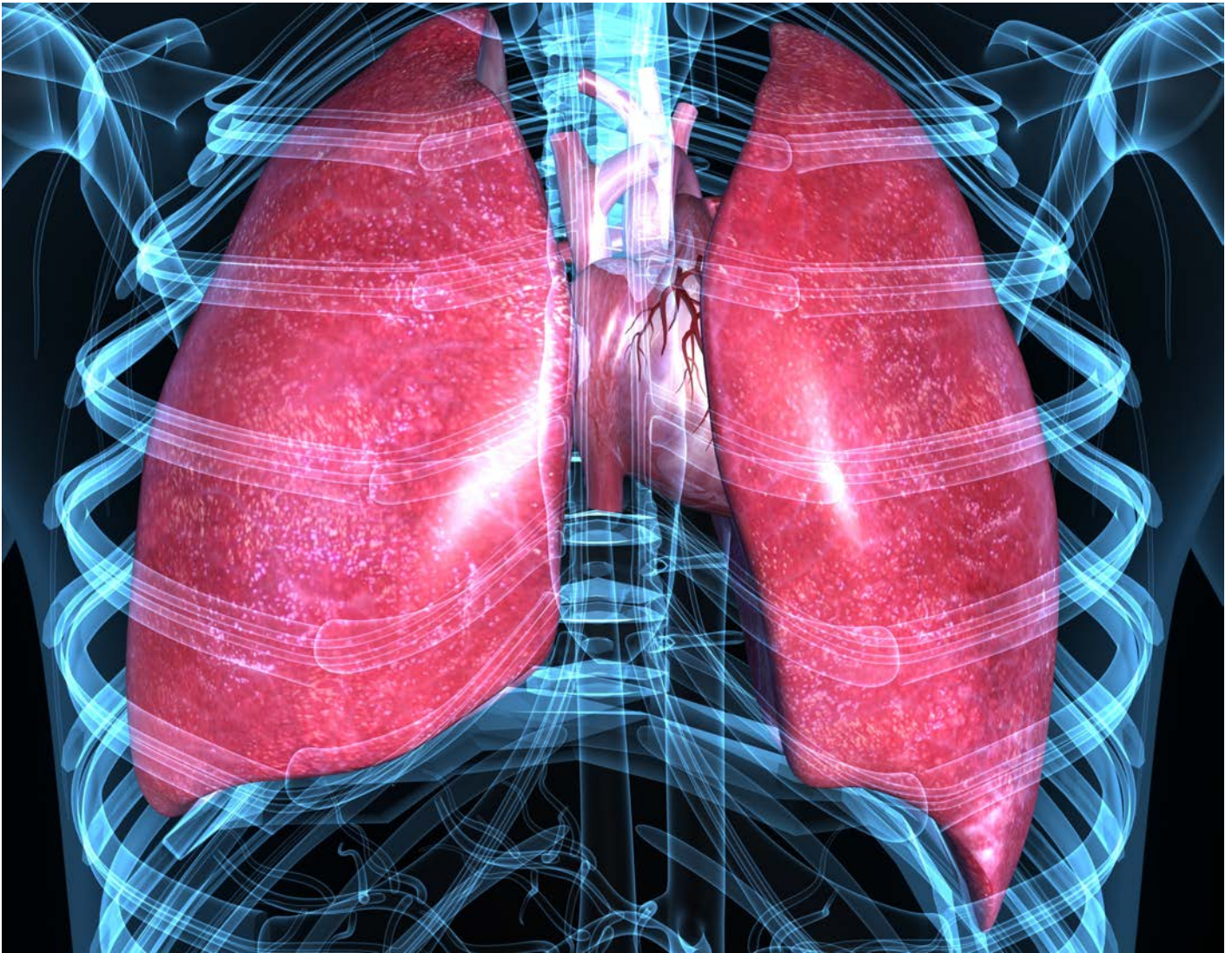
Recent findings from the “Translational Approach to Understanding RAGE pathway in ARDS” (TAURA) project now support an association between the RAGE pathway and the risk of developing ARDS. Indeed, in a prospective observational study from Dr Jabaudon and Professor Constantin’s group (CHU Clermont-Ferrand, Université Clermont Auvergne, France), the value of a molecular endotype comprising circulating levels of RAGE isoforms and

AGER gene variants was assessed to identify patients at highest risk of developing ARDS among those admitted with common ARDS risk factor(s) to one of five participating French intensive care units (ICUs) ([Jabaudon M. et al. Sci Rep 2018. doi: 10.1038/s41598-018-20994-x](#)).

“The focus on identifying patients before they develop ARDS has increased substantially with the validation of a lung injury prevention score (LIPS) to predict the development of ARDS in 18% of patients at risk of developing the disorder.”

The primary outcome was ARDS development within seven days of ICU admission. Of the 500 patients enrolled, 464 patients were analysed and 59 developed ARDS by day seven. Higher baseline and day one plasma sRAGE, but not esRAGE, were independently associated with increased ARDS risk. AGER SNP rs2070600 (the Ser/Ser genotype) was associated with markedly increased ARDS risk and higher plasma sRAGE in this cohort. These findings suggest that among at-risk ICU patients, higher plasma sRAGE may identify those who are more likely to develop ARDS.

However, rapid on-site testing will now be required to incorporate biomarker



profiles into eligibility requirements for prevention trials, unless clinical predictors of underlying biology can be developed. Candidate targets for pharmacological prophylaxis are many, but pharmacological prophylaxis development requires further understanding of how patients' endotypes contribute to the risk of clinical lung injury. ARDS prevention trials must overcome key challenges relating to their preventive focus and because most patients develop ARDS within 48 hours of ICU admission early recognition is needed to allow time for biological action arising from tested intervention.

A better understanding of early pathophysiological changes that precipitate ARDS should help to identify

biologically homogenous cohorts for inclusion in trials on novel candidate therapies. In addition, preventive trials should focus on patients with similar risk factors, rather than similar risk scores, to ensure some degree of homogeneity.

As many ARDS risk factors (such as shock) are independent predictors of death aside from ARDS itself, simply restricting the study population to patients at highest risk of ARDS may be ineffective. Thus, the aim of future work should be to identify the population who will benefit from prevention, i.e., patients at highest risk of ARDS in whom the development of ARDS would worsen the patient-centered outcome.



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Diet and health: A complex relationship

Senior Scientist at the British Nutrition Foundation (BNF), Dr Lucy Chambers, offers food for thought, by detailing the complex relationship between diet and health

This last century has seen a remarkable transition from the leading cause of death worldwide being communicable (infectious) diseases to those that are non-communicable (non-infectious), which now account for around three-quarters of deaths globally. The term 'non-communicable diseases' describes a diverse group of conditions that can affect health in numerous ways, but which are unified by common risk factors. Topping the list are poor diet and smoking. Poor diet alone is a risk factor for one in five global deaths¹.

Advances in science and technology and socio-economic and political changes this last century have had a major impact on the way food is produced, processed, distributed and sold, and our eating habits and diets. At the same time, nutrition scientists have been acquiring, organising and communicating evidence about the relationships between our (changing) diets and health.

Nutrition is a multidisciplinary science and those working in the area tend to use a title related to their research approach; they are epidemiologists, biochemists, biomedical scientists, geneticists, behavioural scientists, physiologists and so on. Nutrition scientists are all interested in the relationship between diet and health but study different aspects of this relationship, at the cellular, physiological, behavioural and population levels and use techniques and tools developed within their discipline that are appropriate for their research questions. This multi-pronged research approach gives rise to a wealth of information that can be pieced together to give more complete answers to the big questions about what relationships exist between diet and health and in whom, why these relationships occur and how these can be modified to improve our lives.

In the first half of the 20th century, advances in biochemistry paved the way for establishing the roles of essential vitamins, minerals, amino acids and fatty acids in health. In the final decade of the 20th century, evidence emerged from both epidemiological and biochemical studies that other dietary compounds, which are not stored in the body and not essential for biological processes, can also impact on health.

Polyphenols are one such group of compounds. These are found in plant foods and beverages, most notably in fruit, vegetables, tea and coffee and thought to exert health benefits by fine-tuning cell functioning and protecting against oxidative stress. Evidence from a number of disciplines indicates that polyphenol-rich foods and beverages protect against the development of non-communicable diseases². For example, there is good epidemiological evidence that the relative risk of developing type 2 diabetes is reduced by ~8% for each cup of coffee consumed per day (up to 6 cups)³. While the evidence base on polyphenols and health has expanded significantly in the last 20 years or so, it is not yet sufficient to develop dietary recommendations on the types and amounts of polyphenols that can reduce disease risk, but this is a hope for the future as it will facilitate public health actions to increase intake of these important compounds.

Research into how diet affects heart health illustrates the depth of understanding that can result from a multidisciplinary approach. Many scientifically robust biochemical experiments, epidemiological studies and biomedical randomised controlled trials together link high saturated fat intake to increased risk of cardiovascular disease, via its effect of raising blood LDL-cholesterol levels⁴, but this relationship is not necessarily corroborated by some studies⁵. Thus, a simple narrative does not fit the totality of the evidence base: it requires

more explanation than 'saturated fat is bad'. What we are now beginning to understand is that whether or not the risk of cardiovascular disease is reduced with lower intake of saturated fat is dependent on what saturated fat is replaced within the diet, which types of saturated fats are consumed and the presence of other nutrients/compounds in the food matrix that contains the saturated fatty acids^{6, 7}. The challenge for nutrition scientists is to communicate nuanced and complex scientific findings in a consistent and accessible way and to be heard over the self-appointed nutrition experts.

The relatively recent advance in the understanding of diet-health relationships with arguably the most potential to improve public health is the idea of 'fetal programming'⁸. This is supported by epidemiological evidence showing that maternal bodyweight and diet quality pre-conception and during pregnancy impacts on the risk of the offspring experiencing ill health, including cardiovascular disease, obesity, type 2 diabetes and some cancers, in adulthood⁹. Evidence for the fetal programming hypothesis is convincing and epigenetics processes – heritable changes to the expression of genes without changing the DNA sequence itself – are likely to explain these effects¹⁰.

This evidence base indicates that increased efforts need to be placed on early preventative interventions that not only support good nutrition during pregnancy, but also before conception. With more than half of women of child-bearing age in the UK overweight or obese, the challenge of improving maternal nutrition is considerable; but the long-term health benefits to be gained from setting children on a healthy trajectory from the very start of life are many¹¹.

Improving human health (and therefore lives) is at the heart of nutrition science. Progress in knowledge about the relationship between diet and health will have little impact on people's lives if we are unable to encourage healthier eating. Behavioural science emerged as a new approach to the study of nutrition in the last decades of the 20th century and has shed light on the eating behaviours that determine the amount of energy and types of nutrients that people consume¹². It is these insights, together with knowledge about the biological basis of diet-health relationships, that will lead to dietary changes needed to reduce the unprecedented rates of non-communicable diseases seen this century. ■

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Raising awareness of aplastic anaemia

Grazina Berry from Aplastic Anaemia Trust, along with Professor Judith Marsh and Dr Shreyans Gandhi from King's College Hospital NHS Foundation Trust, explore the rare and serious condition of aplastic anaemia (AA)

Aplastic anaemia (AA) is a rare and serious bone marrow failure disorder that can be fatal. Most cases are acquired, but it is increasingly recognised that inherited types of AA are more common than previously thought and can present in adults, not just in children. AA may be mistaken for other bone marrow failure disorders.

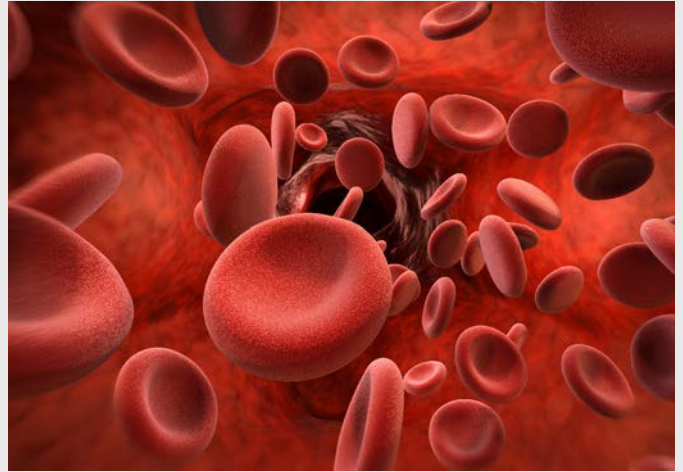
In most cases, it is an auto-immune disorder, where the immune system attacks the stem cells. These cells are the 'queen bee' cells within the bone marrow making all the different type of blood cells. This results in a deficiency of the blood making cells and the consequent downstream effects of low blood counts, in all the cell types.

The three main blood cells are the red blood cells, white blood cells and platelets. In aplastic anaemia, these blood cells are reduced and the stems cells in the bone marrow – replaced by fat cells. AA can be very severe, severe or non-severe.

Deficiency in red cells causes anaemia and people affected may experience fatigue, shortness of breath, headaches and occasionally angina chest pain. A low number of white blood cells increases the susceptibility to infections, such as sinus/throat, skin and chest infections. Low platelets cause a tendency to bleed, leading to nose bleeds, unexplained bruising, blood blisters in the mouth, but also serious bleeding episodes such as into the brain cavity or from the gut which can be fatal.

AA can affect anyone – of any gender, of any age, but it peaks in the young (late teens/early adulthood) and the elderly (around 60 years).

Treatment for AA is complex, often prolonged and involves high cost medications not easily available.



These include immune suppressing medications, stem cell transplantation and the newer generation drugs like 'eltrombopag.'

Missing a diagnosis of inherited AA can result in the wrong treatment that can be fatal or result in life threatening side effects and missing other possible family members who have inherited the same condition.

Treatment for inherited AA is different from acquired AA. The diagnosis of inherited AA requires special tests including gene testing, but this gene testing is not routinely available for all the known inherited types of AA. Neither the number of AA patients being diagnosed each year in England is known, nor how successful all types of treatments are.

Immuno-suppressive treatment has been the cornerstone of treatments in AA, to stall and prevent the immune attack on the stem cells. The alternative major treatment approach is stem cell transplantation that replaces the damaged cells with healthy stem cells from a 'matched' sibling or volunteer donor.

AA treatments are prolonged, complex and high cost. We do not definitively know the prevalence of AA in

England, although it is estimated that between 1-2 adults will be diagnosed in every 1 million people, or over 100 in England annually. There is no formal reporting of treatments and their outcomes (other than stem cell transplants) and no routine referral system for specialist opinion.

The Aplastic Anaemia Trust is the only organisation in the UK, in existence for over 30 years, dedicated to raising funds to enable research and providing much needed emotional and practical support to patients and their loved ones. And we cannot and do not operate alone. We believe in the power and importance of collaborations in research and treatment and have enjoyed long-standing effective working relationships with leading clinicians at St Georges, King's College Hospitals and other treatment centres in the UK.

A good example is our clinician colleagues at King's College Hospital, London who have been working tirelessly to enable a better understanding of the disease and explore treatment options for patients across different demographic categories. For example, they've been reviewing stem cell transplant outcomes from the international bone marrow registry database in a cohort of patients aged greater than 50 years with aplastic anaemia. This has confirmed a sentiment long held that stem cell transplantation is a very feasible option in a good proportion of patients who might be elderly but are otherwise fit and healthy. However, treatment guidelines for older patients with AA are incompletely developed and stem cell transplantation often remains a late or unconsidered line of therapy for patients who have not responded to standard immune – suppressive treatment. They are also exploring novel therapies based on the research they are doing in the laboratory.

Whilst good scientific progress is being made, numerous challenges remain:

- Statutory funding available for research into rare bone marrow failures is extremely limited;
- Existing resources for patients are stretched, thus focusing on clinical rather than psychosocial, emotional and practical support;
- The understanding of AA and its causes is still limited, as is routine genetic testing (restricted to only a few academic centres in the UK) – leading to challenges in diagnoses and therefore treatment of patients;
- There is no formal and consistent pathway for specialist advice for patients;
- Whilst estimates suggest that between 100 and 150 people are diagnosed with AA every year in England alone, many of whom are children and older adults, the exact numbers of patients diagnosed annually is unknown, as is the variety and effectiveness of treatments undertaken and;
- Whilst success rates of bone marrow transplantation continue to improve, with around 80% of patients surviving, this is dependent on the age of the patient, and treatment and recovery are long & costly processes with profound impact on patients and their families.

The effects of the disease are devastating for patients and for their families and friends, not to mention the financial hardships for people afflicted during the 'working years of their life' – making a strong case for the co-ordination of health care, emotional well-being & practical support to deliver the most and best holistic care of people with this rare but devastating illness. The existence of organisations like ours – close to what the patients' needs are and nimble enough to act fast and effectively, is crucial.

Of utmost priority is the need to gather and analyse systematically key data to support healthcare providers to plan effectively for future AA services, to improve accuracy of diagnosis of inherited and acquired AA, to provide healthcare quality improvement and efficient continuity of care to enable correct and equitable access for expensive and new treatments, ensuring appropriate use of the limited resources but with maximal output within our health service system. ■

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Do we know what red blood cells look like?

Anna Bogdanova, Professor and Head of Red Blood Cell Research Group at the University of Zurich explains how we know how red blood cells look like and if so, what they tell us

The simplest way to know whether cells exist is to look at them. The first known images of red blood cells date back from 1678, when Jan Swammerdam sketched blood globules he saw using a magnifying glass of Antonie van Leeuwenhoek. These globules were later viewed at somewhat higher magnifications and more details of them were seen. We still cannot use the predictive power hidden in red cell shapes. RELEVANCE consortium members are working to both decode the information red cell shapes offer us and translate it into improved patient diagnoses.

The RELEVANCE project team is contributing to each aspect of this quest, by working with images of living or fixed cells at a variety of magnifications and conditions. Clinical haematologists are used to performing the analysis of red cell shapes in fixed blood smears. Can we automate these tests to make them free from the subjective attitude of a human observer? Can we change from the analysis of static fixed cells to the monitoring of "living" flowing cells exposed to shear, inflammatory factors and other stressors present in our body?

Here are what our early stage researchers (ESRs) tell us about their progress.

Valeria Rizzuto, Josep Carreras Leukaemia Research Institute, Barcelona, Spain (ESR3)

The evaluation of RBC morphology is fundamental since aberrations of RBC shape can provide essential information in establishing a differential diagnosis of anaemia. Here are the challenges we face.

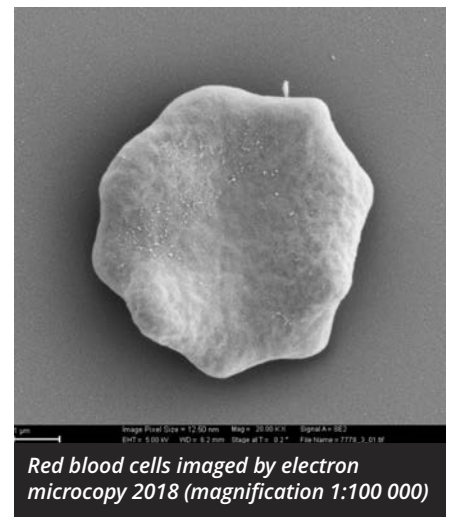
The red cells of patients with rare types of anaemia are intolerant to transportation that have severe impacts on cell morphology. Thus, it would be ideal to perform morphological analysis at the spot, with as little volume as possible and as little technical and human errors and inconsistencies as we can possibly afford. We need more advanced, robust and reliable tests coupled to new approaches in analysis to detect red cell shapes that we plan to develop together with partners from Arivis AG. We currently use peripheral blood smears counting the number of cells with abnormal shapes. Together with our biologist-partners, we plan to get more information about cell shape features in fixed and native red cells, by introducing new parameters to describe cell morphology and by implementing new tests to observe the morphological response to stress.

Greta Simionato, Saarland University, Saarbrücken, Germany (ESR4)

We believe that studying shapes provides a fast and inexpensive approach to learn more about the patients' condition and molecular causes of disease. We are currently working on the improvement of imaging techniques. We apply confocal microscopy for



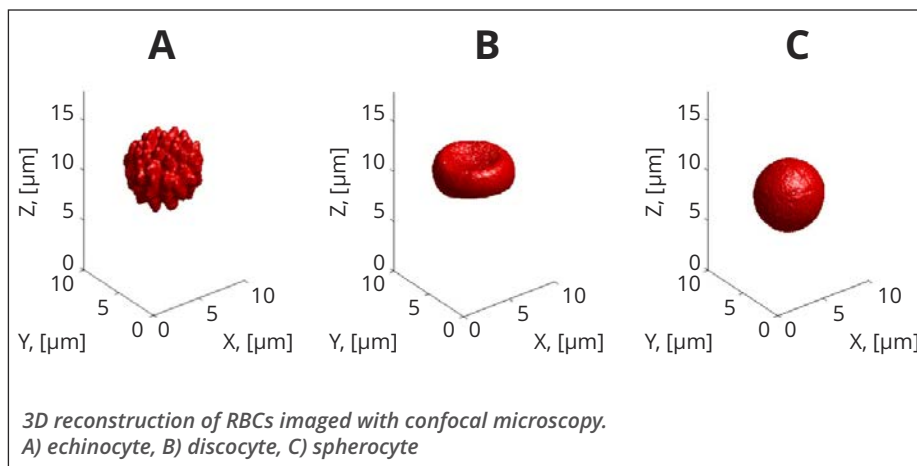
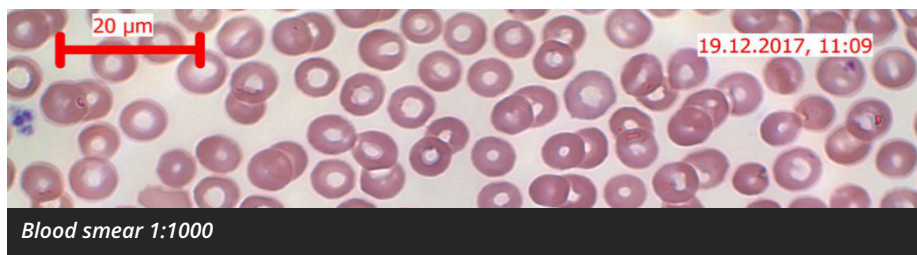
Red blood cells as sketched by Jan Swammerdam in 1678 (magnification 1:70 to 1:250)



Red blood cells imaged by electron microscopy 2018 (magnification 1:100 000)

transferring 2D- into 3D-images of cells. We develop new approaches for image analysis that include the extraction of quantitative parameters describing distinct elements of cell shape such as roundness, border regularity, volume and surface area. We explore the predictive power of these parameters for diagnosis and severity prognosis for patients with rare types of anaemia. We develop automatic cell shape recognition and a classification system, using a neural network approach to achieve fast, unbiased and more sensitive cell shape analysis.

Sinja Novosel, University of Zurich, Zurich, Switzerland (ESR7)
Our role within the consortium is to



bridge the research to the clinical and industrial demands. We develop a set of tests to challenge red blood cells and assess their responses to physiological stressors, such as acidic pH, Ca^{2+} uptake, or shear stress. These tests will serve better visualisation of the abnormalities and red cell membrane architecture that cannot be clearly monitored in cells “at rest”. We decipher the links between the mutations in proteins building membrane skeleton and the specific shapes cells prefer to acquire.

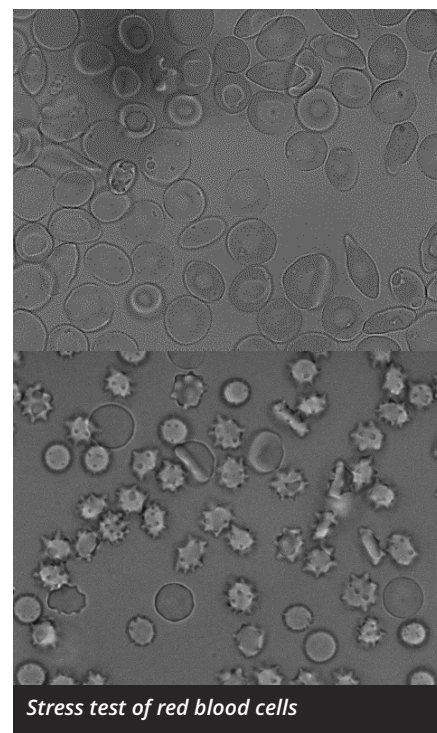
We also study the biological mechanisms behind heterogeneity in red cell shapes and properties. These tests will be then implemented in a new prototype of a microfluidic device that will be used for automated cell shape analysis. This device will address hydration state, deformability and membrane stability of individual red blood cells. Information on the physiological and pathological “meaning” of red cell shape preferences and heterogeneity of cell shapes will be then implemented for the development of the algorithms for red cell shape analysis and its interpretation for clinical applications.

Niamh Kilcawley, Epigem Ltd, Redcar, UK (ESR1)

A major challenge that we are faced with is the volume limitations associated with the screening of blood from newborn infants and neonates. For this, it is necessary to only use microliter sized samples. The first two working prototypes of a microfluidic instrument has been developed with the aim to run these low volume blood samples for the screening and detection of rare anaemia and are currently on probation in a clinical lab in Division of Pediatric Hematology of Emek Medical Center in Afula, Israel and with the team of Red Blood Cell Research Group at the University of Zurich. For me, this is a new phase in my work – a transition from building to testing. Next step will involve improving the microfluidic system. Together with the other partners, we will evaluate the predictive potential of the tests.

Niamh (on behalf of other ESRs)

We believe that the RELEVANCE project will make a massive difference to so many people. By studying red cells in depth, we can progress not only our knowledge of red cells and their muta-



tions, but also progress the treatments and procedures for improving the quality of life for these patients. The interaction between all the sciences, universities, hospitals/clinics and SMEs gives all the ESRs access to such a broad range of education – that is not typical in a normal PhD situation. It also gives us connections to each other and the possibility of great collaborations which is very good ‘life learning’ for anyone who wants to pursue a career in science.



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Access to rare disease therapies in Europe

Simone Boselli, Public Affairs Director of EURORDIS shares the fascinating findings of a new position paper that offers a synthesis of their analysis, reflections and perspectives on access to rare disease therapies in Europe today

Introducing the new position paper from EURORDIS calling for urgent, radical change to ensure patients' full and fast access to rare disease therapies in Europe, Simone Boselli, Public Affairs Director explains that there is a disconnection between the European markets for such therapies.

Each European market, of which there are 28 have their own processes for guaranteeing access to therapies for people with rare diseases, Simone underlines, adding that when it comes to accessing existing therapies there is an average wait of 18-24 months across Europe. That wait is at a much higher rate than those who wait for to be treated for more common diseases, Simone explains.

Simone then reveals that there are 30 million people with rare diseases in Europe today, but having said the number of rare diseases identified is in the 1000's. One of the main hindrances to treating rare diseases is the fear that such a measure could break the bank, Simone adds. However, the current research around the average prices for treatment is quite modest on an annual basis for each patient, Simone tells us before introducing the key findings of the *Breaking the Access Deadlock to Leave No One Behind* paper in his own words.

"Developing novelty therapies for rare diseases might be more expensive, however, and this concerns cutting-edge science. However, there is a mistrust of some of the companies who are trying to maximise the profits for drugs that deal with orphan diseases. This directs us to the very important point of improving the dialogue between the different parties involved, including the patient, to understand novelty therapies and the type of data and evidence the competent authority will need for faster approval of and access to

rare disease therapies. *Breaking the Access Deadlock to Leave No One Behind* is the result of a long process with a number of stakeholders."

The position paper sets out a new four-pillar approach to tackling the challenges that prevent patients' access to healthcare and medicines, as well as the ambition to have three to five times newer rare disease therapies approved per year by 2025, three to five times cheaper than they are today. Simone is keen to reveal more about this to us, explaining that the new four-pillar approach aims at restructuring the overall approach to accessibility to rare diseases therapies, in addition to back-end issues such as pricing and reimbursement.

Simone then stresses that EURORDIS want to make access to rare disease therapies more affordable and sustainable, and to do this, the issue needs to be viewed in a more comprehensive way starting from basic research and clinical trials to the point when the medicine is delivered to the patient. A new blueprint is therefore required, to ensure that research and developments are fast-tracked, so the cost of rare disease therapies can be reduced.

"There are new types of clinical trials and reference networks developing at the European level, which we hope will be able to connect the community and therefore, treat the patient faster and to reduce the cost of clinical development. At the same time, we need to speed up R&D process, even though today we have a much greater number of these available.

"The second aspect, is that we need to have more dialogue downstream between manufacturers and regulators to determine the value of the required medicine, because sometimes, the data required by

the assessors is different to what the regulators see around the safety aspects of the medicine so that it can be approved for use at a much earlier stage.

“The third point is around how we determine the price of the medicine; indeed, we need to set up a transparency system to determine this. The price should reflect the level of innovation that the medicine brings and from a rare disease perspective, European added value is very important. Also, we are quite conscious that as science progresses, we will find new therapies for new rare diseases for which the budget might not be available. We also need to help everybody understand that the overall impact of the budget for rare disease therapies is very limited, for example, in terms of dispensing orphan drugs is only around 6% of the overall pharmaceutical budget spending (18% of total healthcare expenditures).

“Developing therapies can really make a difference as we can edit and sequence the DNA, but we can also intervene on the causes of rare diseases. Overall, however, these are expensive treatments to make, so that is why we really need to think through a new approach as a community, we also need to be aware that their limits on what we can spend on this. Having said that, we need to help those with life-threatening and limiting diseases to potentially lead a much better life.”

“This leads to the fourth pillar, in that many of the therapies are arriving with uncertainties or conditional approval, so we argue that continued evidence generation in the cycle of a medicine is necessary and must be linked with budgetary spending. This pillar looks at the overall lifecycle, to ensure that the patient gets access to therapies and that they can be financed.”

The reason why EURORDIS suggests this new approach is because the current system in Europe is not working, Simone explains. He says that EURORDIS see situations in several countries, where there is no agreement on or reimbursement around rare disease therapies. At the end of the day, it is the patient who will suffer if they do not have access to the right therapy, so this deadlock needs to be broken, Simone argues.

The conversation then moves on to reveal Simone’s thoughts on concerning access to medicine for those with rare diseases, many of which are of genetic origin. Around genome sequencing and areas related to gene therapies, you can see that there is an unprecedented opportunity to understand some of the causes of rare diseases, Simone stresses.

“Novel scientific developments allow us to edit and sequence the DNA, but also to better understand the causes of rare diseases. Therapies derived from such methods can, however, be expensive. This why we really need a new approach across the entire rare disease community including industry to make sure every patient can access the treatment they need. In the meantime, and particularly when a treatment is not available to the patient, we also need to provide support to those with life-threatening and limiting diseases so that we can ensure they have better daily lives.”

In closing, Simone tells us that the underlying causes of rare diseases can be grouped together with the power of 6,000 different diseases behind it. He concludes the interview by explaining this crucial point to us, in his own words.

“It is only by ensuring a collective response to this problem that we will get adequate results. This is important, and while we may struggle to get to that point, the level of a European and international response to rare diseases is the adequate level we need so that together we can produce responses that go across borders so that nobody is left behind.” ■

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Severe asthma shows the tip of the iceberg of personalised medicine

Isabel Proaño Gómez, Communications Manager at European Federation of Allergies and Airways Diseases Patients' Associations (EFA) explores the issue of severe asthma and how our understanding of it is evolving

"I knew it!". This is what many adult asthma patients are thinking today. They knew there was something wrong with the way their lungs behave, despite their asthma medication. Science is not knowledge set in stone, and the patient community knows it very well: their daily burden is and should be at the heart of medical research developments.

Patients with what we know today as severe asthma suffer from aggressive and sudden symptoms. No matter how hard they try to control it, asthma attacks, coughing and wheezing surprise them in the middle of something, ruining their day, week, month and their life.

Patients whose asthma is severe relate this kind of experiences very often go to their doctors. Although asthma is a well-known chronic disease, which in its allergic form can even disappear in childhood with the correct treatment, asthma touches 30 million Europeans below 45 years old. The minority of patients with severe asthma (10%) suffer a real burden, with acute symptoms that can lead to a deadly asthma attack.

Severe asthma requires accurate diagnosis and research

Our understanding of asthma is evolving at a quicker pace now. A century ago, asthma was divided between allergic and non-allergic asthma, but this classification has significantly changed, and physicians are referring now to the genotypes and phenotypes (the genes and environmental factors that explain the existence of a disease). On top of that, thanks to new recent laboratory techniques, researchers are now looking for biomarkers, which are specific chemicals in our blood, urine and sputum that could tell us more about who is at risk of developing what type of asthma.

Although no specific biomarker has been defined for

Image: © TBLM studios



Isabel Proaño Gómez, Communications Manager at European Federation of Allergies and Airways Diseases Patients' Associations

asthma yet, the asthma patient community is expecting to participate in new research following up on what we have. At European Federation of Allergies and Airways Diseases Patients' Associations (EFA), we took part in the U-BIOPRED research project, a multi-year Innovative Medicines Initiative project working on the biggest European asthma patient data cohort and highlighted what we already felt: asthma is definitely more complex than expected and we need to define different types of severe asthmas more precisely.

Delayed diagnosis undermines self-confidence and health

In the meantime, severe asthma diagnosis has to rely on the patients' experience more than on innovative tests. In the last decades, the concept of asthma severity has progressed from the classification by lung function, to the patients' degree of asthma control. In my opinion, this evolution is already showing that care for asthma patients is shifting towards the priority that matters: to what extent can patients cope with asthma? The response to the question has already enabled the commercialisation of new treatments, but is knowledge distilling across countries and healthcare professionals?

“Patients whose asthma is severe relate this kind of experiences very often to their doctors. Although asthma is a well-known chronic disease, which in its allergic form can even disappear in childhood with the correct treatment, asthma touches 30 million Europeans below 45 years old. The minority of patients with severe asthma (10%) suffer a real burden, with acute symptoms that can lead to a deadly asthma attack.”

The good news is that things are shifting with precision medicine or, more preferably, P4 medicine; predictive, preventative, personalised and participatory. People with severe asthma need personalisation and to be able to set their own goals to live and plan this life healthier. When it comes to diagnosis and management, we might be adopting the “one patient, one asthma” approach.

The bad news is that many patients are right now fighting their asthma without having a proper diagnosis on its severity. In severe asthma, the patients' response to treatment is irregular and to define it, doctors look at elements like the number of hospitalisations and long-term use of oral corticosteroids in high doses, which have severe secondary effects. Asthma severity is defined by medication. Even with that, patients need to wait approximately a decade to get a proper diagnosis of their asthma, which undermines their trust in finding a solution but also their self-confidence.

Asthma demonstrates trust in patients is key

As we have captured in our “Severely, asthma” video series, people with severe asthma have been pointed by the finger of a wrong inhaler technique or not following

the prescribed treatment. Yet their experience with asthma can be a source of knowledge and innovation for researchers and healthcare systems. People with severe asthma are determined for health. The experience of severe asthma diagnosis is, therefore, the tip of an iceberg that we need to confront for the 21st-century personalised healthcare era. ■

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Do we know the cause of asthma and COPD?

Michael Roth, Research Group Leader at the University Hospital Basel & University Basel share his expertise on asthma and COPD, the most prevalent chronic inflammatory diseases of the lung globally

Asthma and COPD (smoker's lung) are the most prevalent chronic inflammatory diseases of the lung all over the world. The WHO (World Health Organization) estimated in 2015 that both diseases together affect more than 400 million people with increasing incidences. The available data from Europe implied that asthma and COPD are largely under- or wrongly diagnosed and therefore many patients receive inadequate treatment.

New epidemiologic studies suggested that in Europe and the Americas the increase of asthma and COPD is slowing down, while it is rapidly increasing in Asian countries. The data published from Africa reflects mainly the situation in the Republic of South Africa and the other countries show a high variability of prevalence which may be due to missing data or that chronic "coughing" is not regarded as a major problem by many. The causes of the increasing prevalence of asthma and COPD over the past decades are unclear.

Major problems with asthma and COPD are: (i) insufficient understanding of the events initiating the pathogenesis, (ii) no clear diagnostic marker(s) for either disease, thus lengthy and repetitive assessments of lung function under different conditions are needed, (iii) acute attacks and inflammation can be controlled by anti-inflammatory and muscle relaxing drugs, but there is no lasting cure available and

(iv) airway wall remodelling is irreversible and does not respond to any known drug.

Asthma is a disease of the airways which limits breathing. The global initiative for asthma (GINA 2017) defined asthma as follows: "Asthma is a heterogeneous disease usually characterised by chronic airway inflammation. It is defined by the history of respiratory symptoms such as wheeze, shortness of breath, chest tightness and cough that vary over time and intensity together with variable expiratory airflow limitation".

This definition is open to interpretation and reflects how little we know about the disease. The fundamental initiating cause(s) of the pathogenesis of asthma is unknown. New studies imply that the long-prevailing assumption that chronic inflammation of the airway is the major cause of all other asthma pathologies has to be revised and the American Thoracic Society stated in 2016 that asthma may only become curable after understanding the cause of airway tissue remodelling.

Different types of asthma have been defined, such as allergic asthma, which develops often together with other atopies of the patient. Seasonal asthma is when a patient is allergic to a natural allergen, such as grass pollen that occurs only during a limited period during the year. Occupational

asthma, a type of allergic asthma, is caused by repetitive exposure to chemical, drugs, or agricultural products.

Patients with allergic asthma have often increased IgE and humanised anti-IgE-antibodies are an effective new form of therapy. Anti-IgE-therapy effectively reduces inflammation and it was suggested that it also reduces airway wall remodelling. However, there are insufficient clinical data available to prove a benefit of anti-IgE antibodies on airway wall remodelling.

Non-allergic asthma accounts for approximately 40% of all patients and can be caused by inhaling cold/hot air, psychologic stress, or exercising. Exercise-induced asthma is known from many Olympic athletes, especially those performing in water or winter sports. It is estimated that more than 50% of these athletes suffer from asthma during training. But the mechanism how changes of the water content in the inhaled air lead to an asthma attack remains unknown. Epigenetic mechanisms are currently investigated but it is too early to draw conclusions.

Less well understood is the pre-condition for asthma, so why do not all allergic people develop asthma? For sure hormones affect the susceptibility to asthma, but how they do it is not well investigated. Hormonal changes as they occur during puberty, menopause or as reduced androgens



“Earlier this year, it was reported that additional causes of COPD have been identified, especially compounds contained within ordinary household cleaners.”

in men often affect the course of asthma in both ways: (i) During puberty many children lose their asthma; while (ii) Later in life hormonal changes often lead to more severe types of asthma. Thus, the pathogenesis of asthma has to be re-investigated.

COPD is defined as: “Common preventable and treatable disease that is characterised by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities, usually caused by significant exposure to noxious particles or gases.”

In Europe and the Americas cigarette smoking is the major cause of COPD, which develops in 20% of smokers. The fact that “only” a fifth of smokers develop COPD raises the question of a pre-condition, which is largely unknown. Some studies imply that the stage of lung maturation may set the lung to develop COPD like symptoms later in life. Two percent of COPD patients develop the disease as the result of a genetic disorder, alpha1-antitrypsin deficiency.

In other areas of the world open fire cooking and heating is the major cause of COPD, often combined with

cigarette smoking. However, earlier this year, it was reported that additional causes of COPD have been identified, especially compounds contained within ordinary household cleaners.

This topic was picked up by many daily newspapers and stirred a discussion how serious the underlying investigation had been. Such reports should be taken with care since there is no information available on how many cleaners suffer from this type of COPD and how frequent the exposure to cleaning detergent must be to cause COPD.

Another question is if the symptoms were correctly diagnosed and not confused with occupational asthma. Inhaled vaporised chemicals or aerosols are assumed to damage the airways, but the type of damage and how it occurs must be investigated in more detail.

The major problem for such studies is the use of household cleaners. Most often, a cleaning person will use different cleaner types for different tasks on one job. This opens the possibility that the COPD causing effect will only happen when different cleaning detergents are inhaled in a certain pattern. The chemicals will

then react in the airway and damage the epithelium and the tissue beneath.

COPD shares many pathologies with asthma and at early stages shows chronic inflammation and airway wall remodelling. However, remodelling is found more in the small airways while in asthma this feature occurs in the large-medium sized airways. At late stages of COPD, the lung structure disintegrates which led to the hypothesis that COPD is the result of an imbalance between tissue building and degrading enzymes.

Similar to asthma, it has been postulated that exposure to risk factors during late pregnancy and/or early childhood pre-dispose the lungs to develop COPD later in life, but a final proof of such an epi-genetic pre-dispositioning will be difficult to prove. It is also indicated that COPD is not as specific for the lung, which is the just the organ where it manifests first. Therefore, new studies on the interaction between the different lung tissue forming cells and the immune system have to be undertaken, as well as studies that take the response of other organs with the lung into account.



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Huntington's disease – accessing hope

Sorcha McPhillips, Chief Executive of the Huntington's disease (HD) Association for Northern Ireland, raises awareness of HD and discusses the impact of hope on the community in the face of new treatments

Huntington's disease (HD) is described as a 'neuro-degenerative' disorder as it damages or kills the neurons in the brain. It is a genetic disease affecting males and female equally. Every child of an affected parent has a 50% chance of inheriting the gene mutation which causes the disease. A simple blood test indicates whether a person has tested positive or negative for the gene mutation. If tested positive, the individual will develop the disease at some point in their lifespan.

HD affects approximately 1 in 10,000 individuals in Europe and is sometimes referred to as a 'rare' or 'orphan' disease, although a recent statistical report from 2016 indicates that the prevalence of HD in the UK has been severely underestimated and that for every person with the faulty gene there are as many as 5 people at risk of inheritance.¹

HD usually affects adults between the ages of 30-50 and is often described as an "adult-onset disease". Although it can occur anywhere from age 2-70, it is less common in children and older people. It is said that those who develop HD earlier in life may find their illness progresses at a faster rate.

- Life expectancy from the onset is approximately 15-20 years.
- HD causes progressive deterioration – physically, cognitively and emotionally until the individual becomes dependent on the help of others.
- No two patients' condition progress in exactly the same way.
- Symptoms can vary widely, and the rate of progression is difficult to predict with any real accuracy.

- HD is referred to as a 'disease of families' where several family members from different generations may be symptomatic at the same time.

As a 'disease of families' no family member is left untouched because if they do not have symptoms themselves or have tested negative they are still affected by the emotional and practical implications of the disease on the family with many people having a caring role to play.

Most of the, approximately 200, HD sufferers in Northern Ireland are cared for at home by family members although many will require the assistance of home care workers, respite in care homes and eventually nursing home care. It is essential for carers, both family and professionals, to develop an understanding of the complexities of HD and how it can impact on all members of the family.

There is no known cure for HD, however, this is an unprecedented time for Huntington's disease families. HD is among the 25% of rare diseases with a known genetic cause and so to some extent, those with HD are among the lucky ones. They can access a diagnosis by blood test and since the cause is known, treatments are possible. The first-ever human trial is underway of a drug that aims to reduce the brain's production of the mutant protein HTT – the known cause of HD. Phase 1/2 of this Ionis/Roche trial has just concluded with 46 patents across nine global sites with participants shown to tolerate increasing doses of a drug delivered by a monthly lumbar puncture.

The results are incredibly positive with significant dose-dependent reductions in the level of the mutant protein – basically the higher the dose administered, the lower the level of protein detected. This trial will



Sorcha McPhillips, Chief Executive

Northern Ireland. Although we have some limited neurological, psychiatric, nursing and genetic expertise in Huntington's disease locally, they do not have the capacity or the administrative support to establish a site here. Families are asking, and rightly so, how can we access these clinical trials before it's too late for us? The postcode lottery is something many are sadly all too aware of as in Northern Ireland only those living within two of the five healthcare Trusts can access a specialist HD nurse. This is an issue which HDANI continues to lobby for but when you have no functioning government where do you lobby? There has been no Minister for Health in Northern Ireland since January 2017 and with that a vacuum against which to push for an end to the inequality of care which exists and the need to promote access to HD research and clinical trials. It truly is a time of hope for Huntington's Disease families around the globe and hope can do exceptional things to the human body and spirit but for families living in Northern Ireland, it seems like hope is just beyond their grasp. ■

To learn more about HD in Northern Ireland watch our video <https://tinyurl.com/y7dudr7m>

1 Baig, S.S., Strong, M. and Quarrell, O.W.J. (2016) The global prevalence of Huntington's disease: a systematic review and discussion. *Neurodegenerative Disease Management*, 6 (4). ISSN 1758-2024 <https://doi.org/10.2217/nmt-2016-0008>

2 For up to date information on HD drug and treatment developments see <https://en.hdbuzz.net/>

3 <https://www.enroll-hd.org/>

now expand to include more participants to monitor the effect on a larger patient group for a longer period. The hope is that this drug could delay or even prevent the onset of HD symptoms. Several other drugs to do the same thing by different approaches are under development and expected to reach trials soon. There are currently 15 clinical trials of different treatments currently underway so there is real hope for a cure.²

These developments bring real hope to families currently living with the symptoms or the future threat of this devastating disease. However, in Northern Ireland, they also bring questions, anxiety and frustration. Participants for clinical trials are usually recruited through Enroll HD study sites. Enroll HD is an innovative way of gathering data on HD patients and their family members, including biological samples, which are then coded and uploaded anonymously on to a global research database which is freely accessible to anyone working on HD research.³

There is an Enroll HD site in Ireland and 28 sites across Scotland, England and Wales, but not a single site in

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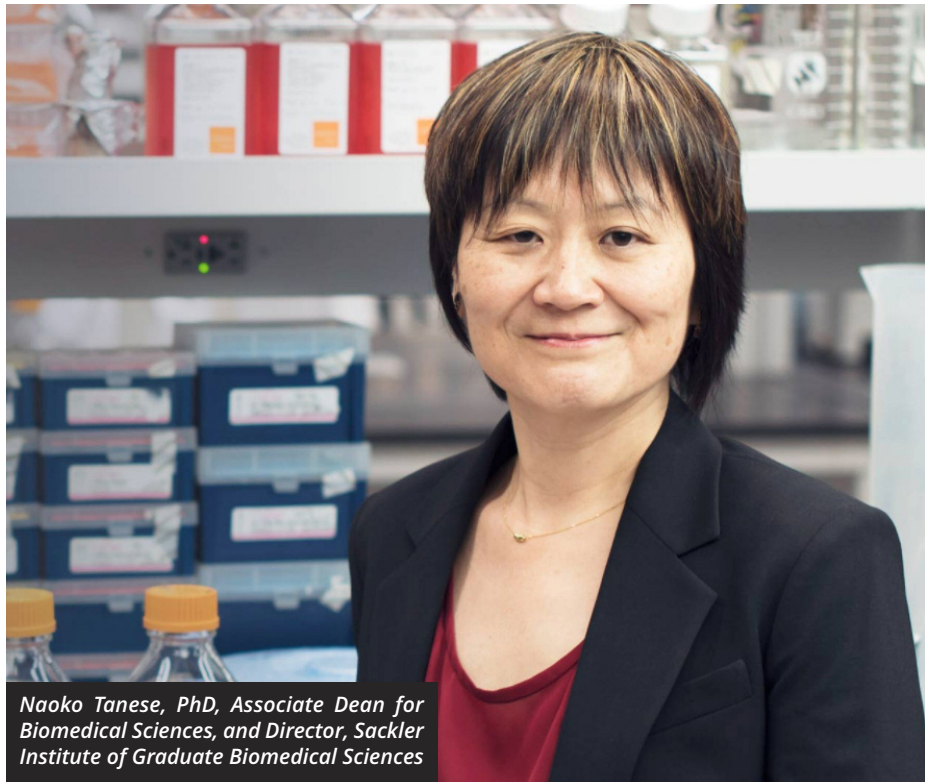
What's in an aggregate? Therapeutic intervention in Huntington's

Naoko Tanese from New York University School of Medicine outlines their work around Huntington's disease (HD) and effective new targets for therapeutic intervention

Huntington's disease (HD) is a rare hereditary neurodegenerative disease that strikes patients in mid-life. American physician George Huntington first described the disease in 1872 after seeing affected residents in East Hampton, New York. Patients generally experience a progressive decline in cognitive, psychiatric, and motor functions. The disease is fatal. In 1993 an international team of scientists discovered the gene that causes the disease. Despite years of intense research, no cures or treatments to delay the onset or prevent the progression of the disease are available.

HD is caused by an inherited dominant mutation in the Huntingtin gene, HTT. This means an offspring of a parent who carries a mutant HTT gene has a 50% chance of inheriting the mutant gene. The mutation results in an increased number of repeats (greater than 40) of the amino acid glutamine in the encoded Huntingtin protein (HTT).

A normal HTT protein has between 7 and 35 glutamines. Increased number of glutamine repeats changes the property of the protein and renders it toxic to cells. The HTT protein is present throughout the body and throughout life. However, mutant HTT is toxic to select cells. Postmortem examination of the brains of affected individuals shows massive cell loss in certain parts of the brain, leaving



Naoko Tanese, PhD, Associate Dean for Biomedical Sciences, and Director, Sackler Institute of Graduate Biomedical Sciences

other cells and tissues intact. This indicates that some neurons are particularly sensitive to the toxic effects of mutant HTT.

The normal HTT protein has been implicated in many cellular functions. However, we have an incomplete understanding of how mutant HTT causes the disease. A better understanding of the functions of the normal and mutant HTT protein is paramount, if effective therapies or cures are to be developed.

Proteins made in cells maintain certain structures dictated by their biochemical and biophysical properties. This is

referred to as protein folding. When proteins misfold, they often lose their normal functions. Cells have developed elaborate mechanisms to remove such aberrant, misfolded proteins. This protects the cells from potential harmful effects of misfolded proteins.

However, misfolded proteins can accumulate over time and form irreversible aggregates that impair cellular homeostasis. These aggregates are a hallmark of many neurodegenerative diseases. They are found in postmortem brain tissues of affected individuals. Age-associated diseases such as Alzheimer's disease, are linked to protein misfolding. HD is

also considered a protein misfolding disease although many other mechanisms are thought to play a role in the disease pathogenesis.

Decades of research have uncovered intriguing properties of different types of protein aggregates, some of which are RNA-protein granules found in normal cells. Each granule appears to have distinct properties and its formation is driven by specific sets of proteins and RNA. Some granules are formed in response to stress. This mechanism serves to halt energy-consuming cellular activities, by sequestering proteins involved in key biochemical processes. Upon removal of the stress, granules disassemble and the released proteins resume their normal functions.

Interestingly, mutant proteins linked to several neurodegenerative diseases have been located within these types of granules. They include mutant RNA binding proteins associated with amyotrophic lateral sclerosis, spinal muscular atrophy, and fragile X syndrome. These RNA binding proteins normally play a role in RNA transport, translation of RNA to make proteins, and formation of RNA-protein complexes.

Mutant RNA binding proteins, however, show altered biophysical properties. They have increased propensity to interact with one another and affect the formation and function of granules. There is increasing evidence that over time mutant RNA binding proteins in these granules steadily accumulate and become converted to irreversible aggregates that are toxic to cells. Neurons are vulnerable to aberrant proteins that accumulate because neurons do not divide. Ultimately the machinery in the cell fails to remove toxic proteins, causing cell death.

Since the functions of normal HTT and the mechanisms by which its mutant counterpart contributes to HD remain unclear, my lab began investigating the role of HTT in RNA metabolism. New imaging techniques have helped us determine the location of the normal HTT protein inside neurons.

Strikingly, we discovered that HTT could be found near neuronal RNA granules. RNA granules are large RNA-protein assemblies responsible for transporting RNA to specific locations in the neuron. To determine whether HTT influences RNA localisation, we reduced the level of normal HTT in neurons grown in a culture dish and examined its effect on transport of RNA. We found that the reduction of HTT in cells disrupts RNA localisation. The result points to HTT contributing to the integrity of RNA granules during RNA transport.

New experiments in HTT

To further investigate cellular processes that HTT is involved in and how they might differ in mutant HTT, we designed experiments to purify normal and mutant HTT proteins from cells and tissues. We next identified proteins that interacted with each form of HTT. By identifying the functions of the proteins that co-purified with HTT, we uncovered new functions for HTT. Analysis of the binding partners of HTT proteins revealed that both normal and mutant HTT interact with proteins involved in RNA metabolism and protein synthesis.

We have thus uncovered new roles for normal and mutant HTT in RNA metabolism. The findings have several implications for the development of HD. We have located mutant HTT in neuronal granules, similar to those associated with aforementioned RNA

binding proteins linked to neurodegenerative diseases. Our results suggest HTT has a role in the formation of RNA-protein granules.

Unlike normal HTT, mutant HTT has a propensity to interact with one another through the increased repeat sequence. At high concentrations, mutant HTT alters biophysical properties of RNA-protein assemblies and shifts the equilibrium in favour of forming aggregates.

Furthermore, a recent study reported stable formation of RNA aggregates containing repeat sequences. Collectively, the findings suggest that mutant HTT together with repeat sequence-containing RNA forms granules that become converted to irreversible toxic aggregates over time. The development of chemical agents that prevent aggregation or disrupt aggregates may serve to reverse the toxicity associated with the mutant protein and RNA. Through understanding of how HTT supports neurons with these functions, we hope to reveal effective new targets for therapeutic intervention.



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Positive progress for people with Parkinson's

The European Parkinson's Disease Association (EPDA) provide an update about the positive progress being made for people with Parkinson's

My PD Journey is a multi-stakeholder European coalition led by the European Parkinson's Disease Association (EPDA) and it is a positive development in terms of the positive progress being made for people with Parkinson's today.

The My PD Journey coalition, on behalf of the EPDA, has developed the Parkinson's Disease Composite Scale – a simple new scale that measures the severity of symptoms experienced by people with Parkinson's in a timely way. It provides a holistic overview of both motor and non-motor symptoms and enables clinicians to continually monitor the individual's condition.

Why develop a new scale?

Existing scales used by neurologists currently explore different aspects of Parkinson's but do not offer a comprehensive overview of the individual's condition. The development of the new Composite Scale was therefore urgently needed as it combines motor symptoms, non-motor symptoms and treatment-related complications; it is also simple and relatively fast to use.

Crucially, it is designed to complement – rather than replace – existing scales by offering a holistic view of Parkinson's. In addition, it grades the relative importance of particular symptoms, considering people with Parkinson's perspectives, which are critical in the delivery of timely and effective treatment and care.

Who led the development of the composite SCALE?

The development of the Composite Scale was led by Parkinson's specialist neurologists Professors Pablo Martinez Martin (Spain) and Fabrizio Stocchi (Italy) – in collaboration with the My PD Journey coalition.

Who is it for?

The Composite Scale was designed as a tool to be used primarily by neurologists and other healthcare professionals familiar with Parkinson's. It is not a tool for self-assessment but can help people with Parkinson's to better understand the complexity of their condition.

“My PD Journey is working with neurological and clinical bodies, policymakers, and patient organisations to promote the use of this new, innovative tool across Europe.”

What does it measure?

The Composite Scale measures motor symptoms, such as tremors, rigidity, bradykinesia and postural instability, as well as non-motor symptoms, such as depression, anxiety, sexual dysfunction, constipation and urinary problems.

The Composite Scale also grades the relative importance of symptoms, considering patient perspectives, which are important in the delivery of timely and effective treatment and care.

How should the scale be used?

The Composite Scale should be used in clinical settings and can be conducted in roughly 15 to 20 minutes, as such freeing up time within the consultation to discuss other things important to the individual.

How and when will the Composite Scale be validated?

Work began on the Composite Scale in September 2014. The initial pilot study and a first validation study were completed in 2015. The first validation study indicated that the scale was a feasible, acceptable,



reproducible, valid and precise instrument for more holistic measurement of Parkinson's symptoms.

“The Composite Scale was designed as a tool to be used primarily by neurologists and other healthcare professionals familiar with Parkinson's. It is not a tool for self-assessment but can help people with Parkinson's to better understand the complexity of their condition.”

A second and more extensive validation study, aimed at reaffirming the first study's findings, is currently underway. Professor Fabiana Radicati (Italy), one of the authors of the scale, is the clinical trial coordinator of this wider validation study. It is being undertaken in more than 20 centres across Europe and was completed in early 2018, shortly after which a report is due to be published.

In parallel, My PD Journey is working with neurological and clinical bodies, policymakers, and patient organisations to promote the use of this new, innovative tool across Europe.

How can I learn more?

My PD Journey is a first-of-its-kind multi-stakeholder project for people with Parkinson's in Europe, led by the EPDA. The Parkinson's Disease Composite Scale is a My PD Journey project, and as such belongs to the EPDA.

Visit www.epda.eu.com for more information about Parkinson's disease and the EPDA work programme. For more specific details about My PD Journey, go to www.mypdjourney.com. ■

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Caring for our kidneys – findings from the Chronic Kidney Disease (CKD) Audit

The topic of Chronic Kidney Disease (CKD) is placed under the spotlight by experts from the London School of Hygiene and Tropical Medicine, the Primary Care Cardiovascular Society and the charity Kidney Care UK

Good kidney function is vital to a healthy life. The importance of the kidneys is often poorly understood by patients and the public and even by some professionals. The recent National CKD audit is a strong indication that there is more work to be done in this area.

About the kidneys

1. They remove waste products from normal metabolism with an effective filter in 1 million filtration units in each kidney called glomeruli.
2. They balance fluid levels in the body and reabsorb over 95% of the fluid they filter.
3. They activate vitamin D which is important to maintain strong bones.
4. They produce a hormone called erythropoietin (EPO) which stimulates the bone marrow to make red blood cells and prevent anaemia.
5. They produce hormones to control blood pressure levels.
6. The majority of drugs require removal from the body after they have been active.

The kidneys are so efficient that function can fall below 20% before we have symptoms from loss of function; but they can be damaged, particularly by diabetes and high blood pressure.

Moderate to severe Chronic Kidney Disease (CKD), where kidney function is less than 60%, affects approximately 5.5% of UK adults and is more common in

older people.¹ Some people argue that CKD is an 'over-diagnosed' condition and that there is no reason to unnecessarily label people with CKD.

However, whilst it is true that there is evidence of CKD in 40% of people over 75, CKD is clinically important because it contributes to an excess risk of cardiovascular disease (heart disease and strokes). The presence of CKD means that some drugs are not properly cleared from the body and it makes someone more susceptible to sudden worsening of kidney function (Acute Kidney Injury, or AKI) at times when patients are otherwise unwell.

Although only a small number of people with CKD progress to end stage renal disease requiring dialysis (or, if possible, a kidney transplant), this reduces quality of life, is very difficult for patients and their families and very costly for the health economy.

Patients in the community are managed by the GP who maintains an electronic health record and including entering diagnoses using Read Codes. These codes can then be systematically searched to enable appropriate care for people with disease. Improving identification and CKD recording (coding) in primary care delivers many benefits for people with CKD³⁻⁵:

- It enables personalised information and education about CKD for the individual. This includes informing patients with reduced kidney function that they should seek timely treatment when acutely unwell (dehydration, vomiting, high fever) to prevent acute kidney injury and of the risk of non-steroidal pain killers such as ibuprofen which may cause further kidney damage especially when taken with ACE-inhibitor and diuretic drugs.



- Opportunities to make lifestyle changes that will help maintain kidney health (weight loss, dietary salt reduction, stopping smoking).
- Practices can set up systems of regular review of kidney function to detect those who progress.
- Improved management of blood pressure, cardiovascular and infection risk. All patients with kidney disease qualify for statin drug therapy to prevent heart attacks and strokes and appropriate immunisation.
- Recognising the presence of CKD enables safer prescribing of medication. Many drugs are excreted by the kidney and the drug dosage needs to be adjusted accordingly.

Through the National CKD Audit, the effectiveness of Chronic Kidney Disease identification and management in primary care was studied in 1,024 primary care practices in England and Wales between April 2015 and June 2016. The Audit has produced the largest sample of patients with CKD in primary care globally; practices who participated in the Audit represent approximately 75% of all Welsh practices and 10% of those in England.

The first part of the National Report, published in

January 2017, focussed on the identification and management of CKD in primary care⁴. It showed that whilst in the majority of cases blood tests for CKD are done, there is great variation on who receives urinary tests. We can detect evidence of kidney damage from blood tests by measuring levels of creatinine, a by-product of muscle metabolism, or by testing the urine looking for levels of a protein called albumin.

Among those identified by blood tests, the percentage of CKD cases that were uncoded ranged from 0% to 80% between GP practices. There was considerable practice variation in achieved blood pressure control, statin prescription and pneumococcal vaccination for those with CKD.

The second part of the National Report, published in December 2017, focussed on outcomes for people with CKD. It showed that CKD in the community posed a massive burden to patients and secondary care and that people with CKD have an increased risk of hospital admission and death.²

Data suggested that unplanned admissions and deaths were more likely among people with CKD that had not been correctly coded in primary care compared to those who were coded; these differences in outcomes

Summary findings of patient outcomes

Patients with chronic kidney disease and moderate to severe function impairment.

1. For every 100 patients, there are 38 unplanned admissions per year.
2. For every 100 patients, there are 7 AKI events occurring at time of admission per year.
3. For every 100 patients, there are 6 CV events per year.
4. For every 100 patients, there are 2 admissions to the ICU per year.
5. For every 100 patients, there are 7 deaths per year.
6. Approximately 95% of patients with CKD stage 3-5 who had a GP nephrology referral code have a corresponding nephrology outpatient appointment within 18 weeks.

were not explained by differences in age. The magnitude of the difference between the rate of unplanned admissions and deaths for patients who were coded, compared with those who were not, increased as kidney function declined.

There are a range of medical conditions and social circumstances which were not captured by the Audit data, which in some cases might account for both the reason why a patient is not coded and why they have an emergency admission or an additional risk of death. Hence, further research is needed to conclusively prove that Read coding CKD in primary care (and the related actions when identifying and managing those patients) indeed prevents hospitalisations and deaths. However, there is good evidence that Read coding in primary care is associated with increased clinical scrutiny⁶.

Overall, the existing data strongly suggest that there is good reason to actively promote CKD diagnosis because it enables informed clinical shared decision making with patients and there are clear improvements in management, prescribing and engagement which flow from having identified patients with CKD. ■

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The current and future challenges of personalised cancer therapy

Managing Director of The Cancer Drug Development Forum, Prof. H. Zwierzina reveals his opinions on the current and future challenges of personalised cancer therapy, including the need for biomarkers

Traditionally, the efficacy of new anti-cancer agents is investigated in large patient populations with histologically defined tumours in randomised phase III clinical trials where the investigational drug is compared with standard-of-care treatment. This process is time-consuming, costly and has a considerable attrition rate. The results of these trials are used to obtain approval from regulatory agencies, such as US Food and Drug Administration (FDA) and European Medicines Agency (EMA) to bring the agent on the market.

During the last two decades, progress and a better understanding of cancer biology broadened this approach from one size fits oncology drug development, into smaller studies with novel agents. Advances in technologies, such as next-generation sequencing enable fast and efficient molecular profiling to detect genetic aberrations in tumours. In combination with the clinical development of agents inhibiting the function of driver genes or their products, personalised therapy with targetable tumour aberrations has become possible in selected patients.

However, this approach does not allow large-scale randomised clinical trials, but only smaller studies where the clinical benefit of a drug may be predicted by signatures of target dependence and host genetic makeup. At the same time, it is becoming evident that the more we know, the more complex drug development becomes. Histopathologically well-defined tumour entities become multiple different diseases classified by genetic alterations. These may differ from one cancer type to another and the ones we commonly see in, for example, lung cancer aren't always the ones we see in breast or colorectal cancer.

Furthermore, in the vast majority of cases, we do not have the drugs to target them. Another issue is that



Prof. H. Zwierzina

Image: © Michael Hoetzel DGFH

usually there is only a very small number of patients with a particular mutation. Thus, we will need to adapt the way we design trials to show whether a specifically targeted drug is effective in a very small patient population.

To accelerate drug development, reduce costs, increase efficacy and bring new and effective agents to patients as rapidly as possible, innovative trial designs are one way to tackle the problem. [The Cancer Drug Development Forum](#) (CDDF) recognises the complex issues of innovative oncology drug development. It organises and encourages multi-stakeholder meetings and workshops among academia, the pharmaceutical industry, regulatory authorities, health technology assessors, patient organisations, as well as payers to address these challenges.

Despite the progress in molecular phenotyping, a huge clinical need remains for minimally invasive tests to



ITOC 5 CONFERENCE Berlin. Prof. Heinz Zwierzina, Marjorie Recorbet (Association Manager) and Anissa Brennet (Association Coordinator).

Image: © Michael Hoetzel DGPh

determine subgroups of patients with a high probability for (non-) response to therapy. Biomarkers that predict clinical outcome and can easily be measured in the serum hold major promises. Although small compared to the costs of oncology drug development, the development, validation and commercialisation of biomarker assays are expensive.

In many instances, a single marker (i.e., assessment of a single biochemical variable) cannot offer the necessary sensitivity and specificity; instead, a panel of multiple markers is required given the complexity of the neoplastic process. Consequently, many investigations now focus on the development of multiplexed assays that screen multiple genes and proteins in the same specimen at the same time. Proteins, the downstream products of genes, are central to the process of carcinogenesis and the targets of almost all drugs. Because of a plethora of co- and post-translational modifications, the nature and quantity of each unique protein cannot be predicted from DNA or mRNA analysis alone. In other words, genomic and transcriptomic approaches can only provide information up-stream of the proteins and their modifications.

In summary, omic biomarker technologies (for example, genomics, proteomics and metabolomics) are ideal

tools for multivariate biomarker discovery, because they markedly increase the number of analytes that can be measured in a single clinical sample and therefore, the range of interpretive options available.

The future will see the widespread use of biomarkers. The regulatory challenges and the hurdles such as finances, access to clinical data and reimbursement will be addressed at the CDDF workshop 'Biomarkers and Patients' Access to Personalized Oncology Drugs in Europe' (Brussels, September 24/25, 2018). ■



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Paediatric sarcoma metastasis: An area that warrants in-depth exploration

Ivan Stamenkovic, Professor of Experimental Pathology at University of Lausanne explores the paediatric sarcoma metastasis and why this warrants an in-depth look at

Metastasis is responsible for 90% of cancer-related death. Several solid paediatric malignancies, particularly sarcomas, display high metastatic proclivity, which renders their prognosis poor, as metastases are for the most part unresponsive to conventional chemotherapy, even if the primary tumour is sensitive. Most of our understanding of the multistep process that constitutes metastasis comes from studies on carcinomas, which, at least in part, mimic the sarcoma phenotype to metastasize.

Most disseminating carcinoma cells undergo epithelial-to-mesenchymal transition (EMT), a reversible process by which they transiently adopt a variable mesenchymal phenotype. EMT appears to be critical for carcinoma cell motility, as epithelial cells are largely non-motile, as well as invasion and possibly other steps leading up to secondary colony formation. Once they have reached their final destination, disseminated carcinoma cells revert to their epithelial phenotype to grow and form metastatic tumours. Being of mesenchymal origin, sarcoma cells are naturally motile and may already possess all the properties necessary for dissemination.

They, therefore, do not need to undergo any phenotypic change and provide ideal cells to study metastasis and determine how metastatic lesions may differ from the corresponding

primary tumours. Extensive genomic studies on carcinomas have shown convincingly that there are no metastasis-specific genetic mutations, indicating that cells with metastatic potential are already part of the primary tumour and that epigenetic modifications are most likely responsible for providing them with the properties necessary to complete all the steps required for metastatic tumour growth.

The same is likely to hold true for paediatric sarcomas, including Ewing sarcoma, alveolar rhabdomyosarcoma (ARMS), synovial sarcoma and desmoplastic small round cell tumour (DSRCT), all of which tend to metastasize early and with high frequency. However, given their mesenchymal origin and phenotype, it will be important to determine whether metastatic properties are confined to a subset of cells in any given sarcoma or whether they are a common feature of most cells.

An essential property of cancer cells is their plasticity. Thus, carcinoma cells may transition bi-directionally between an epithelial phenotype and EMT or between a stem cell phenotype with tumour initiating properties and a more differentiated phenotype that is not tumorigenic. A pro-metastatic phenotype may therefore not be stable, but rather may be acquired transiently depending on the micro-environmental stimuli to which

a tumour cell or subpopulation thereof is exposed at different stages of tumour progression.

Like carcinomas, sarcoma cells display plasticity and may transition in a dynamic manner from metastasis-competent to non-metastatic variants and vice-versa. This phenotypic instability renders therapy particularly challenging for several reasons. Firstly, it is necessary to define the epigenetic profile that is responsible for conferring metastatic properties and to develop therapeutic strategies that can target the relevant epigenetic modifiers or their effects in a way that can cause the cells to lose key properties required for metastasis.

Secondly, it is necessary to understand the mechanisms by which cells without metastatic properties can acquire or re-acquire them. Understanding tumour cell plasticity is at least one requisite in the quest to counter the ability of malignant tumours to metastasize.

A major focus of metastasis research in recent years has been the isolation and characterisation of circulating tumour cells (CTCs). Once again, circulating carcinoma cells have attracted the greatest attention and it has been demonstrated that CTCs display variable EMT and CTC clusters are more effective in generating metastases than isolated CTCs. Very little work has been done on paediatric sarcoma



Spine metastasis: MRI of thoracic and lumbar spine

CTCs, but it will be of interest to determine to what degree sarcoma CTCs differ from bulk tumour cells, whether they require adaptation to sheer stress and whether they are enriched in cancer stem cells.

The relevance of tumour plasticity has been underscored by studies on the CTC phenotype in response to therapy. CTCs from different types of carcinoma have been observed to display increased EMT in response to chemotherapy, suggesting that EMT may confer at least partial resistance to therapy. Much less work has been done on paediatric tumour CTCs and it will obviously be of major importance to determine how such CTCs adjust their phenotype in response to therapy.

Moreover, CTCs may further modify their phenotype once they penetrate a secondary tissue, such that the phenotype observed in the circulation may undergo substantial changes as the cells adapt to the newly colonised tissue in which they must survive and divide. This continued dynamic phenotypic adjustment constitutes a major challenge to precisely identifying the epigenetic changes that are responsible for endowing tumour cells with metastatic properties.

One of our primary goals is to elucidate the epigenetic mechanisms that underlie paediatric sarcoma plasticity and to develop therapeutic approaches that could counteract their effects and possibly redirect the epigenetic changes

themselves to generate cells that lack the ability to disseminate and initiate tumour growth.



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The prostate gland: A most troublesome piece of tissue

Europa Uomo – European Prostate Cancer Coalition Secretary, John Dowling shares his thoughts on the prostate gland, described as a most troublesome piece of tissue

The prostate is an unusual part of a man's body. It continues to grow as we get older. "Ounce for an ounce or gramme for gramme, the prostate gland is the most troublesome piece of tissue in a man's body". These apt words of my friend, Prof Louis Denis, an eminent Belgian urologist and a prostate cancer survivor, sum up why prostate-related matters tend to loom large in the lives of men of a certain age.

Prostate problems affect nearly every man at some point in his life – whether it is the problems associated with an enlarged prostate which can have a really striking effect on a man's quality of life – or an infection of the prostate (prostatitis), which should be treated quickly and medically. Then, of course, there is the big bad bogie-man – prostate cancer.

But all is not what it seems. Most prostate cancer tumours can be spotted early given recent developments in MRI. Most tumours are low-risk and don't need active treatment. The known side-effects of radical treatment, in terms of quality of life, must be set against the possibility of an apparently low-risk tumour becoming a high-risk tumour. Increasingly, men in the low-risk category are being advised to consider active surveillance as a valid treatment option. But, it must be admitted that it's a bit of a puzzle for men to get a cancer diagnosis to be told: 'perhaps the best treatment is no treatment at all'.

There is now widespread acceptance among clinicians that there was abuse (they prefer to say overuse) in the use of the PSA test over the past 20 years. The radical treatment of men by surgery or radiotherapy after a prostate cancer diagnosis of low-risk cancer has subjected many men to unnecessary incontinence and sexual dysfunction (impotence), when they could have possibly avoided these conditions entirely. In those

cases where a tumour does eventually progress and enter a more aggressive phase, the egregious side-effects may have been postponed for many years. This postponement now enables men to access much better surgical and radiological treatments with lesser side-effects than before. These are the lucky guys. Others, however, are not so fortunate. They had high-risk prostate cancer from the get-go. They may have had a family history of prostate cancer, they may be African-American or Afro-Caribbean, they may just be unlucky. Treatments for this cohort of men are not as successful as for the majority. Only 12-14% percent of men are diagnosed with prostate cancer. Only 3% of men die from prostate cancer.

Aggressive or high-risk prostate cancers are often killers. Men with high-risk cancer may be advised to contain their cancer with androgen deprivation therapy (ADT). This starves the prostate cancer cells of their favourite nourishment – testosterone. While effective for a time it is far from a cure. Most men on ADT will become resistant at some point. In recent years the second line ADT treatments such as Enzalutamide, Abiraterone, Radium 223-dichloride have been deployed. But these are not a cure, they are life-extending treatments and they are very, very expensive.

In February 2018, the US FDA approved the first drug to be shown to be efficacious for non-metastatic castrate-resistant prostate cancer – its medical name is Apalutamide and its brand name is Erleada. This treatment is for men who have been on ADT for some time but whose PSA starts to rise. Despite scans and tests, the doctors cannot tell where the cancer has moved to. The tumour is too small to be detected but it is pumping out more prostate-specific antigen. Erleada is still not a cure. It postpones the spread (metastases) of the cancer for an average of two years.

Now two extra years or more when you are in your seventies or eighties is not to be sneezed at.

There are a few things to be said about the current state of play with prostate cancer. Prostate patients are now much better informed and becoming more articulate about their disease. In keeping with the growing empowerment of patients, they are also training as patient advocates. Prostate patient organisations are developing at a national and international level. My own organisation – The European Prostate Cancer Coalition – Europa Uomo is 15 years old this year. We are behind our womenfolk, however, who have organised and lobbied for services for the early diagnosis and treatment of breast cancer.

“Prostate problems affect nearly every man at some point in his life – whether it is the problems associated with an enlarged prostate which can have a really striking effect on a man’s quality of life – or an infection of the prostate (prostatitis), which should be treated quickly and medically. Then, of course, there is the big bad bogie-man – prostate cancer.”

We men have a long way to go. Prostate cancer in some countries is just not talked about, not by men, not by public health policymakers. Invariably, this is accompanied by a late presentation and high mortality rate. Europa Uomo has recently been putting a lot of resources in terms of developing prostate patient organisations in Eastern Europe in the hope of raising awareness and achieving better diagnosis and treatment. We have appointed a patient officer – based in Warsaw – to help us build our organisation and message in that part of Europe.

We know researchers and clinicians will find a truly reliable, inexpensive, non-invasive biomarker test which will allow for the early diagnosis of prostate cancer. We must also find a way of reliably sorting the indolent from the threatening tumours. We must continually seek to build awareness about prostate cancer. We must continue to build capacity with our member organisations, to train members, to participate at a national level in every way that they can.

As a European-wide voice of prostate cancer patients, our Coalition must participate effectively in the work of the European Medicines Agency, in various European Commission and Parliament initiatives and in partnership with other European cancer patient groups and professional organisation. As former Vice-President Joe Biden said at the Human Proteomics Congress in Dublin last September, clinicians and patients must emerge from their silos and learn to work together. Patient organisations must do likewise.

While the massive longitudinal studies, like the ERSPC ⁽¹⁾, continue to provide very useful information, the clinicians and the health policy decision makers still oppose systematic population screening. They have good reasons for doing so, but their patients are increasingly sceptical. The scene on the ground is chaotic with widespread opportunistic screening. Overtreatment continues to blight men’s lives. The researchers will have to find a treatment for advanced prostate cancer that does not give just a couple of years, but which will provide a lasting protection against cancer progression. Our Coalition aims that no man should die of prostate cancer. The recent advances in genomics, proteomics and other fields offer the prospect that such an aspiration is not merely a pipe dream. ■

1 ERSPC – European Randomised Study of Screening for Prostate Cancer, 2009 et seq.

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Non-invasive radiofrequency hyperthermia

Steven Curley from the Michael E. DeBakey Department of Surgery, Baylor College of Medicine and a group of experts from Brown Foundation Institute of Molecular Medicine, McGovern Medical School, University of Texas Health Science Center share their expertise on non-invasive radiofrequency hyperthermia (NiRFH)

Non-invasive radiofrequency hyperthermia (NiRFH), is an oncologic intervention that is being used as an adjunct to cytotoxic chemotherapy or ionising radiation [1]. It involves the application of high-frequency electromagnetic fields to produce mild hyperthermia (39-45°C) in malignant tumours.

While NiRFH has been extensively investigated clinically for several tumours (e.g. central nervous system, lungs, breast), clinical studies of NiRFH for hepatic malignancies remain elusive [2]. This is primarily due to technical challenges associated with the anatomic location of the liver and the high energy cost of transmitting the electromagnetic field through adipose tissue, which often leads to insufficient heating of the liver, overheating of subcutaneous fat and chest wall structures and skin burns.

In our own work, we have demonstrated significant problems and highly variable results when attempting to produce low-level hyperthermia in normal liver in a porcine model using a single capacitive end-fire antenna and receiving plate [2]. The skin and subcutaneous tissue experienced rapid heating and clinically relevant hyperthermia in the liver was attained in less than 40% of the animals tested.

We hypothesise that the currently available NiRFH field equipment is inadequate to heat tumour tissues in liver reliably and reproducibly. We have developed a mechanistic mathematical model of NiRFH treatment for primary hepatic tumours and liver metastases. The model, built on basic principles of physics, takes into account the narrow therapeutic index of hyperthermia, i.e., the constraints of the maximum tolerated dose by the fat and minimum effective dose for a tumour.

Using known human tissue frequency-dependent specific absorption rates (SAR) of RF energy, we produced a novel closed-form solution (Equation 1) of the heat equation describing the energy transfer in tissue and then tested the model to evaluate variables including frequency, increasing subcutaneous fat thickness and differential electrical properties of liver and malignant liver tumours. The model indicates that clinically effective temperature increases in liver (to 43-45°C) are *physically unattainable* due to the excessive heating of fat tissue at all frequencies and powers currently used.

The model demonstrates that, while it is possible to limit temperature increases in the fat by acting on a number of variables, including cross-

section of the beam, power, time duration of the RF treatment and frequency, the relative increase in temperature in the liver is always a fraction of the corresponding temperature increase in the fat at all frequencies. The model solution for the change in temperature (ΔT) with ΔT_L for liver and ΔT_F for fat is:

$$\frac{\Delta T_L}{\Delta T_F} = \frac{c_F}{c_L} \left(1 - \frac{x_F}{L_F}\right) \frac{SAR_L}{SAR_F} \quad (1)$$
 where c_i represents the specific heat in fat ($i = F$) and liver ($i = L$), x_F is the thickness of fat tissue and L_F is a characteristic length scale of the tissue, which depends on the relative SAR therein. It is found that the ratio of length scales $\frac{x_F}{L_F} \ll 1$ under all conditions. Since the ratio in SAR ($\frac{SAR_L}{SAR_F}$) is approximately 1/10 at all frequencies (Figure 1, adopted from Ho *et al.* [2]) and the ratio in specific heats ($\frac{c_F}{c_L}$) is approximately 1/2, it follows that a number of converging beams of the order of $n > 24$ is predicted to be necessary just to achieve equal temperature increases in the fat and liver.

This does not take into account the further penalty of significant heat dissipation coming from the vascular heat sink effect due to the high blood flow rate in the liver (17 ml/min/kg = 1,190 ml/min flow rate in a 70 kg human) [3], or even higher flow rates in a hypervascular liver cancer (shown to be higher than normal liver due to

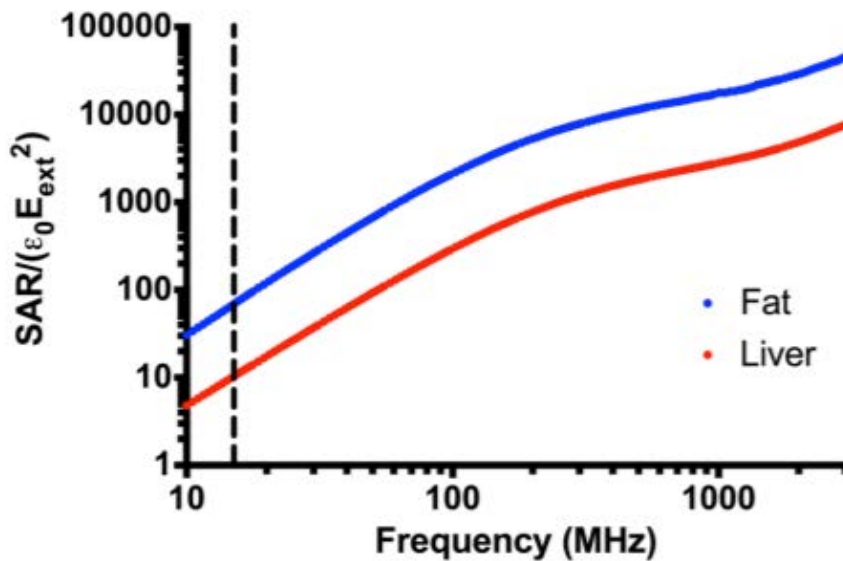


Figure 1. Relative SAR for subcutaneous fat and liver from 10 MHz to 3 GHz as measured with direct permittivity probes placed into tissue during variable frequency RF treatments in a large animal (pig) model. Adopted from Ho et al. [2] with permission

increased hepatic arterial flow rates in hepatocellular carcinoma) [4].

To develop a model for predicting RF therapy efficacy, we will integrate our energy transfer model with a spatio-temporal tumour response model [5], which has been used to understand and predict tumour response to chemotherapeutic drugs in patients. The energy transfer model will solve for energy deposition into the tumour tissue and feed this information into the tumour response model, which will then predict the extent of tumour kill by solving a system of differential equations with tissue- and treatment-specific parameters. The resulting integrative model, based on a combination of physical transport and electromagnetic theories (accounting for tissue heating for different tissue types), will be calibrated and validated with patient data and then prospectively used to optimise RF treatment for individual patients.

We recommend, based on our preliminary analysis, that a large number of multiphase array variable frequency (patient-specific) RF beams be used

clinically. Precision cancer care based on patient-specific genetic, proteomic and metabolomic analyses will become the standard of care; NiRFH should also be designed to meet a patient's cancer-specific and body mass-related electrical properties using mathematically determined frequency, power and treatment duration parameters.

Another possible approach to overcome the high adipose tissue SAR of RF (while avoiding heating and injury to fat-bearing tissues or adjacent organs) is to use nuclear magnetic resonance (NMR) Fourier decomposition techniques to focus the intensity of the RF at a desired depth in a liver tumour, thus bypassing the fat [4]. Finally, the use of RF-absorbing metallic-nanoparticle-based sensitizers that specifically localise in liver malignancies and are shielded from ionic charge buffering offers another possible means to achieve targeted hyperthermia [6].

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The illusion of cancer and death: Illusion of the self

Sumith A Kularatne, PhD, discusses his thoughts on the illusion of cancer and death

The moment we hear the word cancer, the thought that immediately crosses anyone's mind is death. So, everyone collapses both physically and mentally. If we learn to drop this inner conflict and accept the reality, we can experience and adore the life without fear. Moreover, we will learn that there is no difference between a so-called healthy person and a cancer patient.

As humans, we all are immersed in our circadian lives to feed our personal egos and desires like machines. As in the movie *The Matrix*, most of us may not be able to perceive this dual nature of the mind while living in the matrix and feeding illusory dreams. According to Vedic teaching, this state of mind is called "the divine game of Lila." We were all born into this world with personal identity or "self" (a physical body and a soul). We have not only forgotten that cancer conquered the soul well before it attacked the body, but also life and death are inseparable. So, every living being including cancer patients is barcoded with an expiration date.

According to the American Cancer Society, ~1,400,000 Americans were diagnosed with cancer during 2008, leading to ~560,000 deaths. On the other hand, about 1,735,350 Americans will be diagnosed with cancer in 2018 and ~610,000 will die. If modern science and technology can cure cancer,

what is the rationale for increasing number of cancer incidence in each year? Whilst the immune system is supposed to eliminate cancer cells within the body, it is not able to differentiate cancer cells from normal healthy cells. As healthy cells, cancer cells also express receptors that signal immune cells to prevent an attack or to keep the immune system in check.

While the treatment of invasive or metastatic cancer is often limited to chemotherapy, scientific ingenuity has created novel therapeutic agents only to find cancer has evolved to develop drug resistance. Cancer may have started from a singularity and spiralled out as "the primordial Om" or may have evolved from a single cancer stem cell as Darwin's theory and then metastasize to distant organs. While curing metastatic disease may be elusive, we may be able to use the idea of the fractal to explain metastatic patterns as Benoit Mandelbrot used it to describe geometrical patterns in nature.

Moreover, no matter what treatment is used for the cancer patient, cancer recurs at any time without a warning. In Greek mythology, the gods commanded Sisyphus to infinitely push a boulder up a mountain, only to have it roll down. So, are we futilely rolling a boulder uphill by searching impermanent solutions for a permanent problem?

J. Krishnamurti has famously said that "it is no measure of [one's] health to be well-adjusted to a profoundly sick society." So, a drug's mechanism of action may be the least to worry. As Kohlberg pointed out in "the Heinz dilemma," we must evaluate the value of human life over the pharma-companies' greed for money. According to the Heinz dilemma, a woman who was in near death from a special kind of cancer was prescribed a new drug that the doctors thought might save her. While the drug was expensive to synthesize, the druggist was charging ten times what the drug cost him to make. Left with no other option, the sick woman's husband, Heinz, stole the drug for his wife.

Although Kohlberg developed the Heinz dilemma to evaluate moral ethics, cancer drugs are extremely expensive when compared to the production cost. On the other hand, most of the drugs are discovered in sweatshops using scientists. As we learned from the Stanford prison experiment, management always likes to have more control, more power, more recognition, more money, and more of everything. Plato's Chariot analogy, as well as Freud's model, explains the nature of these human behaviours.

In Plato's Chariot analogy, a chariot (one's soul) is driven by two powerful winged horses whereas, in Freud's structural model, the soul is driven by



consciousness and unconsciousness. One horse is noble, rational and moral in nature (mirroring consciousness) while the other horse is wild in character (mirroring unconsciousness) and driven by basic instinct such as aggressiveness, sexuality and control.

In today's world, there are many people seeking spiritual enrichment by engaging in religious activities such as rituals, chanting, praying, singing, etc. However, most of those can be seen as human performing some conditioned activities rather than searching for one's self. As humans, while following religious habits on Sundays, we ride the wild horse comfortably during the rest of the week. We are waiting for The Second Coming of the saviour; however, no one willing to get up on the cross except partaking in the sacrament.

As Ludwig Feuerbach depicted, we may have already realised that "we create God in our own image by unconsciously projecting our idealised perfection as a divine being." On the other hand, Gaunilo's may have convinced us of the non-existence of God by his "Lost Island" analogy. In contrary, how are we going to explain the existence of

evilness, discrimination, abuse, natural calamities, death from cancer, etc. In the allegory of the cave by Plato, three prisoners lived chained in a cave from their birth. The only thing they could see were shadows cast on a blank wall by the objects passing on a raised walkway behind them.

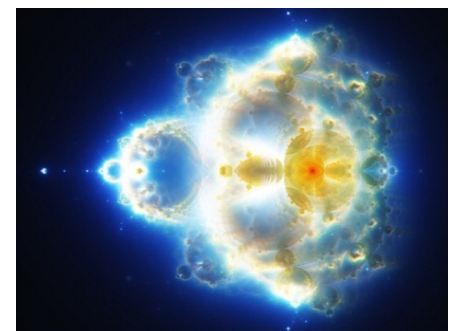
Plato showed the misconceptions about knowledge and wisdom, such as restored organised religions through false prophets, using the prisoners' guessing game from the shadows. He made the story more intriguing by allowing the escape of one prisoner into the real world, represents a philosopher who searches for wisdom, who ultimately comes back to the cave to relay the reality to remaining two. However, the two prisoners not only disbelieved him, but also threatened anyone who tried to free them from the cave. Although Plato wrote the allegory of the cave in ~400BC, it looks like; humanity is still searching the path to escape from the cave.

Although Rene Descartes, the father of modern philosophy, developed a "method of doubt" to objectively evaluate all that he believed to be true, he is famous for the saying "Cogito Ergo Sum" (English: "One thing I know for sure, I exist") without a doubt. He was a devout dualist in the sense that the self consists of an immaterial soul that is absolutely distinct from a finite, material body.

On the other hand, David Hume, a devout empiricist, claimed there is no self. Most of us may have never realised the no-self (minimal self), or what the Buddha called anatta. It goes beyond the body and the soul. Based on Buddhist philosophy, self can be defined as an impermanent (anicca) flow of energy (desire) through the

continual interaction of five aggregates (i.e. physical form, sensation, conceptualisation, disposition to act and consciousness) with right assembly that brings continual suffering (dukkha). We were named by the parents and told who we are by the society. If there is a self, we should have control over of sickness, ageing, death, social impacts, authoritative influences and natural calamity.

Once we realise the true nature of life and death and at the same time, the reality of self, we all will learn to die before we die. We will learn to let go of our ego construct by identifying the root for suffering. The intention of this article is not to make cancer patients walk away from medicine or their religious beliefs, but to inspire them to find the middle path (according to Buddha) or the golden mean (according to Aristotle). Simultaneous treatment of both soul and body may give a better outcome for the therapy and your soul will remain cancer free.



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TGF- β signalling – Tumor biology in prostate cancer

Identifying the molecular signalling pathways leading to advanced prostate cancer to improve therapy and diagnosis

Prostate cancer is the most common tumor in men in the Western society and the incidence is expected to increase. However, we still lack good molecular tools to identify aggressive prostate cancer.

Our aim is to identify the molecular signalling pathways leading to advanced prostate cancer. This knowledge will be used to design novel therapeutic strategies and improved molecular diagnostic tools.

TGF β signal transduction

Our research is focused on TGF β signal transduction, tumour biology and molecular pathology, particularly in prostate cancer. TGF β plays an important role for regulation of migration and invasion in several kinds of cancer cells, including prostate cancer cells.

In aggressive prostate cancer there is a correlation between the amount of secreted TGF β and poor prognosis with development of metastases. We have found that the ubiquitin-ligase TRAF6 is a crucial co-regulator of TGF β -induced non-canonical and oncogenic responses, as it associates with the TGF β type I receptor. TRAF6 promotes also expression and activation of proteolytic enzymes, such as TACE and presenilin1, which cleaves the TGF β type I receptor to liberate its intracellular domain (ICD). The generated ICD translocate to the nucleus in

an unknown manner, where it contributes to gene transcription of pro-invasive and metastatic genes. We focus our research on exploring how TGF β regulates invasive and metastatic behaviour of prostate cancer cells. We have access to unique collections of biobanked material at Biobanken Norr in collaboration with researchers here in Umeå.

Collaboration

We collaborate with national and local cancer researchers in the field of prostate cancer and renal carcinoma.

We collaborate with [SciLifeLab Drug Discovery Platform](#) in order to design novel and more specific cancer drugs.



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“Our aim is to identify the molecular signalling pathways leading to advanced prostate cancer. This knowledge will be used to design novel therapeutic strategies and improved molecular diagnostic tools.”

Cancer research and training in the United States

The work of the National Cancer Institute (NCI), the federal government's principal agency for cancer research and training in the United States, is profiled here by Open Access Government

The National Cancer Institute (NCI) is the federal government's principal agency for cancer research and training in the United States today. Their impressively sized team of around 3,500 people is part of the National Institutes of Health (NIH), one of 11 agencies that make up the Department of Health and Human Services (HHS) in the United States. In particular, NCI has two broad roles: cancer research plus training and support for cancer researchers.

NCI's mission statement is as follows: "NCI leads, conducts and supports cancer research across the nation to advance scientific knowledge and help all people live longer, healthier lives."⁽¹⁾

NCI is a leader of the cancer research enterprise, collectively known as the National Cancer Program and is the largest funder of cancer research in the whole world. It's true to say that NCI manages a vast array of research, training and information dissemination activities that reach across the entire United States, meeting the needs of all demographics – urban and rural, rich and poor, urban and rural and all ethnic-racial/populations.

When it comes to funding, NCI receives its funds from Congress. The bulk of NCI's budget supports extramural grants and cooperative agreements to facilitate research taking place at universities, hospitals, medical schools, cancer centres, research laboratories and private firms in the United States and further afield.

On the impact that NCI's investments have had, we know that this has led to declines in the rates of new cancer cases and cancer deaths as a whole in the United States over the last few decades. In keeping with this impressive improvement, the number of cancer survivors in the country has more than doubled

from 7 million in 1992 to more than 15 million in 2016 and unfortunately, it is predicted to rise to more no less than 26 million by 2040. These trends reflect advances in the detection of cancer detection, diagnosis and patient care which have led to people living longer and healthier lives than has been known previously.

The PanCancer Atlas

One example of research taking place, that is funded by the National Institutes of Health concerns the completion of a detailed genomic analysis, known as the PanCancer Atlas, on a data set of molecular and clinical information from over 10,000 tumours – that represent 33 types of cancer.

"This project is the culmination of more than a decade of ground-breaking work," says NIH Director Francis S. Collins, M.D., Ph.D. "This analysis provides cancer researchers with an unprecedented understanding of how, where and why tumours arise in humans, enabling better-informed clinical trials and future treatments", she adds.

"TCGA was the first project of its scale to characterise – at the molecular level – cancer across a breadth of cancer types", adds Carolyn Hutter, Ph.D., director of NHGRI's Division of Genome Sciences and the NHGRI team lead for TCGA. "At the project's infancy 10 years ago, it wasn't even possible, much less on such a scale, to do the types of characterisation and analysis that were being proposed. It was a hugely ambitious project."

The project focuses on cancer genome sequencing and on different types of data analyses, for example, investigating gene and protein expression profiles, as well as associating them with clinical and imaging data.⁽²⁾

Sorafenib improves progression-free survival for patients with rare sarcomas

In other news, interim results from a randomised clinical trial for patients with desmoid tumours or aggressive fibromatosis (DT/DF) show that the drug sorafenib tosylate (Nexavar) extended progression-free survival, compared with a placebo. The trial was sponsored by the National Cancer Institute (NCI), designed and conducted by researchers with the Alliance for Clinical Trials in Oncology (Alliance) and supported by Bayer HealthCare AG, which provided the study drug.

“Sorafenib is a novel way of treating this rare cancer,” comments lead investigator and study chair Mrinal M. Gounder, M.D., sarcoma medical oncologist at Memorial Sloan Kettering Cancer Center in New York City. “The promising results of this phase 3 trial represent a paradigm shift in the approach to treatment of patients with desmoid tumours.”

“Currently, there is no standard treatment for this rare disease and the effectiveness of the treatments that are used for it – for example, surgery, radiation and chemotherapy – is generally limited,” adds Jeff Abrams, M.D., clinical director of NCI’s Division of Cancer Treatment and Diagnosis. “But the interim results of this trial are promising and may offer a new treatment alternative.” ⁽³⁾

The development of vaccines for the human papillomavirus (HPV)

In other noteworthy news, Douglas R. Lowy, M.D. and John T. Schiller, Ph.D., of the Center for Cancer Research at the NC) were recognised for their contributions toward the development of vaccines for the human papillomavirus (HPV) in February.

On winning the 2018 Szent-Györgyi Prize for Progress in Cancer Research, Sujuan Ba, Ph.D., co-chair of the 2018 prize selection committee and president of the National Foundation for Cancer Research (NFCR), which awards the annual prize, said that Drs Schiller and Lowy: “have made monumental impacts in the field of cancer sciences and could not be more deserving of this award.”

NCI Director Ned Sharpless, M.D. adds: “We at NCI are very proud to see Dr Lowy and Dr Schiller awarded this prestigious prize for their important work in cancer

research. Their receipt of the Szent-Györgyi Prize for their extraordinary research recognises how important discoveries come from building on earlier work and how those efforts can lead to major breakthroughs in public health.” ⁽⁴⁾

Looking ahead

Looking to the future, everybody at some point in their lives has been touched by cancer, perhaps through a loved one dealing with it by the experience of a personal diagnosis. While incredible strides have been made in advancing scientific knowledge of the disease, there remains a great deal more to be done. In this vein, NCI will always support the most innovative laboratory research and clinical trials to transform the data we have today into tomorrow’s most revolutionary clinical discoveries.

The last word goes to NCI who explain in their own words how they are leading the way in understanding, preventing and treating cancer: “From basic science to clinical science, from implementation science to cancer care delivery and from advanced technology development to data-sharing and analysis systems, NCI is leading the way in how we understand, prevent and treat cancer.” ■

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Sunlight-induced carcinogenesis: Angiogenesis in skin cancer progression

Dr Olga V Volpert's work on sunlight-induced carcinogenesis at the MD Anderson Cancer Center is explored here, including why angiogenesis is critically important in skin cancer progression

Sunlight-induced carcinogenesis has become a concern since the 1980s when the depletion of the ozone layer was first noticed. Long-term exposure to ultraviolet B (UVB) component of sunlight is a risk factor for both non-melanoma and melanoma skin cancers. The incidence of skin cancers is increasing, with 2-3 million non-melanoma skin cancers and 132,000 melanoma cases occurring globally each year. Skin is sensitive to photodamage even after short-term exposures to UVB.

As with other cancers, angiogenesis is critically important in skin cancer progression and UVB-induced vascular changes in the skin have been attributed to increased production of pro-angiogenic cytokines and chemokines, such as vascular endothelial growth factor (VEGF), cyclooxygenase (Cox)-2, basic fibroblast growth factor (bFGF) and interleukin-8 (IL-8).

Thrombospondin-1 (TSP1), a large glycoprotein abundant in healthy adult tissues is a major inhibitor of angiogenesis. Loss of TSP1 has been implicated in the progression of many cancers including breast and colon carcinomas and skin cancers. In the skin, TSP1 produced by keratinocytes in the epidermis acts as a gatekeeper of the vascular changes associated with and required for cancer progression.

Therefore, TSP1 seems an obvious candidate for prevention or treatment

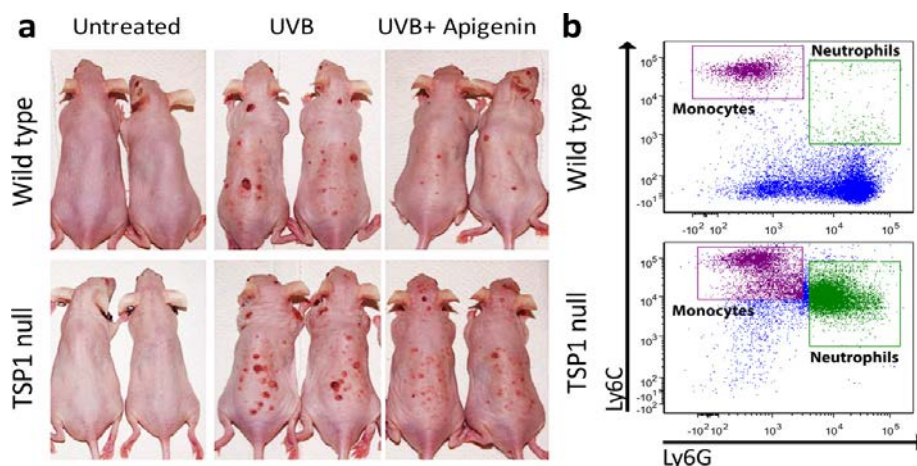


Figure 1. Loss of TSP1 blunts the anti-cancer effects of apigenin. (a) Wild type and TSP1 null mice were treated as indicated at the top of the panel for 22 weeks. TSP1 null mice develop multiple skin tumors despite apigenin treatment. (b) Bone marrow of wild type and TSP1 null mice treated with UVB and apigenin was analyzed by flow cytometry, to measure the neutrophil (Ly6G-high, green) and monocytes (Ly6C-high, purple) cells. In TSP1 null mice apigenin does not block mobilisation of inflammatory cells.

of cancer. However, a very large protein with complex functions is difficult to manufacture for clinical purposes. What if there was a compound that impedes subcutaneous angiogenesis by keeping normal, high TSP1 levels in the skin? There may be such a compound coming from a medicinal or culinary plant, chamomile or parsley.

Chamomile flowers are known since antiquity, for their healing properties. Apigenin, an active ingredient found in chamomile, has potent chemopreventive properties against UVB-induced skin cancer. In addition to its cytotoxic effects, potentially useful for arresting the growth of rapidly multiplying tumour cells, apigenin inhibits angiogenesis.

Using cultures of human and mouse

keratinocytes, as well as mouse models, Dr Volpert and colleagues carried out studies confirming the anti-angiogenic effects of apigenin and showed that it can reverse TSP1 loss in the UVB-exposed skin. This is the first known report of apigenin directly controlling endogenous anti-angiogenic protein. Treatment with apigenin, before or after UVB irradiation, restored TSP1 levels in cultured cells and in the skin.

They also found that, like apigenin, an active TSP1 peptide inhibited the production of Cox-2 and VEGF and reduced UVB-induced cancer-related vascular effects, angiogenesis and epidermal thickening. These studies strongly suggest the benefits of apigenin for therapy or prevention of skin cancer and provide mechanistic insights into its protective action.

No
exosomes



Late-stage
exosomes



Early-stage
exosomes

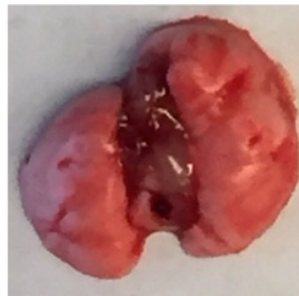


Figure 2. Early stage (PEDF-positive) exosomes block melanoma metastasis to the lung. Mice were treated as indicated at the top of the panel and melanoma cells injected in the bloodstream. Two weeks later, lungs were examined for metastasis (B16F10 pigmented melanoma can be visualized due its dark coloring).

Angiogenesis inhibitor alters the immune landscape in skin

Further studies by the Volpert group, indeed, showed that apigenin efficiently inhibits the UVB-induced skin carcinogenesis in wild-type mice but loses its anti-cancer effect, in which TSP1 gene is disrupted (TSP1 null) (Fig. 1a). Surprisingly, the most dramatic change in TSP1 null mice is in the inflammatory component of a tumour. It appears that TSP1 interferes with the UVB-induced production of inflammatory cytokines IL-6 and IL-12 and that in mice null for TSP1 far more inflammatory cells – neutrophils and inflammatory monocytes are recruited from bone marrow to skin where they produce growth factors to support cancer progression (Fig. 1b).

Angiogenesis Inhibitor is transferred by exosomes to bolster innate immune surveillance

Exosomes are tiny physiological vesicles (50-150 nanometres in diameter) formed through the endosomal pathway and released by all cells in the body. Exosomes are carried in biological fluids, like serum and urine. Studies of

the past decade have identified exosomes as natural vehicles assisting communications between cells and distant tissues.

These natural nanovesicles bioactive molecules to the recipient cells and change their properties or behaviour. Most studies show that exosomes released by cancer cells promote metastasis by creating permissive environments at the sites of their arrival (metastatic niches).

One of the major effects of cancer exosomes is immunosuppression. By transferring immunosuppressive cytokines and immune checkpoint inhibitors, cancer exosomes can incapacitate natural killer and cytotoxic T cells. This deficient host immune response serves to protect disseminating cancer cells and facilitate metastasis.

In a recent study, Dr Volpert and colleagues determined that cancer cells can also activate early immune surveillance. Working with melanoma as a model, they have demonstrated that at an early stage, melanoma cells alert the immune system of the host

to the presence of metastasis by sending out exosomes, which activate highly specialised cells called patrolling monocytes.

In the absence of cancer, patrolling monocytes constantly scan the blood vessel to seek out and eliminate damaged or dying cells. In case of metastatic cancer, the patrolling monocytes can detect and destroy lurking cancer cells. The Volpert group showed that one of such exosome-associated activators of patrolling monocytes is a known angiogenesis inhibitor, pigment epithelium-derived factor (PEDF).

Once activated with PEDF-containing exosomes, patrolling monocytes kill and engulf cancer cells on their own or recruit other cancer-killing immune cells, called natural killer cells. This is yet another case where anti-angiogenic protein 'doubles' as an activator of immune response and stops the spreading of cancer cells to the distant organs (Fig. 2).

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Chronic lymphocytic leukaemia (CLL) and acute myeloid leukaemia (AML): Leukaemia patients watching and worrying

Bethany Torr, campaigns and advocacy officer at Leukaemia Care discusses the impact of chronic lymphocytic leukaemia (CLL) and acute myeloid leukaemia (AML) on patients

The perception of a leukaemia is often that it is a cancer that requires very quickly treating and is immediately life-threatening. This may be the case for acute (or quickly progressing) leukaemia. However, the most common leukaemia diagnosis in adults is chronic lymphocytic leukaemia (CLL), a slowly progressing and incurable blood cancer, that in two-thirds of patients does not immediately require treating at diagnosis. Instead, the patients will 'watch and wait'.

Patients on 'watch and wait' will have regular blood tests and appointments to monitor the progression of their cancer. Treatment will not be started until the amount of CLL cells within the blood has increased to a point whereby healthy cells are significantly depleted, and this is causing problems. For many patients, this can take several years and for around 1 in 3, their CLL will never progress to a stage where it requires treatment.

This significantly differs from acute leukaemia, such as acute myeloid leukaemia (AML) that is the most common form of acute leukaemia in adults. In this instance, the number of leukaemia cells increases very quickly and if it is not diagnosed and treated promptly, there is a high risk for patients.

Traditionally, the treatment for both CLL and AML are chemotherapies. Chemotherapies are non-specific treatments. This means they are not targeted at cancer cells specifically and destroy healthy cells. This leads to significant side-effects and toxicities of treatment.

In AML, intensive treatment against the cancer is immediately necessary, but many patients are not fit enough to tolerate the treatment because 66% of



Bethany Torr, Campaigns and advocacy officer

patients are over the age of 65 years old. In contrast, unless CLL has progressed significantly, there is no immediate life-threatening reason to put patients through intensive chemotherapy. In fact, past practice demonstrated that treating patients early on leads to greater issues from chemotherapy toxicities than caused by the CLL. For this reason, 'watch and wait' was introduced.

During this time, CLL patients are often able to continue working if they are in employment and experience fewer effects on their finances, ability to walk and perform daily tasks compared to those who have been treated. In other words, patients on 'watch and wait' are living with their cancer.

This why a report published by the All Party Parliamentary Group on Blood Cancer in January this year was titled the 'Hidden Cancer'. A patient living with a blood cancer could be anyone among us and for those on 'watch and wait' it isn't necessarily obvious that they are



doing so. In this sense, the cancer is 'hidden'. However, just because CLL may not be visibly affecting someone, the diagnosis and living on 'watch and wait' often have significant effects on emotional well-being. Therefore, many people refer to the scheme as 'watch and worry'.

In a recent survey, Leukaemia Care identified that more than half of patients (53%) living on 'watch and wait' felt more depressed or anxious since diagnosis, with 1 in 8 of these patients feeling constantly depressed or anxious.

Something that significantly contributes to this, is the lack of support and information provided for patients on 'watch and wait'. Perhaps unsurprising when 3 in 5 patients aren't offered any additional support, such as buddying or clinical nurse specialist access (identified to be the most influential factor for a positive patient experience). Half of the patients aren't given any guidance on finding further information and 68% aren't given guidance on using the internet, such as signposting towards trusted websites.

Many patients describe feeling as though they are left to cope by themselves during the time between their

follow-up appointments, particularly after the initial diagnosis. Patients are living with uncertainty, knowing they have an incurable blood cancer, but not knowing how long it will be until they require treatment. Indeed, if they will ever need treatment. It can be hard to come to terms with a diagnosis and without signposting to information and support, there can be many unanswered questions and concerns. This is not only difficult for the patient, but also for those around them such as family, friends and employers who all must adjust to the diagnosis. ■

Leukaemia Care
YOUR Blood Cancer Charity

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Acute myeloid leukaemia (AML) research and application

The current state of metabolomics research and application in Acute Myeloid Leukaemia is placed under the spotlight by Bradley Stockard and Jatinder Lamba from Department of Pharmacotherapy and Translational Research, University of Florida

Acute myeloid leukaemia (AML) represents 1.3% of all new cancer cases, with 21,380 new cases anticipated in the United States in 2017¹. AML is a clinically challenging and heterogeneous disease that can become rapidly fatal if untreated. Despite continuing advances in treatment options, global 5-year survival rates are approximately 27% for adult patients and 60% for paediatric AML patients².

The heterogeneous nature of AML is characterised by the presence of numerous genetic lesions and chromosomal abnormalities present in its many subtypes. Although the most common mutations in AML have been defined, there is still a gap in our understanding of the molecular mechanisms underlying the variation in survival outcomes.

Due to these challenges, there is an ongoing search for molecular markers that can improve prognosis assignment and prediction of treatment and survival outcomes in AML patients. For the most part, studies conducted to identify these predictive markers have been focused on genomics and epigenomics based methods. However, the growing field of metabolomics has shown significant results in many forms of cancer and haematological malignancies. In the case of AML, metabolomics research has been very limited, but the results have been

promising. This article reviews the literature currently available for AML metabolomics.

***In vitro* metabolomics of drug response**

One of the earliest studies in AML metabolomics, was an *in vitro* metabolomics study conducted on AML cell lines³. The objective of this study was to use nuclear magnetic resonance (NMR) metabolomic profiling to study the effect of bezafibrate (BEZ) and medroxyprogesterone acetate (MPA) on AML cell lines and provide evidence for the underlying mechanism of action of BEZ and MPA. The cell lines showed significant changes to tricarboxylic acid (TCA) cycle intermediates following exposure to BEZ and MPA in the form of an increased conversion of alpha-ketoglutarate to succinate. This study shows the potential benefit of conducting *in vitro* metabolomics studies to explore the impact of drug treatment in AML cell lines. Specifically, these results highlight the importance of energy production pathways for AML cells, an ongoing area of focus in AML metabolism studies.

Application of glucose targeted metabolomics in AML prognosis

Rapid cellular proliferation is a major feature of many forms of cancer, including AML. This feature of elevated proliferation requires AML cells to upregulate multiple metabolic pathways involved in energy production,

such as glycolysis and the TCA cycle⁴. A particular feature of TCA cycle reprogramming in AML involves mutations in the gene encoding for isocitrate dehydrogenase 1 and 2 (IDH1 and IDH2). IDH isoforms normally catalyse the decarboxylation of isocitrate to form α -ketoglutarate, an essential step in the TCA cycle. However, mutant forms of IDH gain an additional function of catalysing the conversion of α -ketoglutarate to 2-hydroxyglutarate (2-HG). These changes to glucose metabolism have been of particular interest in AML metabolomics studies.

Recently, two major metabolomics studies have been conducted for adult AML patients, targeting glucose related metabolites for investigation. In the first study, patients were enrolled in a clinical trial to evaluate the prognostic value of serum 2-HG levels in AML patients⁵. Results showed that 2-HG could be used effectively as a prognostic factor in patients that were positive for IDH1/2 mutation.

A follow up study was conducted by the same group to evaluate the prognostic value of 10 different metabolites related to glucose metabolism in adult AML patients⁶. The investigators determined that increased abundance of five of these glucose metabolites, including lactate, 2-oxoglutarate, pyruvate, 2-hydroxyglutarate and glycerol-3-phosphate, were significantly associated with worsened survival

outcomes. The investigators used these metabolites to develop a prognosis risk score for each study patient. Ultimately, the results showed that prognosis risk scoring was able to predict poor survival outcomes in low scoring patients without the use of other prognostic factors. Together, these studies have helped confirm the importance of altered glucose metabolism in AML and they support the potential clinical relevance of metabolomics for AML patients.

Global metabolic profiling in AML

While the exploration of altered glucose metabolism in AML continues to yield significant results, the changes to many other metabolic pathways are not as well understood. To address this, multiple studies have taken a more untargeted approach to AML metabolic profiling to evaluate global changes to metabolism. A study by Wang, Y et al. using ¹H NMR spectroscopy found significant differences in multiple metabolic pathways between healthy controls and AML patients, including glycolysis, TCA cycle, protein and lipoprotein biosynthesis, fatty acid metabolism and cell membrane component metabolism⁷.

Another study by Musharraf et al. involved the global metabolic profiling of AML patients, as well as acute lymphoblastic leukaemia and aplastic anaemia patients. 27 metabolites were found to be significantly different between leukaemia patients and healthy controls⁸. Related metabolic pathways included fatty acid and ketone body metabolism and steroid hormone biosynthesis.

Finally, a more recent study conducted by Tan et al. focused on differentiating metabolic profiles of AML patients who achieved complete remission with cytarabine and anthracycline

chemotherapeutic regimens as compared to those who were non-responders⁹. The study identified two differential metabolites of interest, dodecanamide and leukotriene B4 dimethylamide, which the investigators were able to use to differentiate patients according to clinical response successfully. Ultimately, global metabolomics studies of AML have helped reinforce the role of glucose metabolism in AML disease progression and establish the importance of other metabolic pathways associated with AML, such as fatty acid metabolism.

Conclusion and future directions

Overall, the current body of research for AML metabolomics shows that this type of study can be successfully applied to improve our understanding of AML disease progression and characteristics, as well as the significant variation in clinical outcomes between AML patients. Many of these studies have identified glucose metabolism and fatty acid metabolism as metabolic pathways significantly associated with AML. However, there have been relatively few AML metabolomics studies published, even compared to many other cancer types.

Additional research is needed to further elucidate the metabolic pathways linked to the AML disease state. Ideally, metabolomics data can be integrated with additional 'omics' data to fully explain the path from gene to phenotype and help contribute to personalising AML evaluation and treatment for the individual patient. The current contributions of metabolomics to understanding AML are promising and its potential continues to be realised with growing interest in the field.

Acknowledgements

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Acute leukemia – driving toward precision and targeted medicine

Eigil Kjeldsen from Aarhus University Hospital gives an expert perspective on the drive towards precision and targeted medicine for acute leukaemia

Acute leukemia results in bone marrow failure, and comprise the two major hematological disease groups, acute lymphoblastic leukemia (ALL) and acute myeloid leukemia (AML). Normal bone marrow function is responsible for the maturation of stem cells (hematopoiesis) that give rise to all cellular components of the blood, including cells from myeloid progenitors. Examples of this include red blood cells (carrying oxygen), platelets (prevent bleeding and aid in clotting of blood), white blood cells such as granulocytes and macrophages (fight infections, removal of dead cells), and cells from lymphoid progenitors such as B- and T-lymphocytes (production of antibodies and killing of invading cells).

The failure of the bone marrow due to acute leukemia often results in anemia, high fever (night sweat) and prolonged infections that cannot be cured by antibiotics. This is caused by an abnormal expansion of immature leukemic cells, commonly known as blasts that may be of either lymphoid or myeloid origin, which ultimately replaces normal hematopoiesis. Individuals with acute leukemia that are left untreated usually die within 3 months.

Acute leukemia is a heterogeneous group of malignant disorders that are not particularly common. Approximately, 250 new cases of AML and 25-35 new cases of ALL are diagnosed annually

in Denmark. However, acute leukemias are set to becoming an increasing health problem as the population ages, mainly because AML is predominantly diagnosed in patients greater than 60-year of age and may also be secondary to previous chemotherapeutic treatment of e.g. breast cancer.

Furthermore, acute leukemias are challenging to diagnose and expensive to treat. Contemporary therapies of acute leukemias include chemotherapeutics, targeted drugs and hematopoietic stem cell transplantation.

Major advances in diagnostics and classification of acute leukemias

The last three decades have witnessed major advances in diagnosis and biological understanding of this disease group. Until the 1980s, the diagnosis of acute leukemias relied largely on morphological assessment and cytochemistry while immunophenotyping (IP) and chromosome analysis were in their infancy. Continued development of IP, chromosome analysis, including cytogenetics and molecular cytogenetics, and molecular genetics, including sequencing as well as targeted mutation analysis, have greatly improved our understanding of the molecular pathogenesis of acute leukemias following the pioneering work of Nowell and Hungerford¹ and later that of Janet Rowley, who established that acute leukemia is a genetic disease².

Two leukemia patients where their leukemic cells appear identical morphologically and by IP the leukemic cells from each of the two patients may harbor different chromosomal or molecular genetic profiles, that would cause an important variation in response to prescribed contemporary therapies exemplify this.

The most recent high-throughput molecular genetic analyses, such as oligo-based aCGH microarray analysis³ and next generation sequencing⁴, have further enhanced our pathogenetic understanding of acute leukemias. Several hundred-specific chromosomal and genetic mutations have been identified until now and we are still counting.

The adoption of WHO classification of hematopoietic neoplasms in 2001, and the subsequent revisions in 2008 and 2016⁵, where diagnosis and classification of subtypes relies on chromosomal and genetic information has had a major impact on diagnostic practice and greatly enhanced treatment outcome.

Impact of chromosomal and/or genetic lesions in leukemic cells

Leukemogenesis requires accumulation of aberrant genomic alterations in the leukemic blasts. Nonrandom (recurrent) chromosomal or genomic abnormalities can be detected in many of the patients with acute leukemias and are usually acquired early in leukemogenesis. They are often termed driver mutations in which genetic alterations contribute to the pathophysiology of the leukemic cells

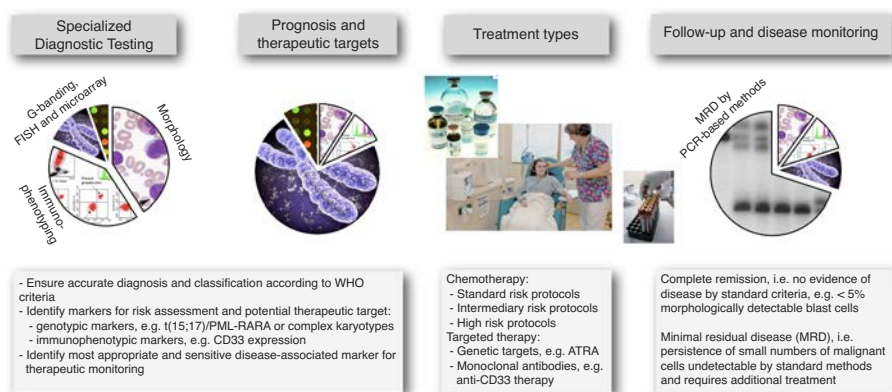


Figure 1. Schematic diagram illustrating the function of integrated hematological diagnostics for optimised treatment options and disease monitoring

conferring their survival advantage, by affecting important cellular pathways, which may include dysfunction of genes encoding transcription factors and signaling molecules that delay or block normal hematopoiesis. There are also passenger mutations that are secondary events during leukemogenesis or disease progression. Together these genetic alterations form the basis of prognostic and predictive markers in disease prognostication, as well as emerging targeted therapies.

Modern diagnostics and precision medicine

Targeted agents denote drugs aimed at discrete genetic or phenotypic lesions specific to the leukemia blasts compared with normal cells. It is known from several clinical trials that targeted therapy is both more effective and less toxic than conventional cytotoxic chemotherapy, which adopts to the "one size fits all" – principle.

Targeted therapy is, however, often more expensive than chemotherapy, because development of targeted drugs requires a great amount of knowledge about e.g. the cellular pathways (i.e. molecular pathogenesis), in which the genetic lesions have an impact.

To detect the critical genetic and phenotypic lesions in a timely manner, it

is of great importance that modern hematological diagnostics can provide excellence in morphology and immunocytochemistry, IP, cytogenetic as well as molecular genetic analyses (figure 1). Morphology and immunophenotyping are very important for diagnosis, whereas genetic changes are the single most important factor for disease group classification, treatment decision as well as prognosis.

Conclusion

The extensive genetic heterogeneity in acute leukemias provides a wealth of biomarkers in precision and targeted medicine, but only few of these known genetic lesions can currently be targeted by precision medicine. This is because it is one thing to identify novel genetic aberrations and another, to understand their cellular impact and subsequently how this information can be used to development of a targeted drug.

Thus, many questions remain on the clinical utility of these emerging genetic abnormalities and their implication as prognostic markers for disease outcome or predictive markers, for targeted therapies in different treatment settings.

The era of precision medicine in acute leukemias has just begun, and new diagnostic and therapeutic strategies are yet to be developed and tested.

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The European Diabetes Forum: Diabetes in Europe today

John J. Nolan, Stefano Del Prato, Juleen R. Zierath from the European Association for the Study of Diabetes e.V. present their approach to address the pandemic of diabetes in Europe today

Diabetes is now pandemic. It affects about 60 million people in Europe ⁽¹⁾, with many millions more likely to be afflicted in the next decade. Such a pervasive epidemic can only be addressed by the collaborative action between many agencies – physicians, pharmaceutical companies, charities, research organisations governments and patient associations. These can all contribute towards better management and care. The establishment of a European Diabetes Forum is both necessary and timely.

The worldwide costs of diabetes care have increased more than three-fold since 2006 and account for 6-10% of total health budgets in Europe. With modern therapies, it should already be possible for every person with diabetes to have a good quality of life and to avoid the serious complications of the disease. Despite the availability of many new pharmacological agents for diabetes including a wide variety of insulin preparations and technologies, many people continue to have poor control and the consequences of avoidable complications of the disease.

The European Association for the Study of Diabetes (EASD) is the organisation for research in diabetes in Europe. EASD aims to support high- quality clinical care with the aim of preventing or delaying diabetes and its complications. Through its research foundation (the European Foundation for the Study of Diabetes), EASD has already invested €100 million in basic and clinical research since 2000 ⁽²⁾. The society's journal, *Diabetologia*, publishes research spanning basic science, translational work and clinical research related to all aspects of diabetes.

The European Diabetes Forum is a new initiative of the EASD, started in 2017, which aims to address the full landscape of diabetes research and clinical care in

Europe. The objective is that the Forum will include (in addition to EASD leadership): industry, foundations, patients and patient organisations, government, regulators and payers. The Forum will focus on research priorities and the unmet needs of diabetes (both research and care) on a continent-wide scale. The Forum will take the lead on strategy for research and care and will serve as EASD's conduit for public engagement with political leaders as well as industry leaders around the globe.

The European Diabetes Forum will place special focus on three core themes: innovation, outcomes and the people with diabetes (patients). Innovation is crucial as a driver for both diabetes research and clinical care. Access to innovation is highly variable throughout Europe. Many stakeholders need to be considered and heard on this issue including people with diabetes, carers, clinicians, specialists and researchers, basic and clinical.

“The worldwide costs of diabetes care have increased more than three-fold since 2006 and account for 6-10% of total health budgets in Europe. With modern therapies, it should already be possible for every person with diabetes to have a good quality of life and to avoid the serious complications of the disease.”

Diabetes is still associated with a major burden of complications, limiting the quality of life and posing an economic challenge to society. Specific aims and timelines will be established to reduce these adverse outcomes. Patients play a crucial role not only in implementing treatments and improving outcomes but also in contributing to prevention strategies.

To deliver on its ambition to advance diabetes research and care, the European Diabetes Forum is working to



coordinate and encourage the energy and ambition of many key stakeholders who are already active in this field. Many agencies work to some degree in isolation, or with focus on one aspect of diabetes without the opportunity to contribute to the unified and overall agenda and the full landscape of this complex disease.

The Forum will make it possible for all these contributors to collaborate advance the agenda for both research and the systems of healthcare. Many of the leading stakeholders are already in dialogue with EASD. A plenary launch of the full European Diabetes Forum will take place on September 30th, 2018, prior to the EASD's Annual Scientific Meeting in Berlin. The EASD welcomes input to this new strategic initiative and will be visiting many of these stakeholders and organisations to communicate about the Forum during the second half of 2018.

Without a coordinated stewardship of the European diabetes agenda for research and care, the ongoing toll

of unwanted health complications and costs threaten the quality of life and welfare of an increasing proportion of the population. ■

1 IDF Diabetes Atlas, 2017 – www.diabetesatlas.org

2 www.EASD.org

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Diabetes & peripheral arterial disease

A change of paradigm improves patients' outcomes with diabetes & peripheral arterial disease, according to the Division of Angiology at the Medical University of Vienna

By way of an introduction, the key points for the current management of patients with diabetes and peripheral arterial disease can be summarised as follows:

- A multidimensional approach based on guidelines including the effort of health care providers and patients increase survival;
- Repetitive patient education to initiate, implement and persist treatment adaptations and;
- The constant vigilance of cardiovascular and metabolic complications.

Type 2 Diabetes Mellitus (T2DM) and its associated macro- and microvascular complications are a well-recognised threat to current and future European health and health care management.

The Vienna based Research Group Insulin Resistance, Inflammation and Atherosclerosis (IRINA) has been investigating the management of peripheral atherosclerosis in patients with diabetes and prediabetes since 2005, as one of its research focus areas. The main reason for this decision was that till 2006, it was acknowledged that patients with T2DM and peripheral arterial disease (PAD) with a foot ulcer do not survive for longer than four years.

Current Research and Results

In 2006, the group started its IRINA

PAD study¹. In this study, patients with both diseases – T2DM and PAD – are managed at a tertiary care centre. The participants were treated by implementing new and at that time provocative treatment (e.g. HbA1c cut-off, as a diagnostic tool, mandatory ACE inhibitors, mandatory high-power statins), which far later (2016-2018) were supported by American² and European cardiovascular guidelines³.

“Our study suggests that a multi-dimensional approach based on guidelines, guideline updates and physicians' expertise at a tertiary care centre can modify prognosis of PAD patients. Still, the constant vigilance of cardiovascular and metabolic complications is needed to achieve this goal.”

Other European and non-European groups also tried to improve patients' outcome: An Italian Group suggested in 2009⁴ the importance of education for patients and relatives concerning the care of diabetic foot syndrome. Dual antiplatelet therapy, the treatment of all other cardiovascular risk factors and rapid endovascular or open revascularisation was performed. This approach resulted in a noteworthy improvement in limb salvage and survival – indeed, major amputation was reduced from 68% to 20% and all-causes of death from 75% to 50% in over six years.

In 2015, a potential major backlash was reported, as a German insurance

company database consisting of over 40,000 PAD patients⁵ demonstrated a one-year mortality rate for patients with severe PAD of up to 35%. The major cause for this unwanted outcome may have been that most of the patients did not receive angiographies and thus associated revascularisation attempts.

In addition, during the last decade, several studies have suggested, that in various diseases the more advanced the disease is, the less stringent doctors and patients seem to be with treatment goals and for example, likewise where mandatory medications are concerned. Partially, this might be because patients and doctors might not have realised the change of the treatment paradigm in the respective diseases.

The same seems to be true for T2DM and PAD. Whereas the pharmacological treatment of T2DM and coronary artery disease (CAD) – a less generalised form of atherosclerosis in comparison to PAD – is well established and used, most patients with T2DM and PAD are undertreated.

In a Danish population-based follow-up study,⁶ between 1997 and 2003, only 26% of patients with lower-limb PAD (n=3424) used antiplatelet drugs, 10% statins and 22% ACE inhibitors/angiotensin receptor blockers (ARB) – in comparison to CAD within six months after hospital discharge.

In the REACH Registry⁷, risk factor management was less frequent in patients with PAD (n = 8322), compared to those with CAD or cerebrovascular disease. Patients with isolated PAD used a statin in 50%, antiplatelet medication in 76% and ACE inhibitors in 33% versus 70%, 84% and 50% of patients in the other high-risk disease groups.

IRINA's contribution

Immediate revascularisation and rigorous pharmacotherapy might be a way out of the knowledge plateau. This approach was tested in the IRINA PAD study¹. The study included 370 PAD patients in the intensified care group (Vienna Medical Center group, VMC) and 332 PAD patients with a single VMC visit and further usual family medicine care (practitioners care patient group, PCP). A combined 702 patients were followed for up during a five-year period¹.

Patients suffering from the unfavourable combination of PAD and T2DM were clearly demonstrated to benefit in survival: 95.3% for normal glucose metabolism, 90.2% for prediabetes and 87.9% for T2DM (p=0.142).

Our study suggests that a multi-dimensional approach based on guidelines, guideline updates and physicians' expertise at a tertiary care centre can modify prognosis of PAD patients. Still, the constant vigilance of cardiovascular and metabolic complications is needed to achieve this goal.

In our study, the prescription and use of medication to achieve risk factor goals increased from 48.8% to 89% for statins, from 88.7% to 90.9% for antiplatelet medication and from 74.3 to 86.1% for ACE-inhibitors/ARB. In our trial, we observed a relative reduc-

tion of all-cause mortality of 73% (9.2% vs. 34%) in VMC vs. PCP patients. Still, non-modifiable risk factors such as inflammation, nephropathy and age remained significant predictors of cardiovascular outcome in the VMC group.

Nevertheless, VMC patients still have a high prevalence of major adverse cardiovascular events (MACE) (15.7%) and all-cause cardio-vascular events (32%). The annual event rate was 3.1% for MACE and 6.4% for all-cause cardio-vascular events. Glucose metabolism (NGT vs. pre-diabetes vs. T2DM) was not responsible for a significant difference for MACE (p=0.059) or all-cause cardio-vascular events. Those achievements were based on a high expenditure of time on both the part of the patients' and the physicians'. In the PCP setting, an equivalent patient management is not adequately reimbursed by state insurances in Austria. Thus, it is remarkable that 74% of PCP patients were on statin treatment and 66%.

Overall, the increased effort of patients and physicians at a tertiary care centre resulted in a 24.8% ABSOLUTE survival benefit within five years¹. In particular, patients with the noxious combination of PAD and diabetes did not exhibit a poorer survival rate. Our data implies that those multi-morbid elderly patients still benefit from intensified care, compared to the usual primary care setting. Similar data from Canada⁸ and Slovenia⁹ suggest that our findings might not be unique, but generalisable.

Future plans

With the over ageing of our European population and the pandemic of pre-diabetes/diabetes, we might see a rise to up to 40 million patients across

whole Europe suffering from PAD and T2DM in the year 2040. Treatment plans are needed to prevent tremendous burden for the people, costs for the states and unwarranted degree of disease as well as early death. The Slovenian, Canadian and Austrian data suggest that such a treatment protocol should be tested by a multi-centre European trial.

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Accelerating innovative treatment for type 2 diabetes

Researchers from the University of Oxford and Novo Nordisk are collaborating to develop better treatments for type 2 diabetes

Together with the University of Oxford, Novo Nordisk is taking its commitment to treat and eventually alter the course of diabetes forward by forming a strategic alliance and establishing the new Novo Nordisk Research Centre Oxford (NNRCO). Type 2 diabetes affects around 3.5 million people in Britain today, accounting for approximately 90% of all diabetes cases. Worldwide, diabetes is the world's fastest-growing chronic disease, fuelled by the global obesity epidemic.

A serious commitment building on 20 years of partnership

This strategic alliance builds on more than 20 years of fruitful cross-fertilisa-

tion between the University of Oxford and Novo Nordisk, the world's leading diabetes care company. In 1999, funding from Novo Nordisk contributed to the establishment of the Oxford Centre for Diabetes, Endocrinology and Metabolism (OCDEM) and in 2013, the Novo Nordisk Fellowship Programme was launched. The programme is one of the company's largest external fellowship investments, currently funding up to 32 postdoctoral and clinical research training fellows at the University of Oxford. It will deliver a cohort of young diabetes researchers with the skills to work across the academia-industry interface and accelerate the delivery of new medicines.

The vision for the research alliance is set by a joint steering committee, with members from the University of Oxford and Novo Nordisk, whose aim is to build successful partnerships with fruitful outcomes.

New research centre to open on University of Oxford campus

In mid-September 2018 the new building for the NNRCO will be inaugurated and provide space for cutting-edge research and technology. The new centre will be near several university departments and units, including the Big Data Institute and OCDEM. Novo Nordisk researchers and post docs will work there, providing a



Artist impression by MAKE architects of the Novo Nordisk Research Centre to open on the University of Oxford Campus. Due for completion mid September 2018

significant new resource to find solutions and innovative treatments for the care of type 2 diabetes.

A focus on translational research for type 2 diabetes and its complications

The collaboration between the University of Oxford and Novo Nordisk is an innovative one, focusing on the translation of early-stage research that has the potential to substantially impact future treatment of type 2 diabetes. The strategic alliance has a bold aim to incorporate the best practices of pharma with the cutting-edge research being undertaken at the University of Oxford. A multi-disciplinary team of scientists will combine industry expertise with Oxford's existing strength in diabetes and metabolism research.

The new centre also presents a terrific opportunity for researchers in the Novo Nordisk Oxford fellowship scheme to enjoy rich and regular engagement with Novo Nordisk team, maximising their scientific learning and understanding of how the pharma industry works.

Funding model to fuel the creation of projects

To kick-start collaborative research between the University of Oxford and Novo Nordisk researchers, funds are available to support pump priming awards to drive the creation of collaborative ideas. Pump-priming awards reflect the partnership's aim not only to discover new and exciting avenues of research, but also to initiate work on collaborative ideas early in development.

Once the NNRCO is established, it is the ambition to share translation expertise in human-centric and state-of-the-art cellular and molecular tools. This includes image based high-throughput screening, stem cell models, single-cell genomics, bioinformatics and mass spectrometry, to name a few of the technologies which will be housed in the new centre.

Proven partnership model

Projects, spanning genetics, advanced imaging and in-vitro cellular modelling, have been funded, enabling researchers from both institutes to work on potential collaborative ideas.

The extensive skills and experience of the outstanding scientists working in this collaboration create a unique opportunity for knowledge and technology-sharing and development. For example, Novo Nordisk scientists will share their experience in early translational discovery and drug development through a series of lectures open to all. This is, besides the research, a crucial element and core strength of the partnership.

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Diabetes: The fastest growing health crisis of our time

Head of Policy, Knowledge and Insight at Diabetes UK, Robin Hewings sheds light on the condition of diabetes in the UK

Diabetes is the fastest growing health crisis of our time. There are 3.7 million people now living with the condition in the UK, a figure that has more than doubled in the last 20 years.

A diagnosis of diabetes is very serious. The condition requires constant self-management, including lifelong, daily injections of insulin if you have Type 1 diabetes or insulin-controlled Type 2 diabetes. If people are not supported to manage diabetes, it can lead to devastating complications. Diabetes is the leading cause of preventable sight loss in people of working age in the UK and is a major cause of lower limb amputation, kidney failure and stroke.

As well as the human cost, diabetes and its many complications cost the NHS £10 billion every year, which represents around 10% of the entire NHS

budget. With the number of people living with diabetes continuing to rise, there is a real risk these figures will rise in tandem to unsustainable levels.

That's why it's crucial that we support people with diabetes to live well with the condition and in doing so, to reduce their risk of developing these devastating and costly complications.

While there have been improvements to the delivery of diabetes care in England and Wales, the overall health outcomes for people with diabetes are still marked by significant levels of variation. Data from the [2016-2017 National Diabetes Audit](#) shows that just 18.9% of people with Type 1 diabetes and only 40.8% of people with Type 2 diabetes are achieving the recommended treatment targets for blood glucose, cholesterol and blood pressure.



Robin Hewings, Head of Policy, Knowledge and Insight

Reducing the number of people at risk of Type 2 diabetes would also help to reduce the impact of the condition on the NHS. Type 2 diabetes accounts for 90% of diabetes cases and unlike Type 1 diabetes, is closely linked to being overweight and obese so, in most cases, could be prevented or delayed by maintaining a healthy weight.

The [NHS Diabetes Prevention Programme](#), a joint initiative between Diabetes UK, NHS England and Public Health England, is doing great work to identify and support some of the 5 million people in the UK who are at high risk of Type 2 diabetes to make the necessary lifestyle changes to reduce their risk.

But we also need to create a healthier environment to make it as easy as possible for all of us to make healthier choices and in turn, reduce our risk of developing Type 2 diabetes. All too often making the unhealthy choice is the easy choice.

This is why we are also calling on the government to introduce mandatory front of pack traffic light food labelling, through our [Food Upfront](#) campaign; ban price promotions on junk food and toughen restrictions on junk food advertising to children.

Diabetes presents a huge challenge but, if we get better at preventing Type 2 diabetes and improving care for people diagnosed with Type 1 and Type 2 diabetes, we can achieve our vision of a world where diabetes does no harm. ■

Thankfully, after many years of campaigning by Diabetes UK, in partnership with people affected by diabetes, the government and our health leaders now recognise that improving the quality of diabetes care is key to helping people with the condition live long, full lives and in turn, reducing the huge burden on the NHS.

This is what, in part, led to the announcement from NHS England Chief Executive Simon Stevens at our Professional Conference in March that a further £40 million has been earmarked to drive improvements in diabetes care, via the [NHS' Transformation Funding](#).

The diabetes Transformation Funding, which was launched in 2017, is a pot of money that CCGs can bid for to target key diabetes services for improvement. The extra funding, combined with the diabetes [Improvement and Assessment Framework](#), which assesses CCGs on how they perform key diabetes services, could help to radically improve health outcomes for people with diabetes if it is sustained.

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Online diabetes competency training: Improving standards and reducing variation

Candice Ward, Lead CDEP Educator from Cambridge Diabetes Education Programme (CDEP) details online diabetes competency training, including the importance of improving standards and reducing variation

Diabetes management is complex, requiring appropriate knowledge to provide optimal diabetes care. The provision of safe, quality care lies within the foundations of healthcare education, continuing professional development (CPD) and evidence-based practice, which are inseparable and part of a continuum during the career of any healthcare practitioner.

The Cambridge Diabetes Education Programme (CDEP), a unique online diabetes healthcare practitioner education resource, is increasingly being recognised as a way by which Clinical Commissioning Groups (CCGs) in the UK can implement far-reaching, cost-effective diabetes education for their staff. CDEP is based on the UK diabetes competency frameworks, which help structure the nature and level of diabetes skills required by all healthcare staff to support safer patient care, improved outcomes and to reduce the financial burden of diabetes.

Beyond providing opportunities for staff to undertake diabetes CPD and obtain accredited study hours and reflection documents, CDEP's clinical feedback portal provides diabetes practice-based evidence for annual appraisals and professional revalidation portfolios.

CDEP offers competencies across five different levels (core, intermediate, diabetes specialist diabetes expert and diabetes consultant) – making it applicable to all levels of staff.

CDEP is endorsed by Diabetes UK, Cambridge University Health Partners (CUHP) and the British Dietetic Association (BDA) and is accredited by the Royal College of Nursing (RCN), the Royal College of Midwives (RCM) and the Royal College of General Practitioners (RCGP).

CDEP is based on adult education principles and is designed to be done in 'bite-size' chunks in appreciation of

the very pressured lives healthcare practitioners lead. The overall time taken to complete a topic will vary from person to person, depending on their prior level of knowledge, IT literacy and reading speed. Topics vary in length, depending on the number of competencies, but on average they take between 1-3 hours to complete. Currently, CDEP offers 15 topics in total, which amounts to 30 hours of CPD time if all 15 are completed.

Staff, with appropriate diabetes competencies for their role, tend to find CDEP improves their confidence by validating their knowledge. The demonstration of competencies is reassuring to employers and can be used as evidence of robust clinical quality assurance, in minimising clinical incidents as well as preventing never events. CDEP also make staff aware of the gaps in their knowledge and this is reflected in the improvement in self-reported competency levels and familiarity with diabetes guidelines.



A quote from a practice nurse working in diabetes

"It has been apparent for some years that the depth of knowledge has been varied among healthcare professionals,

which can be detrimental to patient care. It also has been difficult to access up to date information and guidelines, which again has an impact on the care delivered.

"On accessing CDEP I have found that I became more confident in delivering diabetes care within both my practice and teaching student nurses and registrars. The resources are second to none and as you are able to access the most up to date research, which has helped broaden my knowledge, and sign post patients to resources that they would find helpful in self-management.

"Using CDEP has been invaluable as a teaching resource as you are able to do as much or as little as time allows, allowing you to access it around work or family commitments. All the nurses in my team have accessed CDEP and found it very helpful, not only for diabetic patients, but other patients with chronic disease.

"I feel very strongly that CDEP has had a major positive impact on my fellow health care professionals and on the care, they deliver."

CDEP's resource library is designed to support the user undertake the competencies and can be accessed prior to, during or following an assessment series. However, we have discovered that healthcare professionals are also using this library as a portal to access resources during clinics to support clinical activity.

On average, 14 people successfully complete a CDEP topic every day of the week. From our own research, completion rates of CDEP are far higher compared to face-to-face education delivered by diabetes specialist nurses, due to the convenience of accessing learning at a convenient time to the user.

To date, CDEP has generated over 7,200 individual certificates following the successful completion of a topic. The average evaluation across all topics showed that 99.6% either confirmed (13.6%) or improved (86%) their diabetes competency, confidence or guideline familiarity.

CDEP offers commissioners a unique online reporting portal to view aggregate data regarding the uptake and utilisation of CDEP within their staffing cohort so they can monitor the impact of CDEP, as well as focus diabetes education strategies to support local face-to-face training initiatives and clinical incentives to drive improved diabetes outcomes.

CDEP was designed and piloted by a multi-disciplinary diabetes specialist team consisting of nurses, dietitians, podiatrists, healthcare assistants, general practitioners and diabetologists. Prior to launch, each new topic is robustly tested by the core CDEP clinical team, external experts in the field as well as the target audience to ensure that the topic is fit for purpose. CDEP undertakes a regular review of all the content to ensure it is up-to-date. User feedback is routinely monitored and actioned as appropriate to enrich the platform.

CDEP has a mobile responsive website, which offers a high quality user experience on a computer, tablet or smartphone. CDEP offers timely support to users and commissioners via email, telephone and teleconferences.

If you wish to find out more about CDEP or have a live demonstration of the online diabetes e-learning tool, please do not hesitate to contact us.



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Tackling the healthcare challenge of diabetes in England

The work of NHS England in tackling one of the biggest healthcare challenges of our time, diabetes, is examined here by Open Access Government

For 70 years NHS England has paved the way to improving health and care in England by sharing out more than £100 billion in funds and holding organisations to account for spending this money both effectively for patients and efficiently for the taxpayer. Currently led by Simon Stevens, the Chief Executive of the NHS England, today it looks ahead towards a vision, through the NHS Five Year Forward View. This plan aims to deliver a better, more joined-up and more responsive NHS in England. It also focusses on the issues that matter most to the public and collaborates, to ensure that health services are designed around patients. And that is on a more sustainable footing, so that it can continue to prioritise and deliver health and high-quality care – now and for future generations.

One area that is becoming more and more of a priority in recent years is the increase in people suffering from cases of diabetes. “Tackling diabetes is one of the biggest healthcare challenges of our time, as the number of people with Type 2 diabetes continues to rise”, states Professor Jonathan Valabhji, NHS England’s National Clinical Director for Diabetes and Obesity. ⁽¹⁾

Estimates expect the number of people with diabetes will rise to 4.2 million by 2030, affecting almost 9% of the population; making it a focal point of the NHS England, one that will be tackled head-on over the coming years.

2017 brought about many new programmes and frameworks to help act against diabetes, such as the fundamental announcement of the expansion of the diabetes prevention programme in June 2017. With the official launch of this programme being over a year ago now, starting with 27 areas covering 26 million people – almost half of the country, the launch of wave 2 will push even further, covering another 25% of the

population. Stevens announced that 13 new areas are now live and ready to offer a leading NHS prevention programme to patients identified at risk of developing Type 2 diabetes.

The latest figures reveal the programme was already, in fact, making good progress, with just under 50,000 people referred in Wave 1 and more than 18,000 on the programme at the end of April. This exceeds the original target set in the NHS Mandate of 10,000 referrals during 2017/18. Wave 2 will hope to bring in an estimated 130,000 referrals and up to 50,000 additional places made available thanks to the expansion.

Funding has also been agreed for another 12 months in the 27 sites that were originally up and running. The ambition is for the programme to eventually cover the whole of the country and these figures could rise to as many as 200,000 referrals and more than 80,000 people on programmes by 2018/19.

Simon Stevens comments: “With more than 18,000 people having already started our diabetes prevention programme, the NHS is doing its bit but this is a battle we cannot win alone.” ⁽²⁾ Wave 2 of the Healthier You NHS Diabetes Prevention Programme is part of a wider package of measures to support people with diabetes and those on the cusp of it, to stay fit, well and prevent further deterioration. Those referred to the programme will receive excellent levels of support, a tailored education on healthy eating and lifestyle choices and bespoke physical exercise programmes.

Furthermore, November 2017 brought the collaboration of the NHS England, Public Health England, Diabetes UK and leading companies from the tech sector to digitally combat Type 2 diabetes.



More than 5,000 people were able to benefit from a pilot project, which allowed five companies to test drive a range of apps, gadgets, wristbands and other innovative digital products. Users were able to access health coaches and online support groups as well as set and monitor their individual goals electronically.

Wearable technology was also available for some patients, to help them monitor activity levels and receive motivational messages and prompts, which is also now being made available on the NHS for the first time. This online method of receiving support truly has the potential to have a similar impact to face-to-face interventions – helping bring down high blood sugar levels and in turn, prevent or delay the onset of Type 2 diabetes.

In closing, it's worth highlighting the following statement from Professor Jonathan Valabhji at NHS England. Valabhji perfectly articulates the efforts being taken by the NHS England and how actions are being taken every day:

“The NHS, along with its partners, is going to great lengths to help keep those with diabetes healthy. It is crucial that we have an integrated approach to tackling not just the prevention of Type 2 diabetes but also the successful management of all forms of diabetes and it is essential that we support the spread of evidence-based interventions to help reduce the harm that diabetes can cause.”⁽³⁾ ■

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The Roche digital solution to the diabetes challenge

Diabetes is described as the epidemic of the 21st Century, in the view of Roche Diabetes Care, who are using digital technology and data management to help patients, healthcare professionals and payers address this costly challenge

There are more than 400 million people globally who live with diabetes¹. In the UK alone, this figure is 4.5 million people². The incidence of the disease, which is a characterised condition by high blood sugar levels, is growing – indeed, estimates suggest that some 629 million people worldwide will have diabetes by 2045¹.

Much of this increase is driven by type 2 diabetes, but type 1 diabetes is still a concern with the number of cases increasing by 4% a year³. Regardless of the type, however, diabetes is a chronic condition, which is posing a costly concern for healthcare systems around the world. Meanwhile, people with diabetes are forced to juggle complex and fragmented data and make difficult medical and lifestyle decisions for themselves 24/7.

In many ways, diabetes has reached a tipping point. Just 6.5% of people with type 2 diabetes in Europe achieve their combined therapy targets⁴; the rest are struggling. In addition, physicians lack time and infrastructure support to sufficiently manage their patients and the disease. Together, this is putting pressure on healthcare systems and the costs are mounting¹; in the UK, for instance, treating diabetes and associated complications represents 10% of the NHS budget, amounting to £10 billion each year⁵. The healthcare challenge presented by diabetes is immense – but it's not insurmount-

able. The challenge is making the system sustainable in the long-term.

The solution to this complex problem cannot solely be delivered by the introduction of another pharmaceutical drug. As Dr Partha Kar, diabetes and endocrinology consultant and associate national clinical director of diabetes with NHS England, said recently during techUK Rise of the Machines event: "It's not a new insulin alone that's going to change diabetes treatment – it's technology".

Roche Diabetes Care believes that digital health solutions and integrated diabetes management solutions have the power that will move the needle, bringing true relief to people with diabetes and developing a transparent system for healthcare professionals and payers that drives optimal care for this chronic condition.

Roche Diabetes Care envisions a holistic approach to addressing the diabetes challenge. Driven by technology and integrated solutions, this one open ecosystem, involving input from partners and other stakeholders, will ensure people with diabetes benefit from improved outcomes, physicians have the means to manage the disease and treatment, while payers can track the costs.

By better managing diabetes and designing more efficient healthcare

infrastructure and support systems, great strides can be made in avoiding the costly and life-altering complications associated with this disease. Roche Diabetes Care's approach aims to directly address the multifaceted and clinical complexity of diabetes currently seen across the healthcare system⁶.

The key to achieving improved outcomes is focusing on the data, with the patient at the centre. Diabetes is a complex condition where people with diabetes must monitor various and often times confusing, data sources including insulin and blood sugar levels, activity and nutrition. This complexity can be mastered by moving beyond drugs alone and taking a holistic approach where tools can integrate and analyse the data to help make treatment decisions, delay disease progression and empower people with diabetes to better manage their disease. This data can also be shared between the person with diabetes, their healthcare professional and their payer.

The Eversense® XL continuous glucose monitoring (CGM) system by Senseonics Inc is one example where Roche Diabetes Care, as the distributor in the UK and some European countries, is combining digital technology with data management in an open ecosystem to improve outcomes for people with diabetes. The Eversense XL CGM system by Senseonics is an implantable CGM

sensor, which can measure glucose values for up to 180 days, compared to seven or up to 14 days for non-implantable systems that are currently available in the market⁷.

The sensor is implanted underneath the skin on the upper arm and communicates with a rechargeable wearable smart transmitter, which alerts the person with diabetes when glucose levels become too high or too low. Meanwhile, real-time insights on glucose data and trends are relayed to The Eversense smartphone app. This CGM system provides people with diabetes more support in managing their blood glucose levels and therefore helps to better manage their condition. Furthermore, this data can easily be shared with the individual's physician for a more personalised approach to care.

In clinical trials, people with diabetes who used The Eversense CGM system for 180 days saw a reduction of 0.35% in their HbA1c, which identifies the average plasma glucose concentration⁷. The higher HbA1c, the greater the risk of developing diabetes-related complications, CGM has also been shown to support people in managing the extreme fluctuations of glucose which can cause both immediate harm and long term damage such as cardiovascular disease.

Systems such as The Eversense XL CGM system are digitising the data in such a way to make it more meaningful and transparent for people with diabetes and healthcare professionals. By managing the flow of this data, systems such as The Eversense CGM system are directly addressing the vast majority of the problems and challenges associated with diabetes. In addition, digitising data allows healthcare to move in the direction of personalised treatment, providing the right treatment for the right patient at the right time, which will also help to



Interview with Françoise Le Poulichet, Roche Diabetes Care, International Business Leader, Insulin Delivery Systems

overcome clinical inertia, improve outcomes and cut costs.

It's particularly notable that solutions such as continuous glucose monitors and digitally connected and integrated diabetes management solutions are what people with diabetes want. Healthcare systems around the world have already witnessed patients who, frustrated by the slow uptake of technology, have turned to reverse engineering and algorithms to create their own diabetes management solutions themselves.

In response to this do-it-yourself movement, the US-based JDRF has called for greater action on the part of industry and regulators to accelerate getting this technology to market and find ways to put in place the regulatory and legal frameworks for safe and approved technology to support the evolving research and development of artificial pancreas technology. Roche Diabetes Care is currently exploring different ways this collaboration with JDRF and other stakeholders could work. This is also an example that tackling the diabetes challenge requires a collaborative and innovative approach

that taps into the new technologies available.

Now is the time to elevate the debate, to involve all stakeholders, including people with diabetes, to work alongside the medical devices industry to address the challenges of this complex condition and to improve the outcomes for people with diabetes and healthcare systems alike.

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Digitally enabling type 2 diabetes prevention models

Hitachi Consulting sheds light on how they digitally enable type 2 diabetes prevention models

Recent reports by the World Health Organization (WHO) identifies that 422 million adults have diabetes and the disease causes over 1.6 million deaths per year. The number of people with type 2 diabetes (T2D) has nearly quadrupled since 1980 and prevalence is increasing in low- and middle-income groups. At an individual level, T2D greatly impacts the quality of life and bears a significant risk of complications and comorbidities.

“The cost of diabetes to the NHS is over £1.5 million an hour or 10% of the NHS budget for England and Wales. In total, an estimated £14 billion pounds is spent a year on treating diabetes and its complications, with the cost of treating complications representing the much higher cost.”

(reference: diabetes.co.uk, 2012).

At a societal and economic level, the prevalence and growth of diabetes present one of the most significant healthcare challenges of modern times.

Further escalation of the growing cost to society is unsustainable!

Why prevention?

Traditionally, healthcare systems have developed to treat illness. Policy, budgets, commissioning and service innovation have been primarily focused on this objective. However, with increasing life expectancy, the

incidence of chronic diseases, such as diabetes are increasing, typically consuming 70% of healthcare expenditure, which is not sustainable.

“90% of all T2D could be avoided with lifestyle change.”

(WHO).

Prevention provides an evidenced and effective means of intervention for those at risk of T2D. Questions are often raised about the scalability of prevention programmes and evidence supporting the sustainability of outcomes – but it can be argued these should not be used to dismiss prevention but guide the evolution of the future approach to prevention.

A holistic and effective prevention strategy is required to stem the growth of diabetes prevalence!

Why smart?

Will 10,000 steps a day help me live to 101? Invariably not. Prevention is not wellness, it is far more complex, and we need a smart approach in shaping prevention to help at-risk individuals and societal challenges. So, what are the key aspects of a smart approach?

1 – Personalisation

The causes of T2D are complex. While a lack of physical exercise, increases in weight and obesity are common traits – diet choice, socio-economic determi-

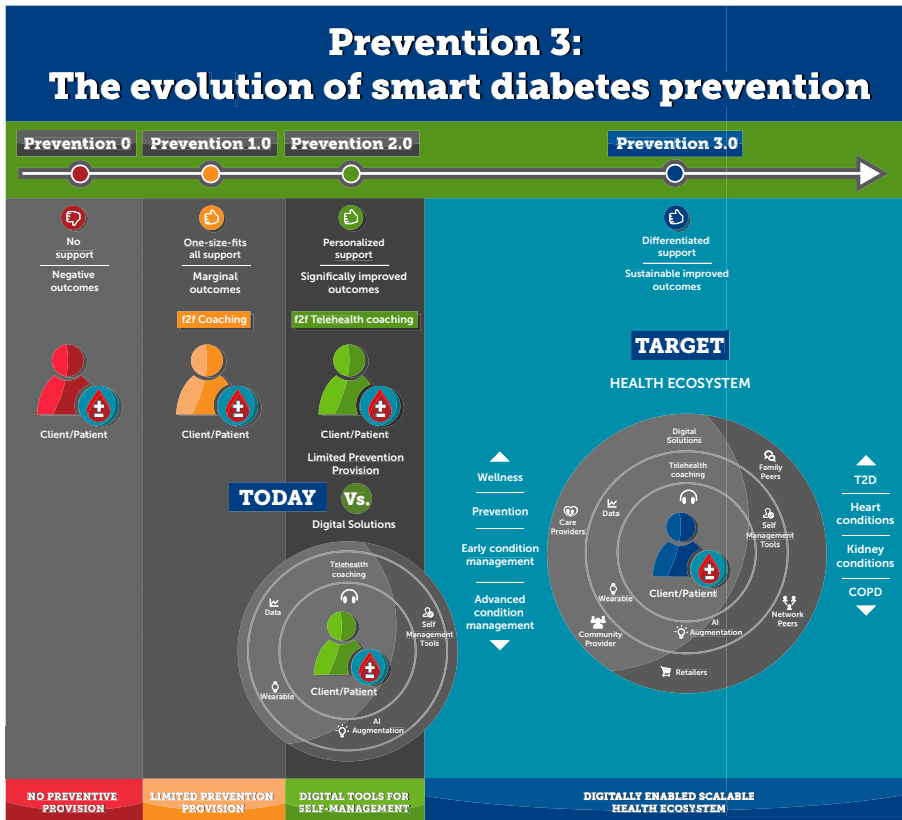
nants and personal circumstance are far more complex and need to be considered to deliver effective, appropriate, safe and sustainable lifestyle change. Prevention pathways should, therefore, be both clinically and insight-led while providing personal and tailored guidance relevant to an individual's needs to help people achieve food and activity goals related to an underlying change in their daily behaviour.

2 – Cost-effectiveness

The ability to deliver public health interventions at an acceptable cost across a range of priorities has always been both a challenge and constraint. To be viable at scale, we must design prevention solutions that can be delivered cost-effectively, yet also ensure they are reliable and sustainable outcomes for the target population. To date, prevention programmes have struggled to provide strong evidence on the sustainability of outcomes.

3 – Scalability

The prevalence and nature of T2D require an approach that can be delivered at scale to reach people in low/middle-income areas. To scale effectively, prevention must deal with a broad cohort – from children to the elderly – the rich and poor – those who are digitally active and those with low IT literacy and every ethnicity. Applying digital capabilities can make a significant impact!



Why digital?

1 – Remote engagement

Delivering cost-effective public health interventions across both geographically dispersed and demographically diverse healthcare economies continues to pose a challenge for scalability. To scale effectively, prevention interventions must leverage digital technologies – from point solutions to the Internet of Things (IoT) devices and wearables. Digital solutions enable remote engagement providing a scalable vehicle driving patient activation, service personalisation and differentiation, allowing citizens to self-manage more effectively, with improved outcomes.

2 – Dynamic pathways

Existing T2D prevention interventions tend to adopt a one-size-fits-all pathway model. Aside from failing to provide cost-effectiveness at scale, this inhibits pathways from being

dynamically adapted to citizen needs and behaviour. To provide the best outcomes for citizens and cost-effectiveness at scale, prevention interventions must adopt a dynamic pathway model, with citizen needs at the forefront. Digital solutions provide data-driven insights that need to enable real-time pathway flexibility based on citizen engagement, outcomes and progress and allowing the right support to be provided.

3 – Workforce optimisation

One-size-fits-all pathway models tend to drive declining workforce productivity, undercutting both cost-effectiveness and the scalability of prevention interventions. To scale effectively, prevention interventions must leverage data-driven insights so that clinical support is targeted in the right way, at the right time. Digital solutions provide an effective mechanism for data-driven insights to enable

dynamic workforce design and management, targeting citizen need at key 'turning points' of the pathway. Digital is a critical enabler for smart prevention!

A journey to prevention 3.0

Many healthcare providers and insurers have embarked on a journey to prevention by developing individual and group therapeutic approaches to lifestyle change. While partially effective, these approaches often fail to fully take advantage of technology and data to sustain positive lifestyle outcomes.

Hitachi Smart Digital Diabetes Prevention leverages digital technologies to provide a scalable and personalised telehealth offering that enhances sustainable lifestyle goals. Hitachi's vision of 'Prevention 3.0' is centred around data-driven insights, wearable technologies and remote artificial intelligence (AI)-augmented human coaching, co-existing in harmony with the wider health ecosystem.

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The emergence of personalised e-health care

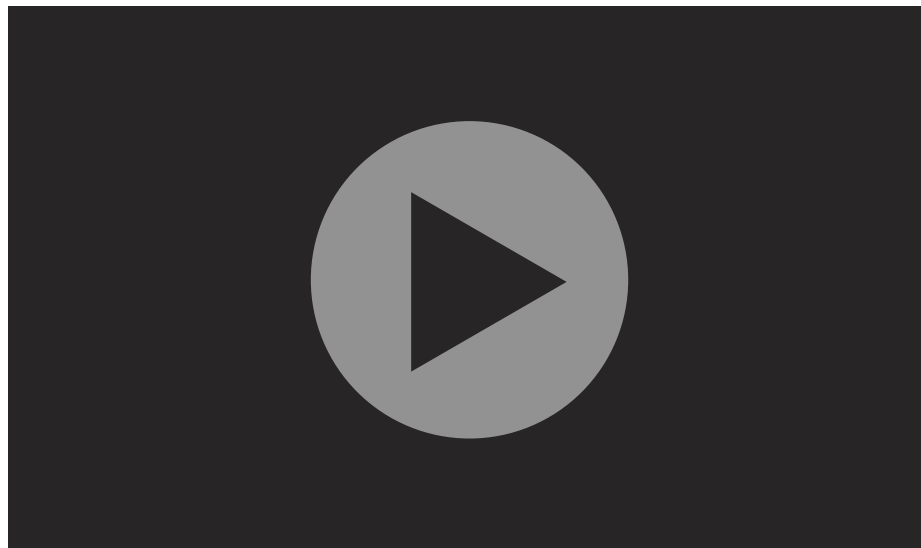
CEO of Liva Healthcare, Kristoffer From explains the emergence of personalised e-health care and asks if e-health can close the gap between doctors and diabetic patients

Type 2 diabetes is a vast and growing, health problem for the UK. 3.7 million people in the UK are currently living with diabetes, 90% of which have Type 2¹. If the current trend persists, over five million people will have diabetes by 2025¹. The health consequences of Type 2 diabetes cannot be ignored. The condition is a major contributor to vision loss, kidney failure, heart attack, stroke and lower limb amputation.

Managing Type 2 diabetes

Traditional interventions for diabetes prevention have focused on counselling and medicine. However, these solutions alone are no longer enough to tackle the long-term health crisis the UK is facing. To reduce the number of people being diagnosed with Type 2 diabetes – we need to address the common root cause – unhealthy lifestyles.

Research has looked into using lifestyle interventions to tackle Type 2 diabetes and has shown promising results. In one study, patients with Type 2 diabetes were given either the standard care of counselling and medical therapy or were subjected to the standard care and, in addition, a lifestyle intervention comprising of a dietary plan and five to six aerobic exercise sessions a week for 12 months. 73.5% of participants receiving lifestyle interventions were able to reduce their drug intake compared to just 26.4% of the standard group.



What's more, over half (56.4%) of those in this group discontinued their medication altogether. Compared to just 14.7% of the standard care group².

The evidence suggests that improving an individual's diet and exercise regime is effective for those diagnosed with Type 2 diabetes. In addition, the fact that lifestyle interventions lead patients to come off medication altogether is also promising for removing Type 2 diabetes, in those that already are diagnosed as diabetic.

The role of digital interventions

The challenge is that medication is an intervention that is easily scaled up and distributed. All it requires is for the patient to remember to take it. Encouraging lifestyle interventions is a far harder task. Making long-term lifestyle changes requires time, dedi-

cation and continuous daily changes to form new, lasting habits.

What's more, achieving weight loss is one thing, but maintaining it is a whole other mountain. For medical professionals, it is incredibly difficult to monitor whether someone is adhering to the recommended lifestyle changes. As such, whilst lifestyle changes may be optimal, they haven't always been a realistic option, leading to a dependence on medication to treat the lifestyle disease.

To make lifestyle interventions more accessible to people, technology is starting to get involved. E-health solutions have been trialled and tested and have proved promising in helping people to lose weight. A recent study, for example, found patients lost 7kg over 20 months through online consultations³.

Digital NHS interventions

The NHS currently spends around £8.8 billion a year on Type 2 diabetes – just under 9% of its total budget. Digital interventions may be able to help tackle this pressure.

There are two key benefits of using digital interventions. Firstly, e-health tools can drive efficiency by being implemented on a mass scale and direct change in a significant number of people's lifestyles. Secondly, because of the potential to reduce medication usage, there are significant cost savings to be made.

This is precisely why the NHS launched a pilot digital stream of the Healthier You: NHS Diabetes Prevention Programme. Over 5,000 patients are expected to benefit as five different technology companies (including Liva Healthcare) provide digital health interventions across the UK. The pilot is testing a range of apps, gadgets, wristbands and other innovative digital products to see their impact on people at risk of developing Type 2 diabetes. The pilot will be run for a year after which the NHS will assess which tool was most effective and should be taken forward and rolled out nationwide.

Keeping the human touch

The question is now whether digital health interventions can replace healthcare professionals entirely. And whether they should. Some health tech companies believe so and are launching products based on an algorithm with no need for human interaction. A recent study into e-health tools, however, found that having a trusted relationship with a healthcare professional was the most important

factor in effecting lasting change in patients using digital interventions to lose weight⁴. Our belief is therefore that algorithms aren't enough; you still need personal relationships.

“The evidence suggests that improving an individual's diet and exercise regime is effective for those diagnosed with Type 2 diabetes.”

For this reason, Liva Healthcare, although a digital health company, is focused on how technology can facilitate the work of healthcare professionals, not to replace them. When using Liva Healthcare, patients are allocated their own personal health coach who they can speak to and discuss their progress on a regular basis. Using an app, the health professional sets and monitors individual goals for their patients. Patients track their lifestyle (e.g. physical activity levels, food intake and blood sugar levels) and have access to an online support group of other patients, as well as a wealth of educational material. The intervention removes the need for patients to tackle lifestyle changes alone. What's more, our research has found health coaches can support up to 400 patients on a weekly basis.

The future of digital health is exciting. Digital interventions have the potential to provide long-term programmes that can reach more people and even remove diabetes diagnoses. However, there is a need for digital interventions to be built on the science behind forming new habits and look at what it takes to make long-term lifestyle changes.

The research suggests it's all about the relationship between a health coach

and the patient. It is the relationship that is going to help people break poor habits. As we look forward to developing a health service that can treat more people, it is clear that digital interventions have a role to play. However, we mustn't take the word 'digital' too literally. We can't just rely on algorithms to drive the behaviour change needed to reduce the number of people at risk of developing Type 2 diabetes. We still need the human touch.

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Understanding stroke in the UK

Esme Russell from the Stroke Association reveals the extent of stroke as a major health issue in the UK today

It's the fourth biggest killer in the UK and a leading cause of disability. Stroke is a major health issue, affecting over a million people in the UK. And it can happen to anyone at any time. But the good news is that there are many simple steps we can all take to reduce our risk of stroke. And when stroke strikes, support is on hand to help stroke survivors take control of their lives again. With the right help, many people can and do recover after a stroke, return to their jobs and live independently.

What is a stroke?

Most strokes are caused by a blockage cutting off the blood supply to the brain. This is an ischaemic stroke. However, strokes can also be caused by bleeding in or around the brain. This is known as a haemorrhagic stroke.

A Transient Ischaemic Attack or TIA is also known as a mini-stroke. It is the same as a stroke, except that the symptoms last for a short amount of time and no

longer than 24 hours. This is because the blockage that stops the blood getting to your brain is temporary.

Although the symptoms may not last long, a TIA is still very serious. It is a sign that there is a problem and you are at risk of having a stroke. Because of this, a TIA is often called a warning stroke.

Is it too late to prevent a stroke?

Being overweight increases the risk of ischaemic stroke by 22% and obese patients have an increased stroke risk of 64%. An unhealthy lifestyle can damage blood vessels, increase blood pressure and make a patient's blood more likely to clot.

But it's never too late for people to take control of their health. While there are some stroke risk factors we can't control, such as age, there are several risk factors, such as poor diet, high blood pressure and diabetes, which if managed effectively, can reduce stroke risk. For example, damage caused by smoking is not irreversible. Having a healthy diet can reduce your cholesterol. And remember, it's important that people who are at a higher risk of stroke try to be as active as possible, as moderate exercise can reduce a person's risk of stroke by almost a third.

Helping stroke survivors on the road to recovery

All stroke survivors in the UK should have a discharge plan when they leave the hospital. This covers all the necessary arrangements for care at home, including links with community services and any special equipment people may need.

Stroke is complex and can result in a range of longer-term problems that people might continue to face after they leave the hospital. These can include the following:

- **Cognitive problems:** Some of the most common areas of cognition that can be affected by stroke include memory, attention and perception;
- **Communication:** Around one in three people have difficulty speaking, reading, writing or understanding after a stroke, leaving them lost for words. But with the right help and support, many stroke survivors are able to find new ways to communicate;

- **Emotional problems:** The emotional impact of stroke is too often underestimated and overlooked. Anxiety, depression and stress are all common for both stroke survivors and their families;
- **Fatigue:** There is no specific medication to treat post-stroke fatigue; however, the condition can be managed. Securing a diagnosis from a GP and identifying whether there are any specific factors causing fatigue is the first step for stroke patients with the condition;
- **Physical problems:** The most common effects of stroke are physical ones, such as weakness, problems with walking and sight loss.

Support available

The Stroke Association helps stroke survivors, their families and carers cope with the aftermath of stroke and support people who are rebuilding their lives. We provide support across the UK in a variety of ways, including practical help and community-based support groups which help stroke survivors make the best recovery they can. To find out more, visit stroke.org.uk.

Recognising the signs of stroke

It's vital to know how to spot the warning signs of a stroke in yourself or someone else. Using the **FAST** test is the best way to do this.

- **Face:** Can the person smile? Has their face fallen on one side?
- **Arms:** Can the person raise both arms and keep them there?
- **Speech problems:** Can the person speak clearly and understand what you say? Is their speech slurred?
- **Time:** If you see any of these three signs, it's time to call 999.

A stroke is a medical emergency. Always dial 999. ■

Call our Stroke Helpline 0303 3033 100

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The impact of stroke

Australian Stroke Foundation details the impact that a stroke can have on people of all ages plus how it can be prevented and treated

Stroke is a devastating disease. It attacks the brain, the human control centre and can turn lives upside down in an instant.

In Australia, it's estimated there will be 56,000 strokes this year – that's one stroke every nine minutes! Stroke is one of Australia's biggest killers and the leading cause of adult acquired disability. Yet stroke is largely preventable, it can be treated, and it can be beaten. This is our challenge.

The Stroke Foundation is an Australian charity that partners with the community to prevent, treat and beat stroke. We stand alongside stroke survivors and their families, health professional and researchers. We build awareness and foster new thinking. We support survivors to live their best possible life after stroke.

What is a stroke?

Stroke can impact anyone of any age, even children and babies have strokes. A stroke happens when the blood supply to the brain is suddenly cut off. This occurs in two ways:

- Ischaemic stroke – when a blood clot stops blood moving through the artery.
- Intracerebral haemorrhage or bleed – when an artery bursts.

Every stroke is different depending on where in the brain it strikes and how severe it is. A stroke can destroy up to 1.9 brain cells a minute, however, the right treatment at the right time can stop this damage. The effects of stroke may include paralysis, speech and swallowing difficulties, problems with memory, hearing and eyesight. Depression is also common.

Image: © Mark Sherborne



Can stroke be prevented?

Around 80% of strokes can be prevented. The best way to reduce your stroke risk is by simply being healthy. Manage your blood pressure and cholesterol, eat well, don't smoke, don't drink too much alcohol and be active.

Signs of stroke

The Stroke Foundation is determined to ensure someone in every Australian household knows the most common signs of stroke by remembering F.A.S.T. and asking themselves these questions.

Face – Check their face. Has their mouth drooped?

Arms – Can they lift both arms?

Speech – Is their speech slurred. Do they understand you?

Time – Time is critical. If you see any of these signs call an ambulance straight away.

Stroke treatments

Over the past two decades, advances in the diagnosis

and treatment of stroke have led to a significant reduction in lives lost. Time-critical treatments for strokes caused by clots include:

- **Thrombolysis** (blood clot dissolving treatment) – administering a drug which can break down and disperse a blood clot. This treatment is possible within 4.5 hours of symptom onset, but the earlier the treatment, the better the results.
- **Endovascular thrombectomy** – angiogram to remove clot using a retractable mechanical device. Australian researchers played a key role in the research for this treatment. Current guidelines recommend this treatment be delivered within six hours of symptom onset with earlier treatment achieving better results. However, the latest research has shown that highly selected patients still benefit up to 24 hours after symptom onset which is good news for those who wake up with symptoms, are alone at the time of stroke or live in rural areas leading to delayed presentation.

Care on a stroke unit is also vitally important in stroke outcomes. Being cared for by a specialised stroke team has proved to be one of the most effective ways of treating a person after a stroke.

Regional and metropolitan divide

The major challenge in accessing best practice stroke treatment and care in Australia is geography. Australia is large, and our population is dispersed.

Regional Australians are currently 19% more likely to have a stroke than metropolitan counterparts. Regional Australians are also less likely to have access to best practice, lifesaving stroke treatment and care. But there is a solution. Technology, more specifically, telemedicine.

Stroke Foundation is partnering with health professionals and researchers in campaigning for a new Australian Stroke Telemedicine Network, giving all Australians fair access to the best in stroke treatment. Telemedicine enables fast assessment of suspected stroke patients in regional areas by metropolitan based stroke specialists. Regionally based clinicians are supported in admin-

istering clot-busting thrombolysis treatment and/or arranging transfer to a comprehensive stroke centre for clot removal.

Support for survivors and health professionals

Stroke Foundation has established innovative online resources to support all health professionals and stroke survivors and their families:

- **InformMe** – A one-stop-shop for health professionals working in stroke. It brings together the latest in evidence-based treatment guidelines, hospital performance data, education and tools to better support excellence in stroke care. More details can be found at www.informme.org.au.
- **EnableMe** – For stroke survivors, their family and carers. EnableMe brings together stroke information, videos, tools and conversation with other survivors and carers to empower stroke survivors to live their best possible life after stroke. More details can be found at www.enableme.org.au.

The future

Despite stroke's prevalence in Australia, stroke awareness remains low and research is chronically underfunded. Stroke's burden on the community and health system is ever increasing, as our population ages and lifestyle becomes more sedentary.

The stroke challenge is looming large. By 2050, it is anticipated there will be one stroke every four minutes in Australia and one million stroke survivors living in our communities unless action is taken. The time to act is now. ■

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New treatments for spinal muscular atrophy

SMA Europe e.V. discusses how new treatments for spinal muscular atrophy open up new challenges for European and national institutions

Spinal Muscular Atrophy (SMA) is a rare disorder of the motor system which affects about 1 newborn in 7,000. This disease is characterised by a deletion of the SMN1 gene and its severity strongly correlates with the age of onset of the first symptoms. By convention, the disease has been divided into several “types” from the most severe (type 1) to forms that manifest themselves in adulthood (type 4).

SMA type 1, which is the most severe form, represents about 50% of people with spinal muscular atrophy. This disease is often fatal in the first year of life. The other types are severely disabling. SMA type 2 patients never walk and develop severe respiratory problems. Less severe types lose the ability to walk before adolescence (SMA type 3) or in adulthood (SMA type 4). The life expectancy of adult patients is normal.

This rare disease has experienced a real breakthrough, as a new drug, Spinraza™, has been shown to not only increase survival beyond 2 years of age, for more than 80% of the most affected children, but also to ameliorate their locomotor development, sometimes allowing them to acquire or regain the capacity to walk. Three other very promising treatments are currently going through clinical trials.

But the road from the European Medicines Agency (EMA) marketing authorisation for reimbursement by national health insurances, is very long. Spinraza™ was approved by the Food and Drug Administration (FDA) in the US in December 2016, closely followed by the EMA in April 2017. These announcements raised enormous hope, quickly dampened by delayed access in some European countries, coupled with the extremely high

selling price announced in the U.S. (About €700,000 for the first year of treatment). To date, many European countries still have not authorised national reimbursement. Infants are left with no choice but to become medical tourists in order to survive.

“SMA type 1, which is the most severe form, represents about 50% of people with spinal muscular atrophy. This disease is often fatal in the first year of life. The other types are severely disabling. SMA type 2 patients never walk and develop severe respiratory problems. Less severe types lose the ability to walk before adolescence (SMA type 3) or in adulthood (SMA type 4). The life expectancy of adult patients is normal.”

Both the FDA and EMA validated this treatment through accelerated schemes which take into account the severity of the disease as well as the effectiveness of the treatment shown in infants. They extrapolated the results obtained from the infant trial and validated the treatment for all forms of the disease, despite the lack of clinical data for adolescents and adults. The clinical results subsequently published, showed an improvement in the health of older patients, even if the effectiveness with age was less significant. This lack of clinical data – coupled with unclear communications about the actual effectiveness of the treatment in older patients – has rendered discussions to assess the target population to be addressed and supported by national health systems difficult.

This gap between the requirements the European agency has in order to authorise a treatment and the national requirements for reimbursement does not allow for a fast patient access to treatments, despite good efficiency in this area.

The second issue highlighted by the arrival of these new treatments is the need to treat as early in life as possible. Indeed, this particular type of treatment

demonstrates a very high efficacy if the child is treated pre-symptomatically, that is to say, in the first days or weeks after birth, before any locomotor loss has occurred.

In a few American states, but also in Belgium, general neonatal screening campaigns based on a genetic test have begun. Neonatal screening policies in Europe vary significantly from country to country: in some countries, early detection of the condition will allow children to be treated, meaning they will not develop symptoms of the disease. Elsewhere, the first clinical signs will have to manifest themselves before an individual is treated. This will invariably lead to them acquiring irreversible damage and lifelong handicaps.

Even if the harmonisation of these policies is not currently considered at European level because of concerns over the cultural and ethical views of each nation, a clear opinion from EMA on the effectiveness of this type of screening must bring reliable technical information to highlight national decisions.

The arrival of these innovative and often expensive treatments is a real challenge if we want to offer all Europeans equal access to healthcare. ■

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Spinal muscular atrophy (SMA) – research from gene and modifiers to therapy

The fascinating research of Professor Brunhilde Wirth is placed under the spotlight, concerning her work in the field of disease-causing genes, modifier pathways and pathomechanisms of neuromuscular disorders, focussing on spinal muscular atrophy (SMA)

Professor Brunhilde Wirth focuses her research on the identification and understanding of disease-causing genes, modifier pathways and pathomechanisms of neuromuscular disorders, mainly of spinal muscular atrophy (SMA) and further motor neuron disorders.

More recently, she has extended her research activities also on osteoporosis and the understanding of bone development and remodelling. In order to identify the genetic cause of the disease, the group applies the most advanced technologies including next-generation sequencing and transcriptome analysis. The laboratory has been developing and is using a large number of different methods and technologies to understand the genetic, biochemical, cellular and pathological basis of motor neuron disorders and osteoporosis. They are generating and using conditional and transgenic motor neuron mouse models, zebrafish and most recently, *Drosophila* models as well as induced pluripotent stem cells. Their utmost goal is the development of therapies, which is a particularly strong interest of the group.

As the Wirth lab has now contributed major research findings for over 25 years, this has enhanced our understanding of:

- The genetic basis of SMA including deletions, rare point mutations or gene conversion events;

- The mechanism for the unusual alternative splicing of the copy gene *SMN2* that differs from the full functional *SMN1* copy by a single silent base exchange;
- The correlation of *SMN2* gene copies with the severity of the disease. Each individual with SMA has no *SMN1* but one-to-six *SMN2* copies. The SMA severity inversely correlates with the copy number of *SMN2* genes. *SMN2* produces only low levels of correct SMN protein which is unable to maintain the function of motor neurons, the mainly affected cell system causing SMA;
- Genetic modifiers, such as increased levels of plastin 3 (PLS3) or decreased levels of neurocalcin delta (NCALD) or calcineurin like EF-hand protein 1 (CHP1) protect against SMA;
- Modifiers act protectively in SMA mouse and zebrafish models;
- The major cellular disturbed pathway in SMA is an impaired endocytosis;
- Therapies using SMN-dependent (such as the HDAC inhibitor, valproic acid or antisense-oligonucleotides (ASOs) such as SPINRAZA and SMN-independent approaches (ASOs against genetic modifiers, NCALD and CHP1).

The Wirth lab is aware that for future



*Brunhilde Wirth,
Chair of the Institute
of Human Genetics*

therapeutic development patenting the intellectual property is essential: their findings to SMA genetic modifiers have therefore been patented.

Prof Wirth believes that once SMA is included in neonatal screening, individuals with *SMN1* deletions can be treated pre-symptomatically with SMN-dependent and SMN-independent ASOs, small molecules or gene therapy approaches, which most likely will allow curing SMA. There is still some way to go until reaching this final goal.



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Work-related musculoskeletal disorders

Cecilia Van Cauwenberghe from Frost & Sullivan's TechVision Group provides a comprehensive overview of work-related musculoskeletal disorders, including impact reduction

Most commonly musculoskeletal disorders (MSDs) are associated with a repeated exposure to occupational ergonomic hazards, including frequent exertion, repetitive bending, twisting movements, or recurrent standing. According to the announcements made at the XXI World Congress on Safety and Health at Work held in Singapore on September 2017 by the European Agency for Safety and Health at Work (EU-OSHA) and the International Labour Organization, worldwide work-related MSDs (WRMSDs) result in the loss of 3.9% of GDP, at an annual direct and indirect cost of €2,680 billion (\$3,325 billion) and comprising more than 120 million disability-adjusted life years (DALY) lost. In the European Union, WMSDs are costing 3.3% of GDP, which implies an annual cost of €476 billion (\$591 billion) and around 7 million DALY.

“According to the study, near 92% of office workers worldwide reported musculoskeletal symptoms, related to persistent postures, prolonged keyboard, mouse use, high workload and distress.”

A recent article published by Sultan-Taïeb et al., 2017, highlights that WMSDs embody a major public health problem and economic burden to employers, workers and health insurance systems. The authors performed a systematic review to investigate the cost-benefit results of organisational-level ergonomic workplace-based interventions aimed at preventing WMSD, as well as, to analyse factors influencing the deployment of these interventions to effectively correlate economic results.

Industry/occupation prevalence rates and adverse health correlations

Shockey et al., 2018, published a comprehensive study attempting to determine which industry and occupation groups presently have the highest prevalence rates of frequent exertion at work and frequent standing at

work, also including analysed data from the 2015 US National Health Interview Survey (NHIS) Occupational Health Supplement (OHS) regarding currently employed adults in the United States published by the US Centers for Disease and Control Prevention (CDC) and the National Center for Health Statistics.

According to the study, the highest prevalence of both frequent exertion and frequent standing at work evidenced by industry was associated with agriculture, forestry, fishing and hunting with 70.9%. Regarding occupation, the highest prevalence indicated more relevant were construction and extraction with 76.9%. The study also enabled to establish important differences among industry and occupation in terms of ergonomic hazards, suggesting the design of targeted interventions to reduce workplace exposure. Indeed, combined together industry and occupation, higher prevalence rates of frequent exertion, generally involving bending, pushing, pulling and lifting co-occurring with standing, were associated with farming, construction and food services, whereas, a high prevalence of frequent standing at work with a low prevalence of frequent exertion was related to education, laboratory testing and office-based services.

It is important to highlight that health risks associated with excessive sitting during the workday involving muscular atrophy are as relevant as repeated exertion. In fact, excessive standing has been linked to adverse health outcomes and unbalanced dietary habits. Coenen et al., 2016, carried out meta-analysis studies on peer-reviewed articles to correlate occupational standing with musculoskeletal symptoms.

Although the authors conclude that more research is needed to effectively advice about how to balance time spent sitting and standing while at work, the report



allows associating numerous variables that may help to reduce WRMSDs. In agreement with these observations, a literature review performed by Waters and Dick, 2015, allows matching prolonged standing at work with adverse health outcomes, such as back pain, physical fatigue, muscular pain and even muscular atrophy. Corroborating these findings, Parry et al., 2017, investigating the potential workplace interventions for preventing musculoskeletal symptoms in sedentary workers, reported a high prevalence of musculoskeletal symptoms amongst sedentary workers. According to the study, near 92% of office workers worldwide reported musculoskeletal symptoms, related to persistent postures, prolonged keyboard, mouse use, high workload and distress.

Musculoskeletal symptoms and conditions **Accurate diagnostics and physical assessment**

WMSDs symptoms are derived from injuries or disorders of the muscles, nerves, tendons, joints, cartilage and spinal discs. Indeed, low back pain, neck pain and osteoarthritis are among the largest cause of loss of

work productivity and work disability. Most WRMSDs can neither be diagnosed specifically nor associated with a strict pathology via physical examination. However, pain, discomfort, numbness and tingling in the affected areas are generally evidenced.

More exacerbated symptoms may involve swelling in the joints, decreased mobility, grip strength, skin colour changes, especially accentuated when work activities imply the long-term exposure to harsh environments such as excessive cold, vibrational tools, excessive levels of humidity or dryness, etc. These complaints can lead to physical impairment and even disability. Symptoms may take weeks, months or in some cases years to develop, so it is important to detect them and act at an early stage.

Early prevention and smart solutions

During the past decade, a vast number of technology innovations have significantly impacted work tasks and habits. Some of these technologies have resulted in an abrupt change in the workforce from less physically

demanding employment toward more sitting standing workload. Most accentuated in developing countries, a sharp rise in physical inactivity and sedentary occupations is being evidenced.

According to Parry et al., 2017, office workers are sedentary for 77% to 82% of working hours. This fact means that an increasing proportion of the population faces a higher potential risk of not only musculoskeletal symptoms, but also additional health risks related to sedentary exposure. Therefore, early prevention is crucial to guarantee a good health for employees.

“A recent article published by Sultan-Taïeb et al., 2017, highlights that WMSDs embody a major public health problem and economic burden to employers, workers and health insurance systems. The authors performed a systematic review to investigate the cost-benefit results of organisational-level ergonomic workplace-based interventions aimed at preventing WMSD, as well as, to analyse factors influencing the deployment of these interventions to effectively correlate economic results.”

A global managerial approach involving time permanence, tasks readjustment and employee rotation and integration, constitute an essential part of any labour healthcare programme, along with the interaction of the corporation management with medical specialists and health and safety professionals. Emphasised by Van Cauwenberghe, 2016, in a Frost & Sullivan Research Service, ‘smart healthcare’ solutions in the context of ‘smart cities’ are starting to introduce eHealth/mHealth intelligent systems and connected medical devices, along with the implementation of online health monitoring and diagnostic systems at work, thereby encouraging health, wellness and well-being in the workplace. These smart solutions constitute a paradigm shift from treatment to prevention even at work.

Acknowledgements

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Therapies for weak muscles

Research into personalised interventions is helping pave the way for a new generation of therapies for weak muscles at the Balgrist Campus

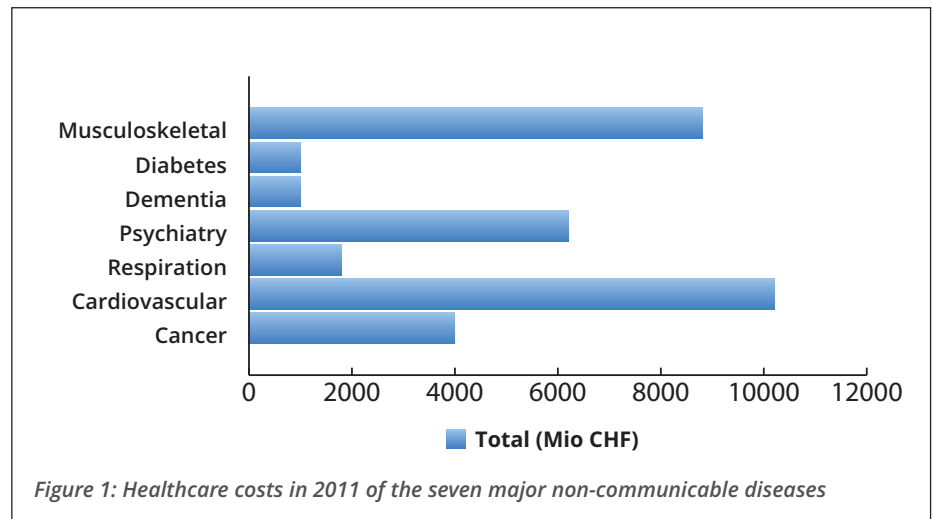
It is estimated that 10% of the cost of healthcare in Switzerland (or the equivalent of €500 billion per annum in the EU) being associated with lost work is related to injury or dysfunction of the musculoskeletal system (Fig. 1). Surgical and subsequent rehabilitative interventions are important part of the therapy that re-establishes musculoskeletal function.

The Laboratory for Muscle Plasticity at Balgrist University Hospital aims to shed light on the underlying mechanisms in skeletal muscle with the goal of translating the findings into more effective clinical applications.

Skeletal muscle plays a major part in control of movement and posture and affects whole body metabolism through its effects on energy expenditure. Affections ranging from simple overuse injury to rupture of tendons and bones, or disease, lead to deconditioning of skeletal muscle as a result of inactivity and damage signals. The consequent loss in muscle strength and fatigue resistance exerts a distinct negative impact on the quality of life and may render the affected individual dependent. In these situations a surgical intervention and rehabilitation may be indicated, yet may come too late as irreversible changes may have resulted.

Focus on muscle plasticity

The Laboratory for Muscle Plasticity investigates the mechanisms that



underlie the conditioning of skeletal muscle structure and function during recovery from surgical interventions and rehabilitation. As shown through research on sport performance, this process is driven by mechanical and metabolic stimuli. It is mediated through a gene response that instructs adjustments in muscle composition with the repeated impact of exercise during training. In consequence, force production and fatigue resistance of muscle may be improved or maintained.

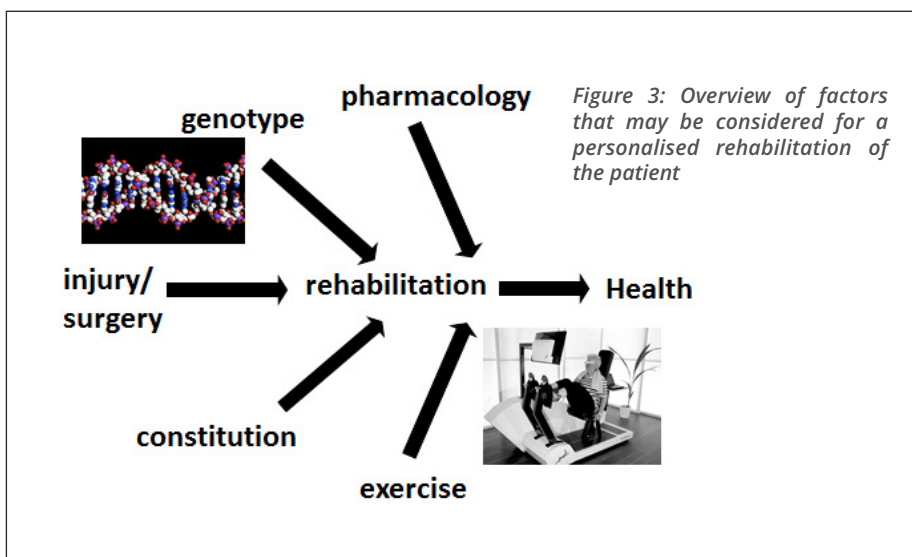
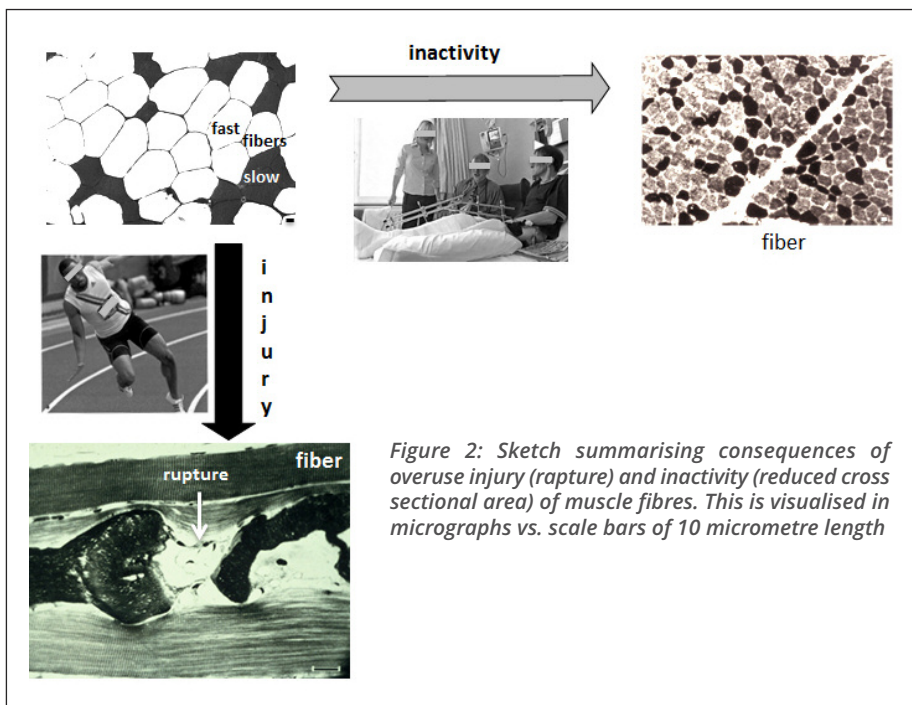
By contrast, a muscle's functional capacity is reduced in the absence of a physiological stimulus by a reduction in the size of muscle fibres and their content in mitochondria (Fig. 2).

In fact, while the safety and effectiveness of physical factors for muscle conditioning are well established, the dose-effect relationship between

exercise and muscle adaptation is often not fully respected in clinical practice. An example of this biological regulation is the important role of muscle contraction and loading in preserving muscle mass of the bedridden musculoskeletal patient after surgery, who would otherwise lose muscle mass at a pronounced rate. Genetic factors (so called gene polymorphisms) significantly affect this adaptation. This indicates that gene polymorphisms contribute to the inter-individual variability of the response to surgical interventions and rehabilitation.

Research projects

The emphasis of the research team lead by Prof Martin Flück at Balgrist is on major musculoskeletal affections that arise in the context of the orthopaedic clinics at Balgrist Hospital. A special focus is put on resolving the contribution of gene polymorphisms



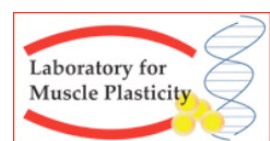
to inter-individual differences in the healing of muscle with re-attachment of the ruptured rotator cuff tendon, and the strengthening of skeletal muscle with rehabilitative exercise in patients.

The aim is to develop personalised forms of intervention that maximise muscle adaptation (Fig. 3). The latter approach is based on previous investigations pointing out the important exercise-intensity and exercise-type related influence of gene polymor-

phisms on muscle response to leisure-type sports activities. This opens a venue to tailor the therapeutically effective exercise intervention for patients which otherwise would demonstrate little plasticity to a generic exercise stimulus and for which pharmaceuticals alone do not work due to the importance of activity-induced muscle metabolism for muscle adaptations. In this regard, the clinical investigation ACE-REHAB into personalised rehabilitation of cardiac patients has been initiated.

Patient-led research

The laboratory is situated in state-of-the-art research facilities at the Balgrist Campus. A key ingredient of this research facility is an open-space landscape where research and development into musculoskeletal medicine is integrated under one roof between clinicians, biologist, engineers, and industry. The facility situates in the vicinity of the orthopaedic hospital at Balgrist; thus providing a pipeline for a reality-driven approach that re-integrates questions from bedside to bench and returns to the patient. The Laboratory for Muscle Plasticity is looking for potential partners that may want to exploit the research options presented in the future campus in the frame of collaboration.



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Arthritis, musculoskeletal and skin diseases including muscular dystrophy

The work of the National Institute of Arthritis and Musculoskeletal and Skin Diseases, including muscular dystrophy (MD), is placed under the spotlight by Open Access Government

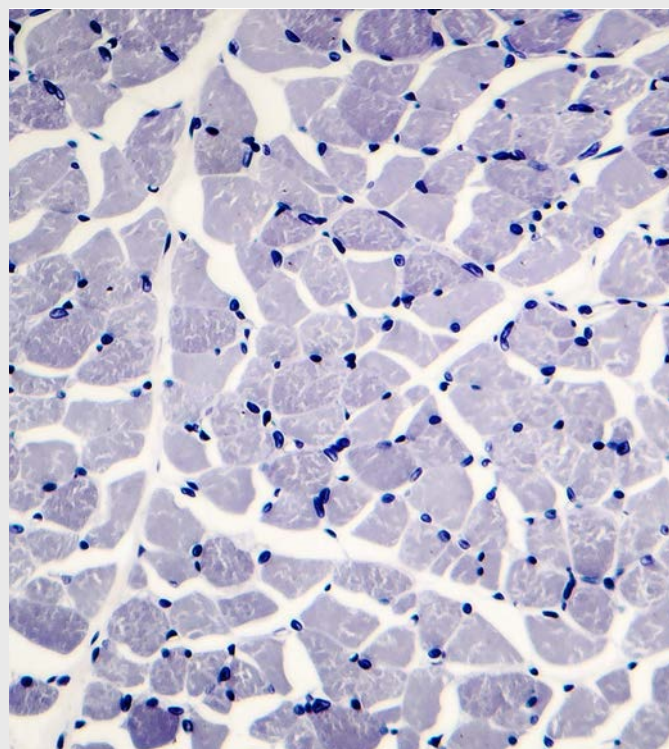
The National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) is one of 27 institutes and centres at the National Institutes of Health (NIH) in America today.

By way of background, NIAMS started in 1986 and strongly supports research into the causes, treatment and prevention of arthritis and musculoskeletal and skin diseases; as well as the training of basic and clinical scientists to undertake such research; plus, the dissemination of information on how research on these diseases is progressing.

NIAMS underlines that most households in America are affected by diseases of the bones, joints, muscles and skin. Indeed, these common and rare diseases impact on people of all ages, racial and ethnic populations and economic status. Unfortunately, many of these conditions affect women and minorities disproportionately and as such, NIAMS is committed to uncovering the reasons for these disparities and therefore coming up with effective strategies to treat and even prevent them.

Also, NIAMS works to understand and treat a vast array of diseases and conditions, such as:

- Autoinflammatory diseases;
- Back pain;
- Connective tissue diseases, such as Marfan syndrome;
- Fibromyalgia;
- Hair loss disorders, such as alopecia areata;
- Lupus;
- Muscular dystrophy (MD);
- Osteoarthritis;
- Osteoporosis;
- Rheumatoid arthritis;
- Scleroderma and;
- Skin diseases, such as psoriasis, eczema and acne.



Human skeletal muscle

Muscular dystrophy (MD)

Another branch of the National Institutes of Health, The National Institute of Neurological Disorders and Stroke (NINDS) provides further details about one of the above-mentioned areas, muscular dystrophy (MD). Before we look at this, however, it's important to consider the wider work of NINDS.

In summary, we know that the NINDS supports a broad programme of research studies on MD. The goals of these studies are to gain an understanding of MD and to develop techniques to diagnose, treat, prevent, and ultimately cure the disorder. It's also worth highlighting that NINDS is a member of the Muscular Dystrophy Coordinating Committee (MDCC).

We know that the muscular dystrophies (MD) are a group of more than 30 genetic diseases characterised by progressive weakness and degeneration of the skeletal muscles that control our movement. Some forms of MD are evidenced in infancy or childhood, while others may not appear until middle age or later. The disorders vary in terms of the distribution and extent of muscle weakness (some forms of MD also affect cardiac muscle), the age of onset, the rate of progression and the pattern of inheritance.

The most common form of MD that primarily affects boys is known as Duchenne MD. It is caused by the absence of dystrophin, a protein involved in maintaining muscle integrity. The onset of Duchenne MD is between 3 and 5 years old and the disorder, unfortunately, progresses rapidly. Most boys cannot walk by age 12 and at a later stage, they require a respirator to breathe. Girls in these families have a 50% chance of inheriting and passing on the defective gene to their offspring. Boys with Becker MD, which incidentally is very similar than Duchenne MD, but is less severe have faulty or not enough dystrophin.

“We know that the muscular dystrophies (MD) are a group of more than 30 genetic diseases characterised by progressive weakness and degeneration of the skeletal muscles that control our movement.”

The website of NINDS also informs us about Facioscapulohumeral MD, which normally begins during the teenage years. It causes progressive weakness in muscles of the face, arms, legs and around the shoulders and chest area. While it progresses slowly, it can vary in symptoms from mild to disabling.

The most common of the disorder in adult form is known as Myotonic MD, which is typified by prolonged muscle spasms, cardiac abnormalities cataracts and endocrine disturbances. Individuals with myotonic MD can be described as having long, thin faces, drooping eyelids and a swan-like neck.

Treatment

At the time of writing, there is, unfortunately, no specific treatment to stop or reverse any form of MD. However, current treatments for MD may include respiratory

therapy, physical therapy, speech therapy, orthopaedic appliances used for support, as well as corrective orthopaedic surgery.

Drug therapy is also used to treat MD and includes:

- Antibiotics to fight respiratory infections;
- Anticonvulsants to control seizures and some muscle activity;
- Corticosteroids to slow muscle degeneration and;
- Immunosuppressants to delay some damage to dying muscle cells.

Also, some individuals may benefit from occupational therapy, as well as assistive technology. Some patients may need assisted ventilation to treat respiratory muscle weakness and a perhaps pacemaker for cardiac abnormalities.

Prognosis

In closing, it's worth highlighting that the prognosis for people with MD varies according to both the type and progression of the disorder. Some cases can be mild and progress very slowly over a normal lifespan, while others produce functional disability, severe muscle weakness and loss of the ability to even walk. While some children with MD die in infancy, others live into adulthood with only a moderate disability. ■

For additional information on the issues discussed here, please visit <https://mdcc.nih.gov/> and www.niams.nih.gov.

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Duchenne muscular dystrophy (DMD)

Associate Professor and Director of Medical School Curriculum at the University of Illinois,
Dr Ahlke Heydemann underlines Duchenne muscular dystrophy (DMD) – a debilitating,
progressive muscle weakening disease

Duchenne muscular dystrophy (DMD) is a debilitating, progressive muscle weakening disease. Currently, there are no cures and no effective treatments for muscular dystrophy (MD). However, there are multiple highly promising therapeutics in the pipeline that should give patients and their families' significant hope. One exciting avenue of research is identifying novel methods of immune inhibition.

Immune inhibition is a promising therapeutic avenue because of the large body of data (from both lab animals and patients) that indicates reducing the chronic inflammation that always accompanies DMD is significantly beneficial (reviewed Evans 2009 and Tidball 2005). In MD mice, various scientists depleted CD8+ T-cells, or CD4+ T-cells, or macrophages, or neutrophils and have demonstrated significant improvement of pathology (reviewed in Evans). Now, researchers must achieve these immune-cell reductions in humans and without side effects.

MD pathobiology initiates with muscle cell membrane permeability, immune infiltrate, myofibre loss and fibrosis. Despite the complicated characteristics of the immune system, its role in acute muscle wounds and MD pathology can be described. In muscle wounds, the immune system is responsible to

clean the wound, create scar tissue to halt bleeding, remodel the scar tissue and then terminate the immune system response. Neutrophils and type 1 macrophages initiate the immune infiltration followed by eosinophils and T-cells.

The type 1 macrophages then transition to the anti-inflammatory type 2 macrophages. The disease is so devastating because of the chronic, ongoing nature of the membrane damage and the resultant asynchronised healing response. One cell may be at the correct stage to repair its membrane and is secreting appropriate anti-inflammatory cytokines, while a neighbouring cell is secreting cytokines to attract macrophages and T-cells and thereby inhibit the first cell's repair process. Interesting data even indicates that the immune cell infiltrate precedes disease histopathology (Spencer 2001), providing more impetus for inhibition of the immune system to treat MD.

In fact, the current standard of care – corticosteroids – is beneficial because it inhibits the immune response. Steroid therapies postpone the patient's need for a wheelchair. However, the steroids cause significant side-effects and other therapeutics must be identified. Among the latest, clinically-relevant, immune inhibition therapeutics are:

- 1) Antibodies against NFκB;
- 2) All-trans retinoic acid;
- 3) TGFβ inhibition;
- 4) IL-10 injections;
- 5) Identifying the best dose and schedule for corticosteroid régime; and
- 6) Fingolimod.

Each of these compounds has a strong scientific rationale for its inclusion in trials against MD. However, my real optimism for these treatments to be effective against MD is that they can be combined with each other and therapeutics that target other MD molecular mechanisms. Thereby, clinicians can tailor-make therapies for each patient and minimise the doses to avoid patient-specific side effects, while still achieving maximum benefits.

MD research has been made possible and greatly accelerated due to the availability of many mouse models. The most commonly used mouse is the naturally occurring dystrophin deficient mdx mouse (muscular dystrophy on the X-chromosome). In addition, the individual sarcoglycans have been genetically mutated to make the range of sarcoglycanopathies, including the gamma-sarcoglycan

mutations (Sgcg^{-/-}). Both of these models, the mdx and the Sgcg^{-/-}, have been bred onto the highly fibrotic DBA/2J mouse strain. Through this breeding, the mice closely resemble the pathology seen in patients.

My lab has focused on immune inhibition strategies because of the strong benefits are seen by this strategy. The mechanism my lab has focused upon is the use of the FDA approved sphingosine-1-phosphate receptor modulator Fingolimod. Fingolimod is FDA approved to treat relapsing multiple sclerosis (MS) and has proven very effective for these patients. MS is an auto-immune disease in which the bodies' antibodies attack and often destroy the myelin sheaths surrounding the nerves. This causes profound muscle weakness and lesions in the brain. Many MS patients have been taking Fingolimod (Gilenya, Novartis) for six years, with few side effects. Fingolimod's mechanism of action sequesters immune cells in the peripheral lymph tissue and thereby inhibits further damage.

This mechanism is very different from the immune inhibition provided by the steroids, thereby allowing the possibilities of co-therapy combining these two strategies. The most important, although rare side effects of Fingolimod are transient bradycardia after the first dose and lymphopenia after prolonged use. The lymphopenia is reversed with treatment discontinuation. Although MD is not a true auto-immune disease, the chronic immune response is pathogenic and must, therefore, be reduced. In addition to its immune inhibition, we have demonstrated that sphingosine-1-phosphate receptor modulation

with Fingolimod provides additional benefits against MD.

In both the Sgcg^{-/-} DBA/2J and the mdx DBA/2J mouse strains my lab has identified that Fingolimod has pleiotropic beneficial effects upon MD disease progression and even initiation. We have demonstrated that a three-week treatment course administered to young animals reduced the disease-proximal membrane permeability, reduced the immune infiltrate, reduced the resulting fibrosis and increased some of the respiratory functional parameters (Heydemann 2017).

Based on published research studies, our initial hypothesis was that Fingolimod would inhibit the pathogenic immune response and thereby reduce the necrosis-induced fibrosis. We had hoped that a slight improvement of membrane strength would also be achieved because of the reduction in cytokines. However, we were very surprised at the data demonstrating such a large reduction in membrane permeability. The treatment reduced the membrane permeability to not significantly different from wildtype levels.

As with most research studies, this study produced more questions than answers. Our current experiments are designed to answer the most important of these questions. Therefore, we are examining how Fingolimod strengthens the muscle membrane. In this pursuit, we have preliminary data that indicates that treatment with Fingolimod re-establishes the remaining – non-mutated – members of the dystrophin glycoprotein complex. We will now establish if this is through

increases in transcription, translation, protein stability or complex stability. We are also conducting additional preclinical trials, such as dose-response curves, longer treatment times, prevention and reversal strategies and co-therapy trials.

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Cannabis developments in North America

Writer, medical cannabis patient, a grower and budtender for GrassRoots Medicinal in Squamish, Caleb McMillan, provides his thoughts on cannabis developments in North America today

American states nullifying federal laws on cannabis prohibition. Canada poised to legalise the herb sometime this year. There is a sense of moving forward. But a scratch below the surface reveals another story.

Alcohol companies, police unions and private prisons have all lobbied against legalisation in California. A pharmaceutical company gave \$500,000 to a group opposing legalisation in Arizona, only to later get DEA approval for a synthetic form of cannabis. Coupled with an unfriendly administration in Washington DC, complete with an Attorney General who has vowed to axe the policy of leaving legalised states be, the outlook in America is grim and uncertain.

In Canada, former police chiefs and politicians are licensed commercial sellers of medical cannabis. While an already existing market, colloquially known as "BC Bud," are so-far locked out and referred to as organised crime, indistinguishable from biker gangs.

Yet, despite this, cannabis continues to provide relief to patients and recreational consumers alike. Whether one uses for therapeutic or medicinal purposes, everyone has cannabinoid receptors in their body. The scientific literature is quite clear we're dealing with a substance far removed from tobacco or alcohol.

For these reasons and others, cannabis should be fully embraced by the global medical profession. Cannabidiol (CBD) oil is already halting seizures within minutes of ingestion. From my experience working at a dispensary, countless patients have weaned off medication that treats inflammation but with damaging side effects. I, myself, reversed anxiety and depression with the non-psychoactive CBD oil. But a holistic approach to the plant includes Tetrahydrocannabinol (THC), the component that gets users "high" or "stoned." It is THC that shows promise in treating cancer tumours.

If the medical community requires clinical studies and drug identification numbers before cannabis can go



“Cannabidiol (CBD) oil is already halting seizures within minutes of ingestion. From my experience working at a dispensary, countless patients have weaned off medication that treats inflammation but with damaging side effects.”

mainstream, then so be it. Clinical trials and cannabis testing are already underway by companies like CannaTech Global, CI Therapeutics, EndoCRO and Steep Hill.

The idea is simple: put government money towards research and ram through legalisation in a highly controlled and regulated manner. One that considers liability issues since the medical profession needs to be able to study and test cannabis without health risks to their patients or broader public health and safety.

But the issue is complex. The standard steps drug companies take from research to market don't apply here. Aside from its centuries-old history as a medicine, prohibition has stunned our knowledge of cannabis and (in consequence) has made the plant a special “bottom-up” grassroots medicine rather than a traditional “top-down” pharmaceutical.

Meaning, it requires looking at government policy differently rather than trying to shoehorn cannabis into traditional regulatory models.

Cannabis is simple and effective. Whether vaped, consumed as an oil, or in a tincture — anecdotal evidence is abundant. It is now time for the medical profession to catch up. But having governments throw money at the issue is like trying to hammer in a screw.

Public policy would be better served to cultivate the underground cannabis industry that exists in North America. These are your cannabis experts, after all. Additionally, gutting some regulations governing the actions of medical professionals and patients will promote risk-taking and thus innovation and opportunity. But a culture overly concerned with legal liability makes this suggestion a hard sell. ■

Caleb McMillan

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Medical cannabis advocacy and education

Board Member for Canadians for Fair Access to Medical Marijuana (CFAMM), Peter Thurley, shares his views on medical cannabis advocacy and education issues

Canadians for Fair Access to Medical Marijuana (CFAMM) is a patient-run medical cannabis advocacy and education organisation that began when founder and outgoing Executive Director Jonathan Zaid ran into access barriers in obtaining his legal medicine. Suffering with a condition known as new daily persistent headache (NDPH), Zaid found that of the myriad of options offered by various doctors, only cannabis provided him with the relief he needed. Instead of taking away his ability to function (a recurring criticism of cannabis-use), it provided him with new ways to thrive.

While attending the University of Waterloo in 2014, he successfully petitioned his student union to include his medical cannabis in their health care coverage plan, becoming the first person to obtain insurance coverage for cannabis in Canada. Since then, he has grown CFAMM into the leading patient advocacy group in Canada. With a large advisory team of patients and working with leaders from across both activist circles and industry boardrooms, CFAMM has highlighted affordability and access issues within the current medical cannabis regime, as well as worked with government, official cannabis growers known as licensed producers and the insurance industry to set up insurance best practices.

While CFAMM has been successful in many measures, there is still a lot of work to do, particularly around affordability issues. Recently, the most pressing issue has been the Liberal government's stated intention to apply either a \$1/gramme or 10% excise tax to both the existing medical market and the recreational market, set to come online in early fall 2018.

Medical cannabis has been legal in Canada for more than 15 years, won largely through hard fought court

battles, several of which were heard in the Supreme Court of Canada. Because of longstanding prohibitionist policies dating back to the 1930s, cannabis has not undergone the usual series of clinical trials that are usually required to prescribe a product as a medicine.

Unlike other legal medications, there is no Health Canada approved Drug Identification Number (DIN) for the product, meaning that it is not eligible for any provincial or federal drug coverage. As a result, cannabis is the only medicine in Canada to which sales taxes apply. With scarce insurance coverage and average costs between \$7 - \$11/g, costs for patients add up fast, especially for persons with chronic illness(es) who live on a fixed government income.

"If there are any lessons the global community should take from the Canadian cannabis experiment, it should be that placing stigma at the feet of medical patients in a half-witted attempt to make an example out of them is a poor way to earn the trust of existing patients. At the end of the day, it will always be medical cannabis patients who will form the backbone of any future open global cannabis markets. Governments risk crossing them at their peril."

Claiming a desire to maintain a fully functional medical market, Finance Minister Bill Morneau introduced the excise tax by explicitly saying that the Government of Canada does: "not want the taxation levels to be an incentive for people to utilise [the medical] system inappropriately."

There is limited evidence to suggest that recreational consumers rely on the existing legal medical system to provide the product they want, choosing instead a broken illicit market. Indeed, this new tax accomplishes

little else than to further increase costs for patients who rely on cannabis as a medication and risks subjecting them to further stigma.

In response to this, CFAMM launched a National #DontTaxMedicine campaign to soften the Finance Minister's position before the 2018 budget. Joining together with the Arthritis Society of Canada, Jonathan Zaid and team amassed more than 16,000 signatures in two months, sending a letter and petition to each signatories' local Member of Parliament, as well as the Minister of Finance. By using a collaborative approach with industry partners and health care patient agencies, CFAMM effectively harnessed the online support of hundreds for visits with local elected officials, where each person delivered the consistent message that cannabis is an important part of their medical treatment.

Despite this work, which also included a protest in front of the Minister's constituency office, the 2018 budget contained little relief for patients across Canada. While token overtures, such as the exemption of low-THC and CBD only cannabis products, were made, Prime Minister Justin Trudeau and his Minister of Finance stuck to the party line.

In a recent column in the Ottawa Citizen, Dr Jenna Valleraini, a post-doctoral researcher whose work focuses on cannabis markets in Canada, notes that the Liberal government's approach is ultimately "wrapped up in ideas of stigma and distrust of cannabis' potential as a medicine, likely tied to its "recreational" use. ... cannabis comes with a relatively low risk profile and it reportedly helps many patients achieve a better quality of life. We should support responsible access to medical cannabis, rather than exacerbate issues around access, affordability and coverage."

If there are any lessons the global community should take from the Canadian cannabis experiment, it should be that placing stigma at the feet of medical patients in a half-witted attempt to make an example out of them is a poor way to earn the trust of existing patients. At the end of the day, it will always be medical cannabis patients who will form the backbone of any future open global cannabis markets. Governments risk crossing them at their peril.

As Jonathan Zaid prepares to pass the reins over to newly appointed President and CEO James O'Hara, CFAMM remains committed to keeping the rights of medical cannabis patients front and centre.

If you are Canadian and haven't already, please register your support for the #DontTaxMedicine campaign by signing the petition over at <http://donttaxmedicine.ca>. If you need support visiting your elected officials, send CFAMM a note at info@cfamm.ca and we would be happy to provide you with some resources for a productive meeting.

"Medical cannabis has been legal in Canada for more than 15 years, won largely through hard fought court battles, several of which were heard in the Supreme Court of Canada. Because of longstanding prohibitionist policies dating back to the 1930s, cannabis has not undergone the usual series of clinical trials that are usually required to prescribe a product as a medicine."

Peter Thurley became a cannabis patient in 2015 after the removal of a 25lb desmoid tumour that burst his bowels and left him with significant neuropathic chronic pain, a panic disorder and PTSD. After seeing a reduction in opioid use and an increase in quality of life, Peter became an accidental medical cannabis advocate. He lives in Kitchener, ON and has recently been appointed to CFAMM's Board of Directors. ■



**CANADIANS FOR FAIR ACCESS
TO MEDICAL MARIJUANA**

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Using innovative digital technologies for the delivery of healthcare in the UK

Jonathan Evans, communications manager at the Association of British Healthcare Industries explains the need to innovate when it comes to using digital technologies for the delivery of healthcare in the UK

The delivery of healthcare varies from Brighton to Birmingham, let alone Bangladesh and Brazil. Yet there are commonalities between areas and, increasingly, providers are tackling similar problems. Namely, ageing populations and increasing rates of chronic conditions. As a result, systems are struggling to provide the level of service they may once have been able to. With this comes the need to innovate and look at alternative methods to support the delivery of healthcare in the traditional clinical setting. For many, digital technologies are the answer.

Through patient monitoring, real-time data analytics, predictive algorithms and the emergence of AI (artificial intelligence), technology is rapidly altering the face of healthcare. Its use in hospitals is increasing, particu-

larly through machine learning and what is particularly exciting is how much of this technology can be utilised at home. If we adopt and integrate digital technology well, it will empower patients and alleviate strain on the system.

“In hospitals, we can expect more and more robotic-assisted surgery being used in our lifetimes as well.

The hospitals of the future and the pathways in which that healthcare is delivered are likely to look very different to what we are used to. It’s what many people are calling the fourth Industrial Revolution.”

In the last few years, we have seen a boom in the number of wearable devices and apps – from equipment that monitors heart rate and blood pressure to

programmes that can track calorie intake and exercise. Such innovations allow a person to make changes to their lifestyle and plan a healthier future. It empowers the user to take ownership of their health and acts as a preventative measure for any potential future health issues.

Partnered with other monitoring systems and powered by real-time data, patients and medical professionals can quickly spot changes or new trends that require immediate attention, keeping small problems in the home. The sooner you can identify a problem, the quicker you are able to access the right treatment. This avoids visits to the emergency room, costly treatments and long-term social care. It is where technology really comes into its own, as the potential savings are enormous.

“Through patient monitoring, real-time data analytics, predictive algorithms and the emergence of AI (artificial intelligence), technology is rapidly altering the face of healthcare. Its use in hospitals is increasing, particularly through machine learning and what is particularly exciting is how much of this technology can be utilised at home.”

The use of data can be broken down into four parts. The generation of data itself, aggregation (pooling it into one place), analysis and utilisation. As a user, the last part, utilisation, is the most important and digitally enabled medical devices and software will drive this. They underpin the value of such innovation and enable healthcare to scale out of hospitals and into the community.

The use of virtual reality (VR) is a fascinating prospect too. Recent news of funding for a state-of-the-art psychological therapy to be delivered via VR in the NHS was welcomed by clinicians and academics alike. This therapy is designed for mental health patients. Via a headset, they follow a virtual coach through computer-generated simulations of situations they find troubling. The coach guides the patient through these scenarios, helping them practice techniques to overcome their difficulties.

Across the Atlantic, a whole host of technology and health companies, like Apple and Johnson & Johnson, have joined an FDA program to fast-track digital health apps. Offering pre-certified companies, a shortened regulatory path to market, the initiative is focused on apps classified as medical devices today. As part of the process, the FDA assesses a company's software design, validation and maintenance before deciding whether to grant it pre-certification. Companies are then able to submit their technical file, which is significantly slimmed down, before introducing the digital health innovation.

In hospitals, we can expect more and more robotic-assisted surgery being used in our lifetimes as well. The hospitals of the future and the pathways in which that healthcare is delivered are likely to look very different to what we are used to. It's what many people are calling the fourth Industrial Revolution. ■

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Cloud computing in medical imaging: Not a matter of if, but when

Nadim Michel Daher, industry principal at Frost & Sullivan reveals his views on the vital role of Cloud computing in medical imaging

In the minds of healthcare IT decision-makers, as several surveys have shown, Cloud-based solutions have long been associated with data security and data ownership concerns. The apprehension does have a strong rationale: Why would anybody move confidential patient data off-premises and willingly become dependent on the network or on a vendor to be able to access and utilise data they own?

While this perception has caused lasting resistance to Cloud adoption in healthcare, especially in the government hospital segment, it has been changing gradually over the last few years. Years that also happened to be punctuated by regular Cloud outages and cybersecurity attack horror stories.

Recognising the Cloud's benefits

The benefits of Cloud solutions, such as their cost-effectiveness and predictability, unlimited scalability and deployment flexibility, have started to outweigh the perceived risks. Cloud proponents even go as far as to admit that vendors are in a better position than their own IT organisations, to proactively protect data while leveraging the latest data security advances. They realise that there are waste and inefficiency inherent to the conventional siloed on-premises IT models and that they could use freed-up time to focus on higher-value enterprise initiatives. Therefore, as they contemplate the second or third generation of various health IT solutions, the standard model of buying, operating and maintaining that in-house is naturally coming into question.

Medical imaging, a precursor

This is especially true in medical imaging, where the unending growth in image data volumes, coupled with long-term data retention policies in place, makes traditional storage upgrade and scale-up mechanisms

clearly unsustainable over the long run. This is why, since the early 2000s, Cloud-based solutions have provided a viable alternative to tape- and truck-based solutions for the long-term archival of medical image studies. While this early adoption has enabled many providers to get their feet wet with Cloud solutions, there is actually so much more today to Cloud use than mere back-office data storage support.

Cloud storage is only the beginning, Cloud computing is next

Two simultaneous and complementary market trends are advancing Cloud-based imaging informatics into new use cases: the continuous expansion of medical imaging applications into niche subspecialty clinical areas and the ongoing diversification in the points of care where medical multimedia content is produced and consumed by various enterprise imaging stakeholders. This is driving the development of the following four core application areas:

- Cloud-based image archiving, which has been advancing beyond “deep” archival towards real-time online accessibility.
- Cloud-based image distribution (for inter- and cross-enterprise image exchange, image-enabled electronic health records (EHRs), patient portals and healthcare information exchanges (HIEs)).
- Cloud-based image diagnosis (RIS, PACS, Teleradiology, Reporting), which can complement or completely replace on-premises image management solutions.
- Cloud-based imaging analytics, with various types of applications that can be delivered on-demand as software-as-a-service (SaaS) or on a subscription basis as part of Cloud-based ecosystems or marketplaces.



A fast-developing but fragmented market

On the vendor front, the industry players can be categorised into three groups as follows:

- The speciality early-movers, who have embraced the Cloud early-on as the core enabling platform for their solutions, built some of their own data centres and who can be credited for the inception of this emerging market.
- The large cross-industry Cloud infrastructure vendors (led by Amazon, Microsoft and Google), who are now fully proactive in developing their industry partnerships as well as native solutions in healthcare, including in imaging.
- The established imaging IT vendors, many of which have been fairly conservative in transitioning their customers to Cloud solutions, but some of which are preparing a major realignment around Cloud-based models.

Double-digit growth rate projections

Cloud-based imaging informatics still represents a relatively small market, totalling \$285.4 million in revenue in 2016 globally. It accounts for 8.5% of the total Cloud-based health IT market and to 3.8% of the total imaging IT market. However, while fairly niche, the market is expected to remain on a very strong growth trajectory over the next few years, growing to \$830.5 million in 2021, or an impressive compound annual growth rate of 23.8%.

New dimensions via enablement and synergies

Transitioning to a Cloud-based imaging IT model is no easy shift, whether for healthcare providers or for vendors. Both have to align with the new purchasing, business, management and governance models that this shift entails and to be able to absorb its unconventional operational, security and financial risk profiles. Yet, as we have moved past the innovator stage and well into the early adopter phase of the Cloud in imaging, now is the time for Cloud solutions to unleash their untapped potential.

For their greatest value is fact not in Cloud technology per se, but in its synergies with the field's most impactful developments: by enabling greater data usability for advanced imaging analytics (big data, radiomics and machine learning), accelerating interoperability imaging research initiatives, or converging with healthcare blockchains, the Cloud will be, without a doubt, a pervasive actor in the ongoing transformation of the medical imaging value chain. ■

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Atom-by-atom: Gas to solid reactions visualised in real time

Professor Jakob Birkedal Wagner, Scientific Director at the Center for Electron Nanoscopy at DTU Cen, provides an absorbing insight into gas to solid reactions that are visualised in real time, atom-by-atom

The abundance of carbon in nature – combined with the variety of assembling the individual atoms into nanostructures with various physical properties such as metallic, semiconducting, semi-metallic etc. – make carbon nanostructures of particular interest and importance where tomorrow's electronic and optical devices are concerned. Single-walled carbon nanotubes and graphene show enormous potential in electronic devices and are already incorporated as transparent conductors in touch-screens, to name just one application.

Single-walled carbon nanotubes (SWCNTs) consist of a hexagonal lattice of carbon atoms rolled into a tube. The specific diameter and chirality (or helicity) of the carbon tube determine whether the nanotube acts metallic or semiconducting. Tubes are typically grown from metallic seed nanoparticles (Fe, Ni, Co, etc). To grow the nanotubes selectively (with a specific chirality) for efficient application, a better understanding of the actual growth mechanism is essential.

Visualising the carbon structure to form at the atomic scale gives valuable insight into the key parameters and processes determining the diameter and chirality of the carbon nanotubes and thereby their electronic and optical properties. *In situ* growth of such carbon structures by means of environmental transmission electron microscopy (ETEM) is a unique opportunity to

follow the growth in real time ^[1,2,3]. At Center for Electron Nanoscopy at the Technical University of Denmark, such growth studies have successfully been carried out in the past years.

Figure 1 shows the transition from gaseous carbon to solid carbon forming CNTs. The elongation process of a SWCNT is shown by a series of transmission electron micrographs extracted from a movie, acquired during exposure of a Co/MgO sample to ethanol (C₂H₅OH) at elevated temperature. The diameter and thereby the chirality of the SWCNTs strongly depends on the size and state of the catalytic particles (in this case cobalt) and the access to carbon atoms, which can be

incorporated into the tube securing growth.

Changes in the amount of accessible carbon either by changes in the carbon supply (gas pressure of ethanol) or by changes in the rate of catalytic cracking of ethanol to free carbon atoms, strongly influence the growth and can be a limiting step for the CNT growth. However, we observe that the same catalyst particle stayed active in terms of nucleating additional solid carbon structures after the growth termination of the first SWCNT. These observations elucidate the importance of an in-depth understanding of the role of catalysts and carbon sources in the continued growth of SWCNTs.

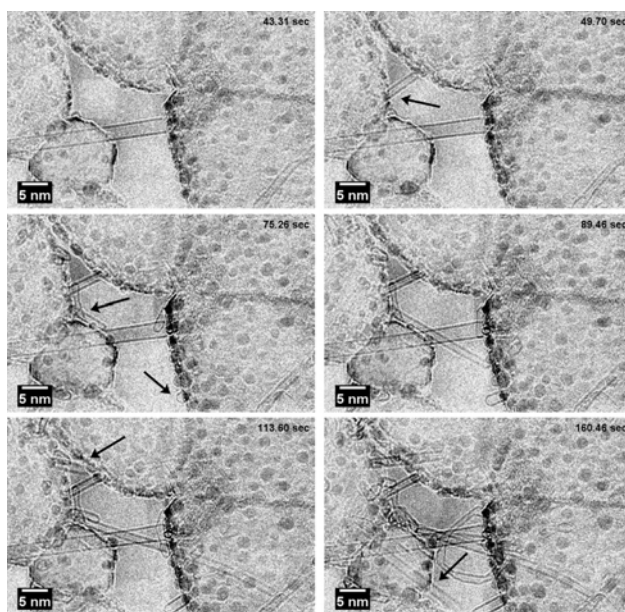


Figure 1. Image sequence of an *in situ* growth experiment performed at 700°C (p(ethanol)=0.1 Pa). Arrows indicating a few newly grown SWCNTs in each frame. The time stamp indicates the time since the valve to ethanol was opened. The images are background subtracted for better visibility of the particles and tubes (courtesy of Jens Kling).

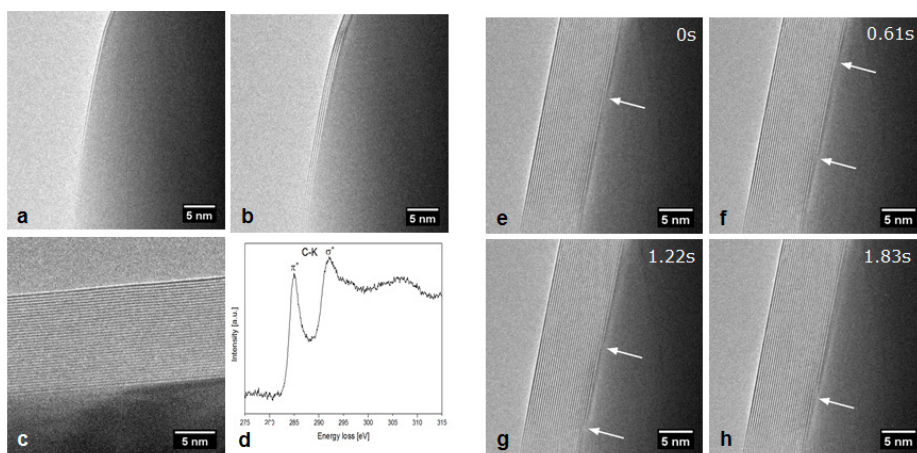


Figure 2. Layer-by-layer growth of carbon on a nickel crystal. $T=650^{\circ}\text{C}$, $120\text{ Pa H}_2/3\times 10^{-2}\text{ Pa C}_2\text{H}_2$. a)-c) well-aligned carbon layers at the Ni surface. d) Electron Energy-Loss Spectrum showing the carbon ionisation edge for a graphitic structure. e)-h) several growth fronts observed at the carbon/nickel interface simultaneously (indicated by white arrows) [3].

Graphene is another low-dimensional carbon-based nanostructure grown from a gaseous source on a seed material. The hexagonal lattice of carbon is confined to a flat 2-dimensional geometry dictated by the seed material acting as a template. The geometry of the seed material makes it slightly more challenging to follow the growth on the atomic scale using ETEM compared to CNT growth.

A process involving reduction of a suitably sized nickel oxide followed by addition of acetylene (C_2H_2) to the gas flow makes it possible to monitor the initial steps in layered carbon growth on metallic nickel. Figure 2 shows stills from a movie acquired during exposure

of a $\text{H}_2/\text{C}_2\text{H}_2$ mixture (total pressure measured to 120 Pa) at 650°C . The carbon structure grows layer by layer from the interface between the carbon structure and the nickel particle in form of a mobile kink in the seed particle.

The interface growth happens even after multiple layers of carbon is covering the nickel particle indicating a transport of carbon, although slower with increasing thickness (see Figure 3.) This indicates a decreasing carbon source at the growth front due to the longer diffusion length through the (defective) carbon layers. Decreasing the C_2H_2 pressures slow down the growth whereas lowering the growth temperature to 600°C results in more

defective and less aligned carbon layers forming on the nickel seed material.

The local environment including temperature, precursor accessibility and atomic configuration of the seed particles, in general, play a crucial role in the resulting carbon structure. The direct view of the growth by means of ETEM is essential to dig deeper into the mechanisms determining the formation of the proposed tailor-made materials with designed properties.

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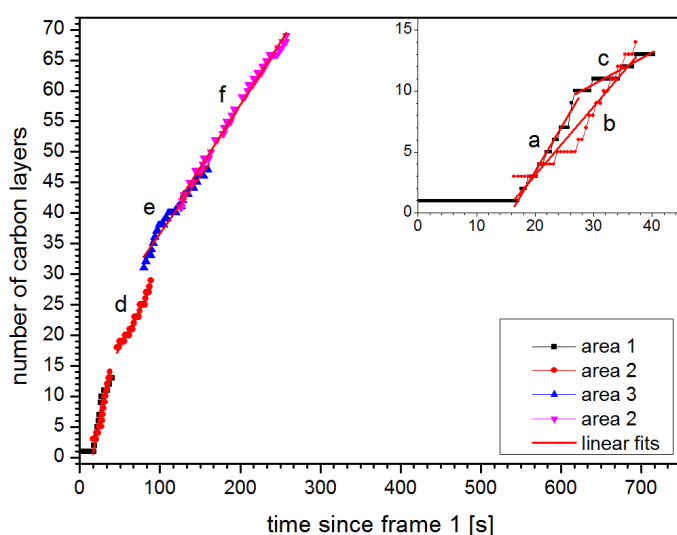
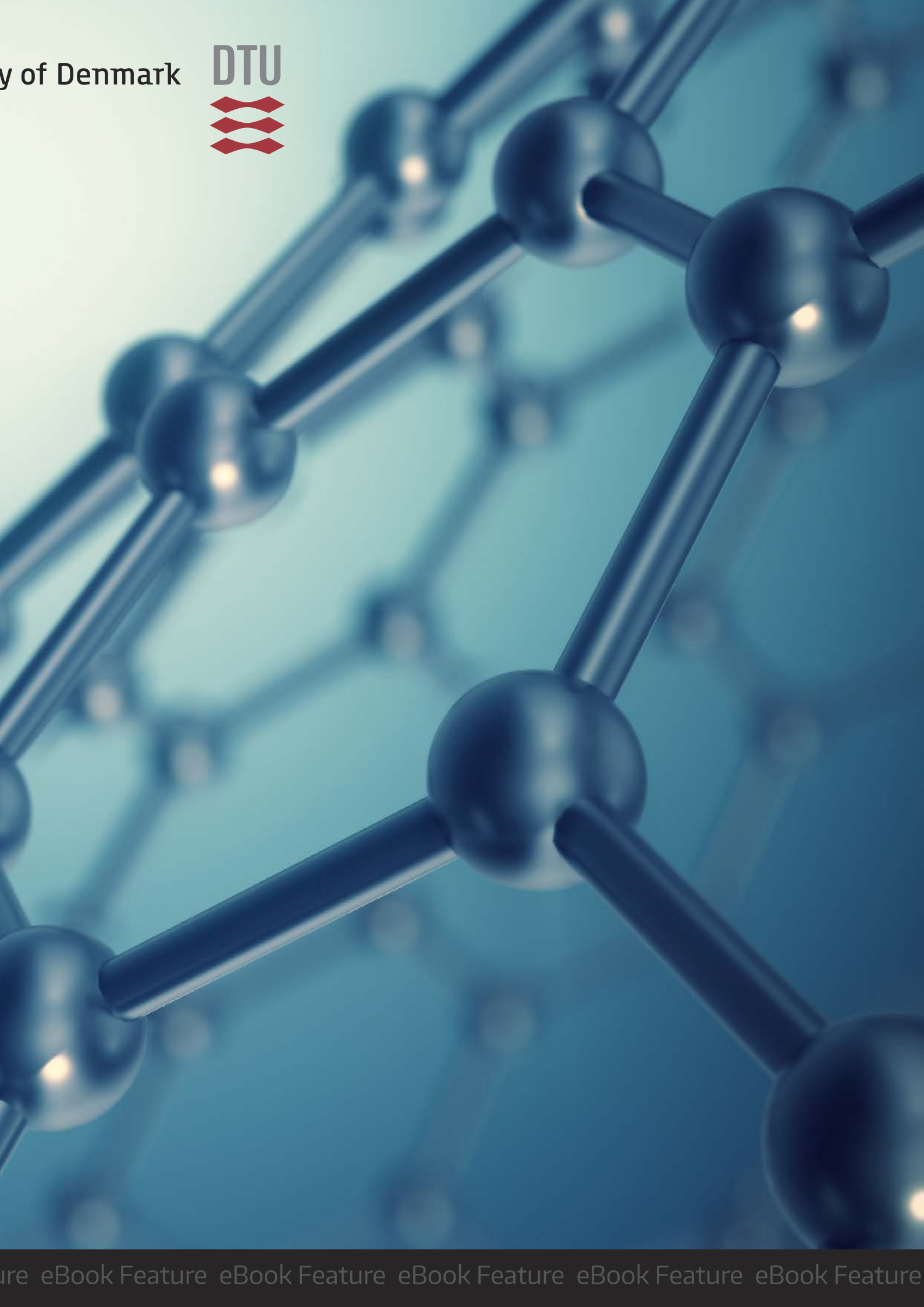


Figure 3. Number of carbon layers per time extracted from *in situ* TEM movies of the growth at three distinct areas. $T=650^{\circ}\text{C}$, $P(\text{C}_2\text{H}_2)=3\times 10^{-4}\text{ mbar}$ [3]

Small is beautiful

This compelling document focuses on attention to detail, hence its apt title, 'small is beautiful'. This intriguing e-book is all about nanoscale imaging research and within that, the fascinating field of electron microscopy.

For more information [CLICK HERE](#) to read our eBook.



The role of advanced technologies in healthcare

The role of advanced technologies in healthcare, including the work of the National Institute of Biomedical Imaging and Bioengineering (NIBIB) in this area, is placed under the spotlight by Open Access Government

On the website of, National Institutes of Health (NIH), we learn that for most of the history of medicine, doctors have relied on their senses – that is vision, hearing and touch – to diagnose illness and monitor a patient's condition.

However, NIH's investment in research over the period of a whole century has helped to completely change medical diagnostics. The new technologies of today allow doctors to find out an increasing amount of detailed information about both the progression and treatment of disease and can even offer personalised treatment based on a patient's genes, we discover.

In addition, NIH-funded scientists have helped to pioneer the development of magnetic resonance imaging (MRI), but they have also made important strides toward uncovering the medical potential of stem cells and as such, they have developed new tools for genome sequencing. With these advanced technologies in place, scientists are finding out how genes affect human health and how a genetic approach can help doctors tailor treatments and prevention strategies for each patient. Certainly, millions of individuals have

already been touched by the exciting era of personalised medicine that has grown directly from this research, we learn. ⁽¹⁾

Advances in medical imaging

One area that concerns the NIH is medical imaging, an area they are thoroughly committed to. Indeed, they have an entire institute, the National Institute of Biomedical Imaging and Bioengineering (NIBIB), who seek to improve health by leading the development, acceleration and application of biomedical technologies.

NIBIB is devoted to integrating the physical and engineering sciences, with the life sciences, to further basic research and medical care. This ambitious aim is achieved through:

- Research and development of new biomedical imaging and bioengineering techniques and devices to improve the prevention, detection and treatment of disease;
- Furthering present imaging and bioengineering modalities;

- Supporting relevant research in the physical and mathematical sciences;
- Encouraging research and development in multidisciplinary areas;
- Supporting studies to assess the effectiveness and outcomes of new biologics, processes, materials, devices and procedures;
- Developing technologies for the early detection and assessment of health status where diseases are concerned and;
- Developing advanced imaging and engineering techniques for carrying out biomedical research at multiple scales. ⁽²⁾

Below, we explore just two examples of the excellent research NIBIB is supporting, where medical technologies are concerned.

Thermo-chemotherapy combo eradicates primary and metastatic tumours in mice

In recent news, we find out that bioengineers at NIBIB developed a smart anti-cancer nanoparticle with precisely targeted tumour-killing activity, which was found to be superior to the previously available technologies.

We are told that state-of-the-art nanoparticle features a very sturdy shell, which is capable of carrying large loads of chemotherapeutic drugs through the circulatory system to a tumour – that is without the leakage that can damage healthy tissue. The nanomedicine is photothermal-responsive, so the cancer-killing load of the particle is released only when it enters the tumour cells and is activated by laser light, we discover.

Reported in the February issue of Nature Communications, this cancer-killing technology is the latest and most effective created by members of the Laboratory of Molecular Imaging and Nanomedicine (LOMIN) at NIBIB, which is led by Xiaoyuan (Shawn) Chen, Senior Investigator.

Fluorescent nanoparticles track cancer metastasis to multiple organs

Researchers funded by the NIBIB have developed fluorescent nanoparticles that light up to track the

progress of breast cancer metastasis, we find out. They are currently testing the particles in mice, with the hope of one day using them in humans, we are told.

Prabhas Moghe, Ph.D., professor of Biomedical Engineering and Chemical and Biochemical Engineering at Rutgers University and his team are developing nanoparticles that can help identify and track cancer metastasis early on, even when a tumour is really small.

“There are still significant hurdles to be overcome before this imaging technique could be used in humans, but it is an important step in moving optical imaging cancer diagnosis forward,” says Behrouz Shabestari, Ph.D., director of the NIBIB Program in Optical Imaging and Spectroscopy. “It has the potential to help doctors to identify tiny cancer cells and track their spread more effectively, leading to early detection and potentially improved treatment planning.”

As well as tracking the spread of cancer, the nanoparticles could potentially be used to differentiate cancer tissue from healthy tissue for surgeons who are removing tumours. Moghe and his team are hopeful that the technology could be positioned for use in humans within the next 10 years. ⁽³⁾

Final thoughts

You can find many more examples of how NIBIB is improving human health, by leading the development and accelerating the application of biomedical technologies in the US today, which this article provides a flavour of. ■

For more information, please visit www.nih.gov.

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Non-radioactive, non-ionising radiation for safe paediatric imaging

E.M. Sevick and J.C. Rasmussen from The University of Texas Health Science Center, The Brown Foundation Institute of Molecular Medicine discuss non-radioactive, non-ionising radiation for safe, paediatric imaging

Medical imaging has transformed the entire spectrum of healthcare, from enabling discoveries in medical science and directing the development of therapeutic interventions, to providing the most optimal and efficient management of diseases in individuals. Yet conventional medical imaging modalities have particular limitations, especially when it comes to the paediatric populations in whom diagnosis and treatment arguably may have the greatest long-term benefit.

Whether it be the ionising radiation of computed tomography (CT) or x-ray imaging; the radioactivity of radionuclide-based imaging agents in nuclear imaging; the long scanning times of magnetic resonance imaging (MRI); or the need to administer substantial amounts of iodinated or gadolinium-based contrast agents whose long-term effects are questionable in adults, much less in infants and children; conventional medical imaging does not advance discoveries in paediatric medicine in the same manner it does in adult medicine.

Under development in our laboratories, near-infrared fluorescence (NIRF) imaging may uniquely meet the requirements for paediatric medical imaging. The technique depends upon administering a trace dose of non-radioactive dye that fluoresces in the near-infrared wavelength range

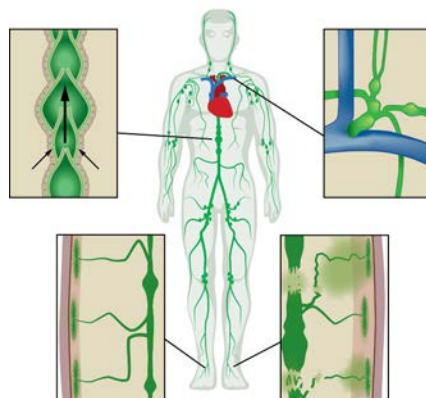


Figure 1: A schematic of the open and unidirectional lymphatic system which begins at the initial lymphatics (lower left panel) that line all organs and carries lymph through lymph nodes and the thoracic duct before emptying into the supraclavicular vein (upper right panel). The system includes series of lymphangions or "lymph hearts" which propel lymph unidirectionally through the lymphatics (upper left panel). The abnormal lymphatic function may be a result of lack of pumping and/or the degradation or malformation of lymphatic vessels (lower right panel). Figure reproduced from O'Donnell, et al., J Vasc Surg Venous Lymphat Disord, 2017.

and illuminating tissue surfaces with dim near-infrared (NIR) light that penetrates several centimetres to excite the dye, causing it to fluoresce. The resulting fluorescence is emitted from the tissues and is captured by an imaging system, consisting of military-grade night vision technology coupled to a digital image capture device.

Because of the superior sensitivity offered by the coupling of these two technologies, trace doses of fluorescent dye can be rapidly imaged with sub-second exposures at tissue depths as great as 3-4 centimetres. This unprecedented performance enables NIRF imaging to be used as a point-of-care diagnostic and removes the need for sedation otherwise needed for paediatric patients. Future developments include extending this depth and generating 3-D imaging, similar to CT or MR angiography.

Owing to its 60 year-record of safe use in humans at much larger doses, we currently employ indocyanine green

(ICG) as the NIRF contrast agent, but other far brighter and more useful dyes remain to be translated into humans. ICG strongly associates with plasma proteins, making it an excellent hemovascular contrast agent and in our work, an excellent lymphovascular contrast agent that, when coupled with the NIRF imaging devices, has allowed some of the first glimpses of lymphatic vascular function in disorders of adults and children.

The lymphatic vascular system has largely escaped routine medical imaging and as a result, comparatively little is known about its role in health and disease. The open and unidirectional lymphatic system begins with the initial lymphatics that lie beneath the epidermis and line all organs. Waste products, immune cells and excess fluid (capillary filtrate) that enter the initial lymphatics are actively pumped through series of "lymph hearts" or contractile lymphangions that transit lymph through lymph nodes to the subclavian vein where the fluid

returns to the blood vasculature (Figure 1).

There are few procedures to image the lymphatics: (i) lymphoscintigraphy, in which a radioactive colloid is injected to image lymphatic transport over several minutes to hours using nuclear imaging and (ii) lymphangiography, in which several millilitres of an iodinated or gadolinium-based contrast agent is injected into lymph nodes or into surgically isolated lymphatic vessels for MR or x-ray imaging, provide invasive and cumbersome diagnostic techniques. As a result, there is little understanding of how the lymphatic vasculature mediates immune response and returns fluid and lipids absorbed from the gut back into the hemovascular system.

Today, despite the paucity in procedures to image the lymphatics, it is generally accepted that it plays a critical role in several chronic conditions in adults, including autoimmune diseases, such as rheumatoid arthritis, cancer metastasis, peripheral vascular disease and neurodegenerative diseases. In children, lymphatic dysfunction has been hypothesized to accompany neurological diseases, such as specific forms of Autism, vascular malformations and cardiovascular deformities.

In translational studies funded in part by the National Institutes of Health and conducted under investigational new drug applications from the FDA, we have used the NIRF technology to dynamically image the lymphatics of over 400 subjects, including 30 infants and children. The imaging begins with an intradermal injection of 0.05- 0.1 mL of saline containing microgram amounts of ICG into the region of interest. ICG administration on the top of the foot results in immediate uptake into the main conducting vessels (Figure 2A) that proximally “pumps”

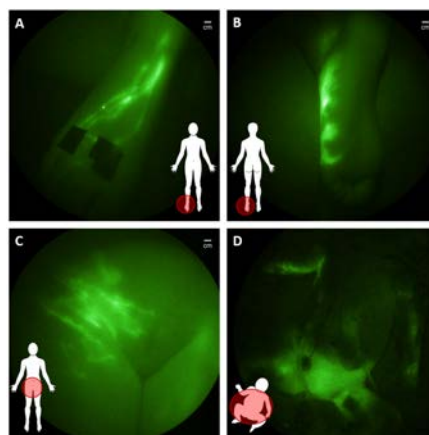


Figure 2: Conducting lymphatics on the top (A) of the right foot and (B) abnormal drainage on the bottom of the left foot of a 17-year girl with congenital lymphedema; Lymphatic congestion in the pelvis of (C) a 16-year girl with congenital lymphedema and (D) a 23-day old male infant with surgery-induced chylothorax.

ICG-laden lymph into the inguinal nodes before entering the central lymph channel that collects mesenteric and peripherally generated lymph for its return to the hemovascular system.

In children and adults with suspected lymphatic dysfunction, we have observed abnormal lymph drainage to the bottom of feet (Figure 2B), as well as pelvic, lymphatic congestion which in adolescents and young adults is associated with lower extremity lymphedema (Figure 2C) and, in some infants, with surgery-induced chylothorax (Figure 2D).

In other studies, concerning infants, we have uncovered impaired lymphatic pumping and imaged retrograde lymphatic drainage into the pleural cavity to ascertain the nature of impaired lymphatic return. These imaging observations, when coupled with genetic and immune profiling, could provide critical clues to develop effective treatments for the paediatric population suffering immune or cardiovascular disorders.

While we have used NIRF to interrogate lymphatic function in children

and adults, it also has the unfulfilled potential to interrogate hemovascular function as well as cerebral spinal fluid production and drainage to address some of our most challenging problems in paediatric patients. In addition, the development of molecularly targeted NIRF agents expands the repertoire of imaging diagnostics in the paediatric population to advance therapeutic discoveries.

For more information on NIRF imaging in paediatrics and congenital diseases:

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No more paywalls: Open Access as of 2020

President of the National Research Council of the Swiss National Science Foundation (SNSF), Matthias Egger reveals the organisation's exciting new open access policy in this interview

Based on a decision by the National Research Council in 2017, all publications produced in SNSF-funded projects will be available in digital format without any charges as of 2020. Science, the economy and society at large stand to benefit.

It isn't just the research that's expensive, its findings are also far from free. Some university libraries pay hundreds of thousands of francs per year to prestigious publishers for their scientific journals. All in all, the Swiss higher education institutions paid 70 million francs for such licenses in 2017. This paywall hampers the spread and application of new knowledge.

Even though a significant share of scientific publications is government-funded, it is the private publishing companies that reap the commercial benefits. For the SNSF, an absurd state of affairs to say the least. "Research results funded with public money belongs

to the public," says Matthias Egger, the President of the National Research Council. All SNSF projects are therefore obliged to offer open access (OA) to the scientific articles and books produced in the scope of the project.

"The SNSF's new open access policy goes hand in hand with the national strategy pursued by the Swiss higher education institutions. In 2017, they decided that all publicly funded publications must be freely accessible by 2024. Open access will soon be the standard mode of publication, in Switzerland and the world over."

From 50% to 100%

Only 50% of publications currently meet the open access requirements of free, unrestricted availability in digital form. But, based on a decision by the National Research Council, the SNSF wants to change this to 100% of publications by 2020. Matthias Egger sees



Matthias Egger, President

In the case of gold road publications, the authors often contribute to the production costs. The SNSF has already been covering the costs of OA articles for some time. It has also covered the costs of OA books since April 2018 and will do so for book chapters as of October 2018.

The Swiss standard as of 2024

The SNSF's new open access policy goes hand in hand with the national strategy pursued by the Swiss higher education institutions. In 2017, they decided that all publicly funded publications must be freely accessible by 2024. Open access will soon be the standard mode of publication, in Switzerland and the world over.

"Research findings funded with public money belongs to the public", Matthias Egger concludes. ■

Matthias Egger President

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many advantages: "The researchers themselves stand to benefit the most from open access: their results will gain greater visibility. And they will be able to access their colleagues' work without any restrictions. It will be a step forward for science." What is more, thanks to open access, the private sector and society at large will be able to rapidly retrieve and utilise a wealth of scientific knowledge.

Gold and green road

How do researchers meet the open access requirements? Either they publish their results in OA journals or OA books that are immediately freely accessible. This is the gold road.

Or they publish their results in a journal with a paywall first, then place them in a public database after six months. Books are subject to an embargo period of 12 months. This is the green road.

Challenges in modern optical technologies

Toralf Scharf, Senior Scientist/Faculty member at ÉCOLE POLYTECHNIQUE FÉDÉRALE DE LAUSANNE EPFL explains the challenges present in modern optical technologies

In the 21st century, optical technologies start to gather fruits for its long investment in research and development supported by technologies developed for microelectronics. The basic driver is miniaturisation and with the maturity of micro- and nanofabrication tools even standard optical components like lenses will change their appearance. Especially the move from single components, to complete systems and their integral optimisation will challenge the research and development activities and opens a disruptive pathway to optical component design and manufacture. Everything gets smaller, everything must interact perfectly, and everything should be designed together.

“A technological and educational gap appears and makes it very difficult to educate engineers with cutting-edge techniques, or to contribute to latest high technology development in research.”

While in former times of technology development, the global players run own research labs and opted for widespread dissemination of knowledge through publications today, the situation is different. The technology drivers keep their activity secret and additionally outsource the technology – by taking care that their developments are not transferred to other projects within the same lab and putting effort into patenting.

The technology development has undergone a fundamental change from an open culture to a more restricted one! One additional aspect is that many innovative developments today come from small enterprises or start-ups before they are transferred to global operators. Such small and medium-sized companies have a completely different strategy for sharing results. It is mainly done based on new products and fabrication secrets. Patents are only important if venture capital is involved.

Moreover, because of limited resources, SMEs are calling often for public research funds and immediately get a conflict of interest: it is important to make results available with open access, as asked for by the funding agencies and keeping fabrication secrets as needed for the running of the business. The push towards open access will nevertheless help SMEs – as they have only limited resources for research and can profit much more from wider dissemination of results – because SMEs are more dynamic to adapt.

At the same time, in our highly specialised technology-driven world top-level research becomes even more expensive. This is mainly due to fact that enterprises specialised in their field invest enormous amounts of money in production facilities and machines to keep the lead in their field. On the other hand, research

funds at Universities are limited and with the trend to common technological platforms, more standard equipment will be used but made available to the wider community.

A technological and educational gap appears and makes it very difficult to educate engineers with cutting-edge techniques, or to contribute to latest high technology development in research. This is also valid for optics fabrication that covers an enormous span of different technology, from grinding and polishing to electron beam writing. One solution here is to establish close collaboration with industry and install industrial PhD programmes.

If we look at technologies, what are the ongoing challenges? As mentioned optics uses many different techniques but with the same goal: achieving the optical quality of the components. The term “optical quality” stands for nanometre precision. For lenses, it means excellent surface definition and quality, but for nanostructured components, its definition becomes more complex and includes uniformity over surfaces of millimetre size. If we look at miniaturisation in optics, we see several challenges.

Firstly, the optical elements need to be connected to the macroscopic world and will need to cover a certain surface or volume. High-quality production over millimetres for nanometre scale structures needs to be developed.

Secondly, to fully profit from the fine structure of the components one would like to change parameters of nanostructures locally. With mm size optical element and a 100 nm sized basic structural element, one ends up with more than 100 million elements. If only a few of them are used for the design of an optical function, then the parameters space for optimisation will not be manageable with conventional design approaches. An optical multidimensional system design can handle many parameters and is based on a rigorous method which needs to become the standard. An optical design will become a big data problem.

A third challenge is the characterisation at different lengths of scale. Often underestimated, is the link between the quality of nanostructures and its optical function which is not easy to establish. The ultimate characterisation technique would have a large field of view in the millimetre range – to see the whole element at once and still deliver nanometre resolution. But such techniques do not exist yet and would lead to data volumes for analyses that are not manageable by the existing informatics infrastructure. The optical characterisation is already a big problem where data is concerned.

With all these different aspects in mind, what is the ideal research project to educate future engineers and scientists? We found an answer in a project that is based on industrial collaboration including all aspect of optical technology. Our activities are based on experiences in the most modern fields of research in optics: nano-photonics including meta-surfaces and meta-materials, micro-optics referring to refractive and diffractive structures and system optics which



takes up the different aspects of integrating such components.

The EU funded Horizon 2020 research project NOLOSS allows 15 fellows to pursue their PhDs in the industry in the framework of a European Industrial Doctorate (EID) Marie Curie Actions. With 12 participants, including nine partners from the industry, this allows us to widen the view of technology development at industrial partners, as they expand their network to SMEs that would not otherwise be possible. Of course, this needs learning and support from all sides.

The funding agencies need to be aware that industries of different sizes work at different pace and need to change direction to keep on track with their business. The universities must understand that a PhD outside of their infrastructure will contribute differently to the universities communities and the fellows must be flexible to accept different workplaces during their studies.

But all this can be managed and the NOLOSS project is an excellent example how it can be done on a scale needed to develop an effective net-

work and to have the most important technologies on board. This said, keeping an open science attitude is not easy and the push for publications and dissemination remains one of the greatest challenges of the project.

Toralf Scharf focuses his research activities at the École polytechnique fédérale de Lausanne on interdisciplinary subjects bringing micro-system, material technology and optics together. With a background in surface physics (MSc), physical chemistry (PhD) and a profound experience in optics he is familiar with all necessary aspects of technology development and application and can communicate with different scientific communities. In over 20 years of project execution with industry and governmental organisations, he has accumulated the right experience to lead and execute the project at different levels.

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Website <https://www.nolossproject.eu>



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Pursuing physics at the forefront of knowledge

Denise Caldwell, Director, Division of Physics at the U.S. National Science Foundation (NSF) provides a fascinating perspective on how the organisation is pursuing physics to the forefront of knowledge

On September 14th, 2015, the twin detectors of the National Science Foundation's (NSF) Laser Interferometer Gravitational-Wave Observatory (LIGO) registered a gravitational wave as it passed through the Earth. The distortion of space-time – predicted by Albert Einstein one hundred years earlier – was generated as two black holes merged into one, releasing the energy of three suns in the process.

The LIGO observation marked the first time scientists had ever directly observed a gravitational wave, an achievement that even Einstein himself did not believe possible. LIGO's success is the result of a high-risk, high-impact investment made over four decades by NSF through its Physics Division, a commitment to build what is arguably the most sensitive detection instrument ever constructed.

Since that first observation, LIGO has witnessed four additional black-hole mergers, followed in August of last year by the first gravitational wave detection of paired neutron stars. That detection was immediately followed by observations from 70 telescopes around the world, providing new insight into the collision from visible light, ultraviolet light, radio waves, x-rays and gamma rays.

The complementary observations brought together two of the three elements in multi-messenger astrophysics: explore the cosmos through observations of gravitational waves, while collecting radiation across the entire electromagnetic spectrum. The third element, an observation that combines data from elementary particles such as neutrinos with electromagnetic data, is on the horizon. As the elements of multi-messenger astronomy are united, humanity will have an unprecedented, comprehensive view of the most powerful events in the universe.

Searching for answers to some of science's most challenging questions is a core goal for the NSF Physics Division. The study of physics as an intellectual pursuit underpins all the other physical sciences and increasingly, the life sciences as well, as physicists and biologists increasingly cooperate to address problems covering a range of scales, from molecule to organism.

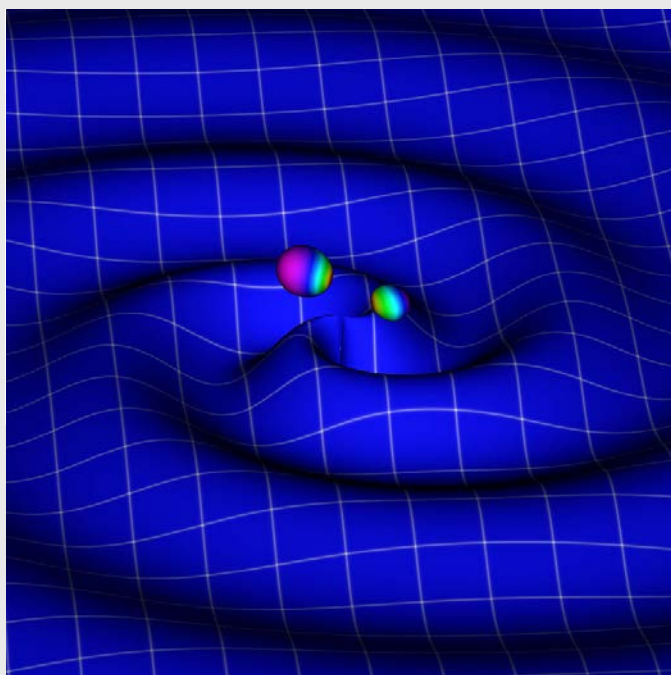
Since 1975, scientists supported by the NSF Physics Division have made seminal contributions to advancing the frontiers of the field, from the vast reaches of the universe to the tiniest particles of matter, helping secure U.S. leadership across science.

We support scientists working at the ATLAS and CMS detectors, part of the Large Hadron Collider at the CERN laboratory in Switzerland, where three years prior to the LIGO discovery, scientists participated in the discovery of the Higgs boson, the last remaining elementary particle needed to complete the Standard Model of particle physics. Our division also supports the National Superconducting Cyclotron Laboratory at Michigan State University and IceCube, an NSF-funded neutrino detector located at the South Pole.

Those efforts are complemented by our support of NSF Physics Frontiers Centers, which focus on addressing the most compelling frontier science questions. In that setting, research progresses through the concerted efforts of large, often interdisciplinary, groups working together.

While large facilities are important for discovery, our division's primary mechanism of support is to individual researchers and small groups. Our funding almost exclusively supports faculty research programmes housed at universities and in this way, we foster scientific progress while ensuring the propagation of ideas

Image: NCSA Gravity Group



Gravitational waves

to students and early career faculty, the next generation of researchers. Significant support for students and junior scientists is inherent to our portfolio, as it is critical to prepare the next generation of researchers for advanced, high-tech work and innovative new technologies that arise in the quest to answer some of the hardest questions that nature can pose.

Through our portfolio of awards, NSF's Physics Division pursues its primary goal "to promote the progress of science", as expressed in the legislation that founded our agency, the National Science Foundation Act of 1950. The awards support research necessary to address scientific questions at the frontier of current knowledge, while at the same time extending and redefining that frontier.

For example, crucial discoveries made by NSF grantees helped launch and lay the groundwork for quantum information science. That effort continues and contributes to current, rapid progress toward 21st Century quantum-based breakthroughs, from quantum computers to high-resolution sensors that could revolutionise measurement technology.

Across NSF there are examples of investment that begin with new ideas generated by the physics community. Those are further informed through workshops,

input from advisory committees, proposal reviews and the scientific expertise of a group of top-flight programme directors, each a scientist in his or her own right. NSF relies on these community-based resources to decide where to direct our physics investment.

The breadth of investments is extensive. Through the Physics of Living Systems program, the division has helped establish and grow a community of physicists who look at the living world as a laboratory through which to learn new physics while at the same time informing breakthroughs in biological understanding. For example, a study of sand lizards moving through sand served as a paradigm for motion in granular media in general, an important concept for the design of robots for exploration.

Through the Nuclear Physics program, scientists are enhancing our understanding of the forces that drive the formation of the elements in the universe. And most recently, a telegram from the NSF IceCube Neutrino Observatory (supported both by the Physics Division and the NSF Office of Polar Programs) announced the detection of a high-energy extragalactic neutrino. That detection was quickly followed by observations from a suite of telescopes across the globe, which reported high-energy electromagnetic radiation from the same location as the neutrino, yet another breakthrough in multi-messenger astrophysics.

As such science progresses – whether it be neutrinos, cold atoms, Bose-Einstein Condensates, astrophysical plasmas, or the origin of the elements in the universe – the Physics Division has had and continues to have, a major role to play in driving scientific knowledge. ■

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Physics: Understanding the elusive dark matter

Richard G. Milner from the Department of Physics and Laboratory for Nuclear Science at Massachusetts Institute of Technology provides an absorbing insight into the search for an understanding of the elusive dark matter, one of the great scientific quests of our age

The search for an understanding of the elusive dark matter is one of the great scientific quests of our age. In the 1930s, astronomers first made determinations of the gravitational mass of galaxies that were significantly larger than expected from the observed luminosities and wrote of *dunkle Materie*¹. Almost 90 years later, there is collective evidence that is substantial and consistent across seven orders of magnitude in distance scale², that an unknown substance (dark matter) shapes the large-scale structure of the universe.

We believe that dark matter interacts gravitationally and that its non-gravitational coupling is of order the weak interaction³, or less. We expect that there must be some new interaction via a mediator between dark matter and atomic nuclei for dark matter to be in equilibrium with other matter in the early universe. We know the approximate density and velocity of dark matter in our galaxy. Dark matter does not form tightly bound systems larger than about 1,000 solar masses, but it appears to account for about 25% of the mass of the universe, that is about five times larger than the matter we can see.

The known, uncharged particles, for example, the neutron or neutrino, cannot account for dark matter. The focus over several decades has been to look for a weakly interacting massive

particle (WIMP) via a rare scattering from an atom in a large detector, typically located deep underground to minimise the rate of background events. The recoil atom's energy is detected. Thus far, no conclusive evidence for WIMPs has been found. The present experiments set the WIMP-atom interaction limit lower than the rate of a low-energy⁴ neutrino interacting with atoms⁵. Searches for WIMPs will continue for at least another decade. However, there is a fundamental limit to this approach due to the inability to distinguish between a neutrino-atom interaction and a WIMP-atom interaction. The WIMP mass region explored by the underground experiments typically ranges from about three proton masses to about 10,000 of the same.

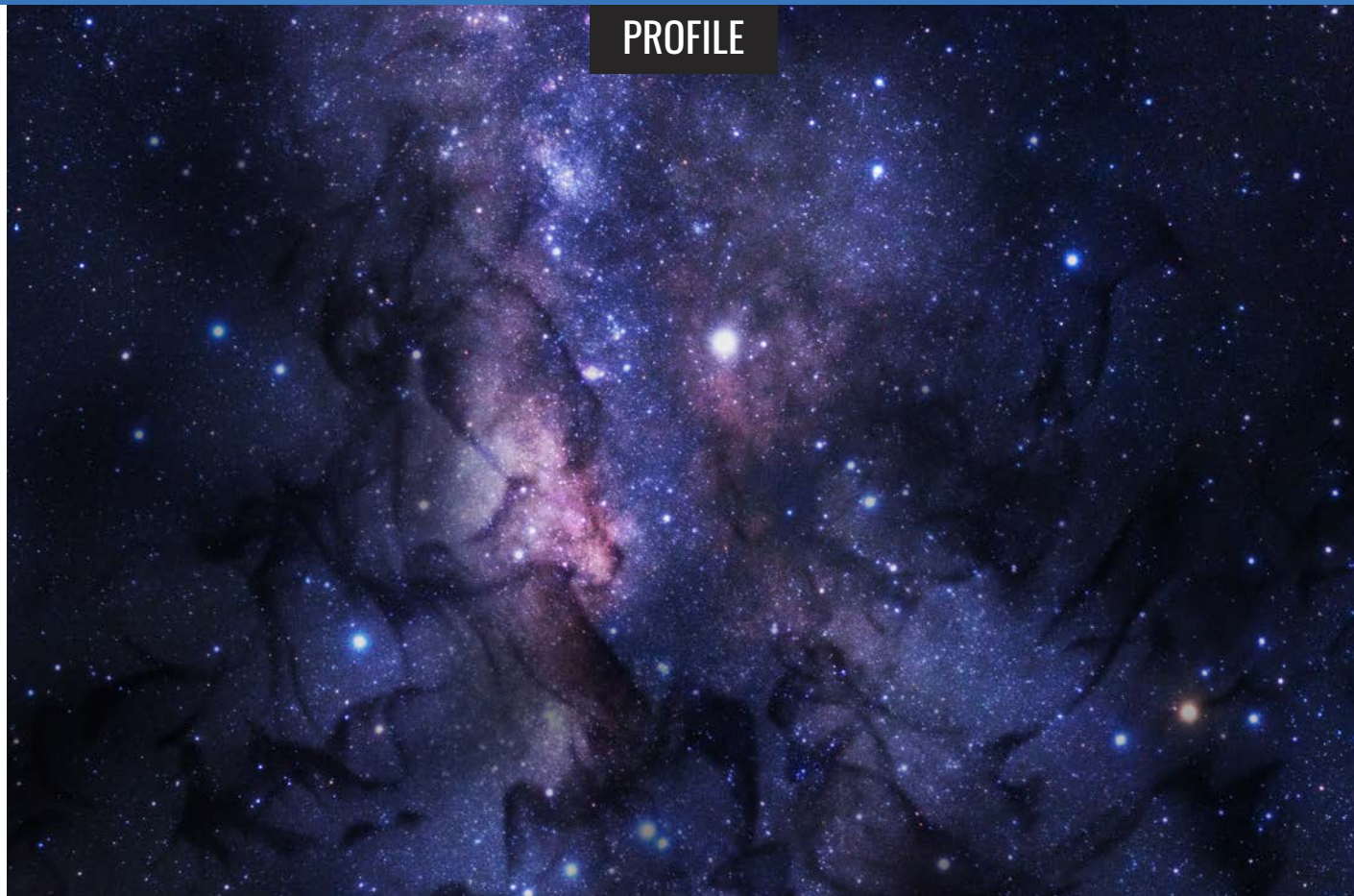
A complementary experimental thrust in the quest to understand dark matter, is to search for evidence of the mediator of a new interaction between our visible world, successfully described in terms of four forces (gravity, electricity and magnetism, nuclear force and weak force) and the world of dark matter. This new interaction would constitute the fifth force.

The simplest mediator widely considered is a dark photon that couples to the known particles via their electric charges. The searches involve experiments using particle beams delivered by accelerators to produce the medi-

ator. The mediator decays either into (a) known, detectable particles that are sought (visible decays) or (b) into the dark sector, which are undetectable, but whose presence is deduced by observation of a large missing energy and momentum in the final-state (invisible decays). The results of the searches are usually summarised in terms of their ability to constrain the mediator-to-known-matter coupling strength and the mediator mass. At the Large Hadron Collider at CERN, Geneva, Switzerland, searching for evidence of dark matter is a major activity at the three principal experiments⁶.

Recently, there has been a focus on searching for a mediator with a mass lower than the proton mass. Astrophysical observations and observed anomalies in measurements involving the muon and nuclear transitions hint at this possibility. Existing experiments, primarily using the decay of the neutral pion, have searched inconclusively for evidence of a dark photon. However, a more general fifth force, where the couplings are no longer simply the charges, remains a viable possibility.

Our MIT group is focused on searching for evidence of a fifth-force, with a mediator of mass less than about 10% of the proton's mass. In collaboration with colleagues, we have proposed the DarkLight experiment⁷ at Jefferson Laboratory⁸, Newport News, Virginia,



USA to produce the mediator in electron-nucleus scattering and searching for visible decays into a positron and electron. DarkLight requires an intense, bright and halo-free electron beam possible only with a new accelerator technology, called an Energy-Recovery Linac (ERL).

A phase-1 DarkLight experiment has been funded and a search, focused in a specific mediator mass region suggested by a reported anomaly, is in preparation. Jefferson Laboratory pioneered the development of ERLs using superconducting accelerator technology and next-generation ERLs are at present under construction at Cornell University, USA⁹ and at Mainz University, Germany¹⁰. Searches for evidence of dark matter via low-energy signals in electron scattering are being planned at both machines.

In summary, the search for evidence and understanding of dark matter is an intensive, worldwide research endeavour by physicists using state-

of-the-art accelerator and detector technology on, above¹¹ and beneath the Earth. Calculations by theoretical physicists are essential for the design of experiments with maximum sensitivity to uncovering new physics. This research drives technology development in high-intensity accelerators, detectors and high-rate data acquisition.

There are major new initiatives underway worldwide and this area will continue to be a forefront activity for the foreseeable future, attracting some of the best and brightest young minds. This curiosity-driven, fundamental research into understanding our universe is made possible by the generosity of the taxpayer via government support of fundamental research¹².

1 F. Zwicky, Helvetica Physica Acta, 6, 110 (1933)

2 From 1 kpc to 10 Gpc: 1 pc = 3.26 light years = 3.1×10^{16} m.

3 The weak interaction initiates the fusion process in the sun and drives beta-decay.

4 10 keV.

5 Present best cross-section limit is about 10^{-46} cm² at a WIMP mass of about 50 proton masses.

6 ATLAS, CMS and LHC: home.cern.

7 DarkLight experiment: arxiv.org/abs/1412.4717.

8 Jefferson Laboratory: www.jlab.org.

9 CBETA project: www.classe.cornell.edu/Research/CBETA/Web-Home.html

10 MESA project: www.prima.uni-mainz.de/mesa.php.

11 Alpha Magnetic Spectrometer experiment: ams.nasa.gov.

12 The author gratefully acknowledges the support of both the Office of Nuclear Physics of the Department of Energy and the National Science Foundation of the United States.



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After Horizon 2020: Linking research, innovation and education

Director of Research and Innovation, European University Association, Lidia Borrell-Damián shares her thoughts on what lies ahead after Horizon 2020, in which she envisions a new kind of impact by linking research, innovation and education

As Europe decides how to best invest in the future of research and innovation, it is clear that Horizon 2020's successor will need more funding. It is also quite certain that its design must be more efficient and simple in its bureaucratic burdens. However, what might be less obvious in our journey to improve the next EU Framework Programme is the potential impact that lies in strengthening links between research, innovation and education.

At the European University Association, we know that universities play an essential role in educating the highly-skilled people who are much needed in all sectors of the economy. They perform ground-breaking research that leads to innovation and, increasingly, they drive activities such as spin-offs, technology transfer and civic engagement. University innovation hubs and spin-off companies, for example, are important tools in transforming scientific results into the innovation

that we need and in renewing our economy. Behind this are research and doctorate programmes generating the latest scientific knowledge. However, better links between these kinds of activities and education, for example in master's programmes, are needed for Europe to fully capitalise on this talent.

One way to do this in the next Framework Programme is to foster the entrepreneurial spirit of students, for instance, by leading them through example. In practical terms, researchers could be encouraged to further share their project expertise and experience with students through teaching and training activities. This would give the research a double impact: on the one hand, it has the potential to translate into innovation, on the other, it would become a useful learning material.

This could be done through special EU grant agreements allowing researchers, for example, funded through the



RESEARCH & INNOVATION

could use the extension either to complete their research project or, better, to create links with industry and business – and to better exploit their research results. In the long-term, this would benefit the sustainability of doctoral education as a whole and foster enduring bonds with industry and business.

Last but not least, intensifying a multidisciplinary approach in the next Framework Programme will be paramount. The Science, Technology, Engineering and Mathematics (STEM) disciplines alone cannot solve the complex societal challenges our continent faces. We need to embed expertise in social sciences and humanities, as well as the arts, in projects addressing energy, climate change, poverty, ageing societies, migration and extremism.

Tackling the UN Sustainable Development Goals in the next Framework Programme will naturally also require an innovative, multidisciplinary approach that encompasses deeper links between research, innovation and education. Horizon 2020's successor must, therefore, incentivise crossover between and among these disciplines if we really want to produce results that will make a difference in our lives.

Long-term public funding, such as that provided by the Framework Programme, is crucial in supporting the research that stimulates the innovation we need. However, the recipe requires a good link between research, innovation and education policies to hit the maximum score in boosting the development of excellent human talent. If Europe wishes to lead innovation globally and see big results at home, this kind of strong and ambitious link must be at the top of the agenda. ■

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Marie Skłodowska-Curie Actions and the European Research Council, to engage in teaching and to include these activities in their time sheets. By putting grantees in contact with students in such a way, we would create natural multipliers of scientific excellence and research values and allow researchers to become the inspiring role models that the next generation of researchers clearly needs. A step like this would foster human talent, the natural driver of innovation.

While excellent research that produces innovation is the main objective of the Framework Programme, we must remember who is, in fact, conducting the research. Often, the people behind the projects are Europe's doctoral candidates and, therefore, they cannot be ignored – especially in our quest for new and diverse forms of impact. A simple step in strengthening the link between research, innovation and education, would be to allow doctoral candidates funded under the programme to have a time extension. The standard three-year duration for doctoral studies is often too short, especially if involving interdisciplinary and international activities and teaching. Doctoral candidates

Research, science and innovation in Europe

Open Access Government places the excellent work of European Commissioner for Research, Science and Innovation Carlos Moedas under the spotlight

Carlos Moedas has been European Commissioner for Research, Science and Innovation since 2014. His responsibilities include ensuring that research funding programmes, particularly Horizon 2020, contribute to the European Commission's jobs, growth and investment priorities. Moedas is responsible for ensuring that EU funding is used effectively and innovation is supported across all member states

Moedas is also responsible for promoting the EU's research and science base on the international stage, strengthening those capabilities across all member states and encouraging the private sector to apply their research to meet the challenges facing society.

In February, Commissioner Moedas delivered a speech to mark European Industry Day setting out how Europe can put itself in "pole position" to be at the forefront of the next big wave of innovation: the merging of physical and digital technologies often referred to as Industry 4.0.

"The next wave – from AI to biotech to two-dimensional materials – they all require leading-edge science," he said.

"But, of course, science alone is not enough. For Europe to lead the next wave of innovation, we need a new force of momentum."

This force, Moedas continued, will be generated by three key elements: science to develop new ideas and the technologies of the future; start-ups and SMEs to combine technologies and new business models; and industry to scale-up innovations and create economic and social impact.

"Without all three as strong components, we won't have the lift-off we need for the future of innovation in Europe," he said.

Supporting this "ecosystem" will be the cornerstone of a new programme for research and innovation to build on the success of Horizon 2020, which over its current seven-year cycle, will see more than €20 billion invested directly in the industry, Moedas added.

But the commission is not waiting until 2021 to introduce what Moedas described as the most urgently needed reform to support innovation – a European Innovation Council.

"Between 2014 and 2020, the EU is expected to invest €500 million in research and innovation on cultural heritage, a sector that employs over 300,000 people and has indirect links to 7.8 million jobs in areas such as tourism, security and interpretation."

Currently, in a €2.7 billion pilot phase, the EIC will bring funding schemes together in a single place, simplify them and make them "innovator-centric", Moedas said.

It will also provide a crucial link between large corporations and SMEs, helping start-ups to access partners across value chains from investors to public procurers and technology providers.

"This will be the formula for winning the next innovation race," Commissioner Moedas said.

In March, as part of the European Year of Cultural Heritage 2018, Commissioner Moedas, alongside the commissioners for Education, Culture, Youth and Sport and the Digital Economy and Society, took part in a high-level Horizon 2020 conference on innovation and cultural heritage.

The event showcased promising innovations to preserve Europe's cultural heritage for future generations,



Carlos Moedas, European Commissioner for Research, Science and Innovation

ranging from providing digital access to inaccessible sites to helping to preserve priceless artefacts and exploring new ways of valuing cultural heritage for creative industries.

The conference also saw the unveiling of a policy review assessing EU-funded research on cultural heritage and proposed improvements to the European Research Framework after 2020.

Between 2014 and 2020, the EU is expected to invest €500 million in research and innovation on cultural heritage, a sector that employs over 300,000 people and has indirect links to 7.8 million jobs in areas such as tourism, security and interpretation.

With 453 inscribed sites, Europe counts for almost half of UNESCO's World Heritage List and Commissioner Moedas said the ambition is to become a global leader in heritage-based innovation through Horizon 2020.

"Cultural heritage is a limitless source of innovation, where traditions meet with cutting-edge technologies," he added.

But while preserving the treasures of the past, the commission is also looking to emerging technologies that will shape Europe's future. This was highlighted by the recent creation of an expert group on artificial intelligence.

From better healthcare to safer transport and more sustainable farming, AI offers many potential benefits to both society and the economy. However, there are also many questions about its potential impact on how we live and work.

The expert group will seek to create a broad alliance of stakeholders, who will discuss how to use and develop artificial intelligence (AI) successfully and ethically. It will draw up draft guidelines on AI ethics based on the EU's fundamental rights considering issues such as fairness, safety, transparency, the future of work and democracy.

Announcing the group's formation, Commissioner Moedas said: "Artificial intelligence has developed rapidly from a digital technology for insiders to a very dynamic key enabling technology with market-creating potential.

"And yet, how do we back these technological changes with a firm ethical position? It bears down to the question, what society do we want to live in?" ■

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ISOTOPICS, a European project for de-risking drug innovation

Christophe Dugave & Karen Hinsinger from CEA-Saclay highlight an exciting European research project for de-risking drug innovation, ISOTOPICS

Excessive drug attrition with less than one drug reaching the market on ten entering clinical trial phases, dramatically impacts on drug innovation and strongly decreases the competitiveness of the pharmaceutical industry. The ISOTOPICS project aims at the development of new late-stage and chemically benign labelling methods in order to facilitate preclinical and clinical studies of drug candidates and to de-risk the drug discovery and development process. It also trains a new generation of 15 radiochemists preparing a PhD with a dual academic industrial experience, an extended knowledge of all drug discovery aspects and a high potential for employability and entrepreneurship.

Skyrocketing of costs to develop new therapeutics (more than 2 billion euros for a new chemical entity to be marketed in 2017, doubled relative to 2007) does not only negatively impact on the pharmaceutical industry development, but also raises serious sanitary and social issues since pharma companies reduce the therapeutic areas they operate in. Consequently, first-in-class drugs have become less common in recent years and, despite a historic number of 35 new therapeutic agents recommended by the European Medicine Agency in 2017 (the highest since 1996), the general trend is clearly downward.

This results from a severe attrition of drug candidates during clinical trials,

(in particular Phase II), with less than 1 molecule reaching the market on 10 entering clinical studies. Such a low success rate may be attributed to an insufficient assessment of the whole-body distribution of the drug candidate during preclinical and Phase 0 clinical trials, as a result of the rate-limiting character of isotopic labelling in the drug discovery process.

As a matter of fact, introducing a radio-isotope in a drug candidate without affecting its chemical integrity is a challenging task, since a drug is usually a complex multi-functional molecule. Moreover, the compelling rise of therapeutic biologics (five antibodies in the top six blockbuster drugs) raises the difficult problem of labelling fragile biomolecules and prompts chemists to develop new chemically benign radiolabelling methodologies.

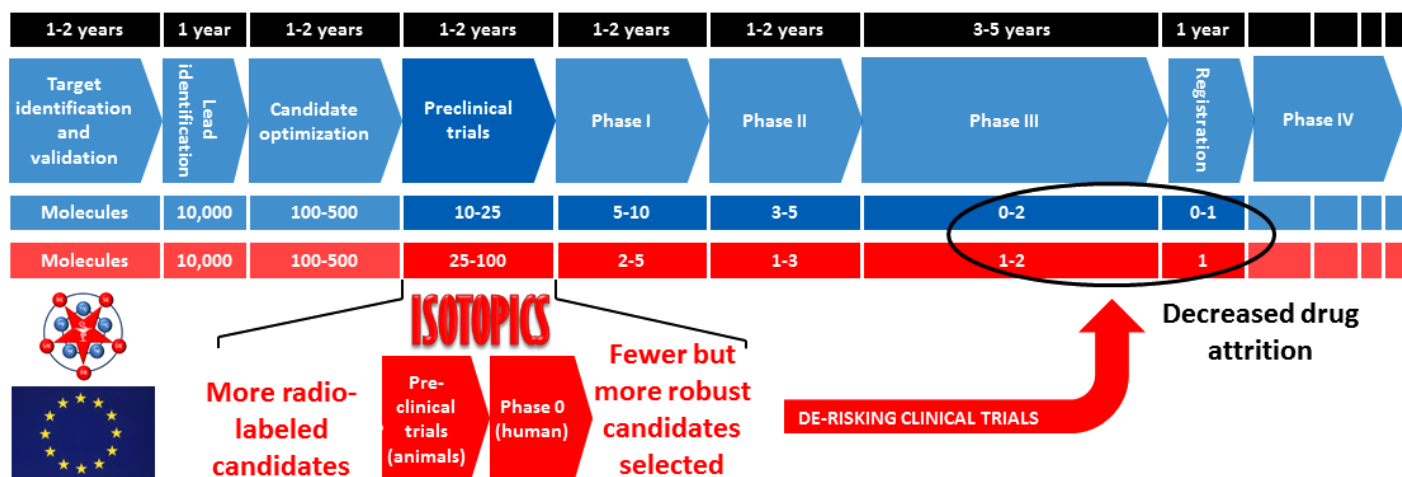
However, a lack of adapted and straightforward labelling methods is not the only issue the pharmaceutical industry has to face up to. There is also an associated need for a new generation of radiochemists capable of understanding medicinal chemistry, but also biochemistry.

The ISOTOPICS European Training Network ^[1] regroups five academic institutes and three big Pharmas: CEA and CNRS in France, the University of Oxford in the United-Kingdom, the Karolinska Institute and AstraZeneca

in Sweden, the University of Liège and UCB-BioPharma in Belgium and Sanofi-Aventis in Germany (but also in France). It aims at training 15 early-stage researchers (ESRs) preparing a PhD through a combination of research work in the laboratory, as well as specific scientific taught courses and workshops, conference cycles and visits of facilities. The training programme also includes seminars dedicated to complementary skills for improving ESRs' employability and entrepreneurship. All students are also expected to perform at least two secondments in partner's premises which expose them to various research conditions in both the academic and the industrial environments.

ISOTOPICS is also aiming towards the development of innovative late-stage labelling methods of drugs with deuterium/tritium and carbon-14 commonly used for drug development, but also carbon-11 and fluorine-18 as positron emitters usable for in vivo imaging.

The ambition of the project is to provide simple, straightforward and amenable procedures for radiolabelling druggable compounds to avoid laborious multi-step chemical synthesis, a pathway which is time-consuming and polluting. Therefore, a remarkable effort has been made for the design of novel isotopic exchange reactions of specific atoms on the end-use molecules in a selective and chemically respectful way.



Comparative schematic timelines of drug development: present situation (blue) and expected ISOTOPICS-improved situation (red).

To date, several major advances may be cited as technological breakthroughs in the fields of deuterium/tritium, carbon and fluorine labelling of small-molecule drugs but also biomolecules. CEA and CNRS teams have jointly developed and tested a series of decorated ruthenium and nickel nanoparticles capable of catalysing hydrogen isotope exchange onto a variety of organic compounds in mild conditions. The method was applied to the isotopic labelling of several marketed drugs (e.g. fluconazole), but also for the deuteration of peptides and oligonucleotides with no alteration of their chirality, even when labelling an asymmetric centre.

In parallel, the Sanofi team has also screened iridium soluble catalysts which have demonstrated a complementary reactivity relative to the metal nanoparticles, thus broadening the pallet of catalysts usable for hydrogen isotope exchange onto end-use molecules [2].

Another group from CEA has recently developed a revolutionary method for the radiolabelling of aromatic carboxyl compounds. This process, which involves a copper-catalysed carboxyl

exchange using carbon dioxide, has been applied to carbon-14 labelling of the antibiotic molecule Flumequine [3]. The same CEA group and the Karolinska Institute team have collaborated for the development of a new late-stage carbonylation of a family of drugs such as domperidone, applicable for carbon-11 labelling.

The AstraZeneca team is also interested in the development of new catalysed reactions for carbonyl insertion. Fluorine chemistry is actively investigated by several groups at the University of Oxford, University of Liège and UCB-Biopharma. A very first application to the selective trifluoromethylation of tryptophane residues on mellitin, a 26-residue peptide which displays interesting therapeutic properties was carried out by University of Oxford [4].

The first project achievements have demonstrated the potential of isotopic exchange reactions which utilise end-use molecules, instead of successive synthetic intermediates for deuterium/tritium and carbon-11/carbon-14 labelling. A particular effort has been made for the ultimate-stage labelling of small molecules with extremely attractive prospects. The first transla-

tion of the methodologies to the radiolabelling of biomolecules has also led to the first relevant applications in the field of therapeutic biologics.

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Nanomaterials in the healthcare sector: The navigation paradox applied to healthcare

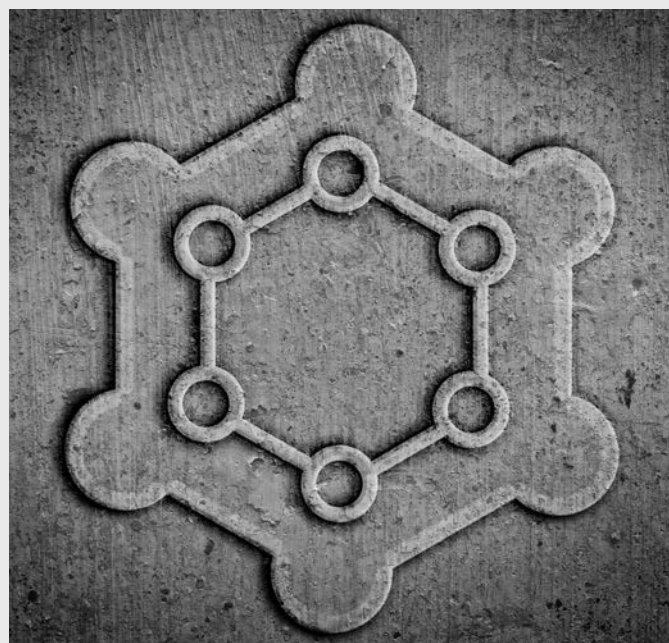
Cecilia Van Cauwenberghe from Frost & Sullivan shares her expertise on nanomaterials in today's healthcare sector, including therapeutic precision versus nanotoxicology risk

The navigation paradox affirms that increased navigational precision may result in increased collision risk. In fact, improved positioning systems have gained significant precision at the expense of a greater probability of occupying the same space on the shortest distance line between two navigational points. According to Drlickova et al., 2017, although nanomedicines potential has revolutionised precision medicine approaches, the unique properties of nanoparticles capable of penetrating inscrutable biological barriers can induce unintended adverse effects on human health and environment, thereby adding some complexity to the balance between therapeutic efficacy due to impressive technological advances and safety due to nanotoxicity issues. Gkika et al., 2018, also depict the conflict between science advocating for the use of high-risk, potentially toxic nanomaterials due to their higher therapeutic target precision and being society reticent to the utilisation of certain nanotechnologies.

Risk assessment and decision-making tools

Chemical and biological risk evaluation, life cycle assessment, safety-by-design, stakeholder engagement and risk governance, among many additional criteria, constitute key items in an effort to address the needs of emerging technologies such as nanomaterials.

The design of new decision support frameworks to assist the solution of the aforementioned paradox has been analysed by Rycroft et al., 2018. The researchers intend to derive a complete characterisation of the risks and benefits that a given nanomaterial may proffer within a specific nanomedical application, based on multicriteria decision analysis. Conscious of the double-edged sword of risks and benefits of nanomedicines, the authors analysed the risks and benefits of a whole decade of nanomedicines development in order to build a valuable, knowledge-based framework focused on



nanotoxicology and risk assessment interventions. This tool not only enriches multicriteria decision analysis approaches but also introduces risk-based decision-making and alternatives-based governance criteria for emerging technologies beyond nanomedicines.

The road ahead: Introducing more science Occupational exposure limits

Specific occupational recommended exposure limits (REL) for nanomaterials are limited. The National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) recommend to workers do not exceed the exposure to 1.0 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) as an 8-hour time-weighted average to respirable carbon nanotubes and carbon nanofibres, as an example.

Workplace design optimisation

The NIOSH advice companies for controlling possible exposure of their workers to nanomaterials in the work-

place through a series of new workplace design solution documents. These four deliverables strategically help optimise the workplace design to guarantee workers' safety during nanomaterials handling.

Bioprotective complexes administration

According to a recent publication authored by Leso et al., 2017, challenges faced during nanotechnology translation to the healthcare industry are numerous. The researchers highlight the high level of uncertainty related to the physicochemical properties of nanomaterials regarding potential toxicity, the difficulty in extrapolating dose-response correlations and the complexity in measuring nanomaterial exposure.

“Specific occupational recommended exposure limits (REL) for nanomaterials are limited. The National Institute for Occupational Safety and Health (NIOSH) and the Occupational Safety and Health Administration (OSHA) recommend to workers do not exceed the exposure to 1.0 micrograms per cubic meter ($\mu\text{g}/\text{m}^3$) as an 8-hour time-weighted average to respirable carbon nanotubes and carbon nanofibers, as an example.”

However, Privalova et al., 2017, demonstrated that highly adverse effects of metallic nanoparticles at organ-systemic level can be manifestly mitigated by background administration of suitable combinations of bioactive agents in innocuous doses aiming for improving the body's resistance to the adverse effects of nanoparticles. These bio-protectors principally consist of pectin, vitamins, glutamate, glycine, N-acetylcysteine, omega-3 PUFA and different essential trace elements. They are suggested by the authors as an efficient auxiliary instrument of health risk management, according to the beneficial results exhibiting interference with toxicokinetics and toxicodynamics of metal nanoparticles.

Artificial intelligent solutions

Ponce and Krop, 2018, illustrate the launch of the EU Observatory for Nanomaterials as a form of impact assessment. The broad goal is to build a framework to trace where nanomaterials are being produced and how they are used and how they are disposed of. With the advent of digital technologies, artificial intelligence, robots, new materials and new processes, nanomedicines are supposed to lead significant progress in the

industry. Therefore, artificial intelligent and smart healthcare solutions must serve to regulate and provide transparency at all levels of nanomaterials manipulation in order to shape the future of technology synergy over solid health and safety bases.

Acknowledgements

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Nano safety, advanced materials for the semiconductor industry and governance of nano-related risk

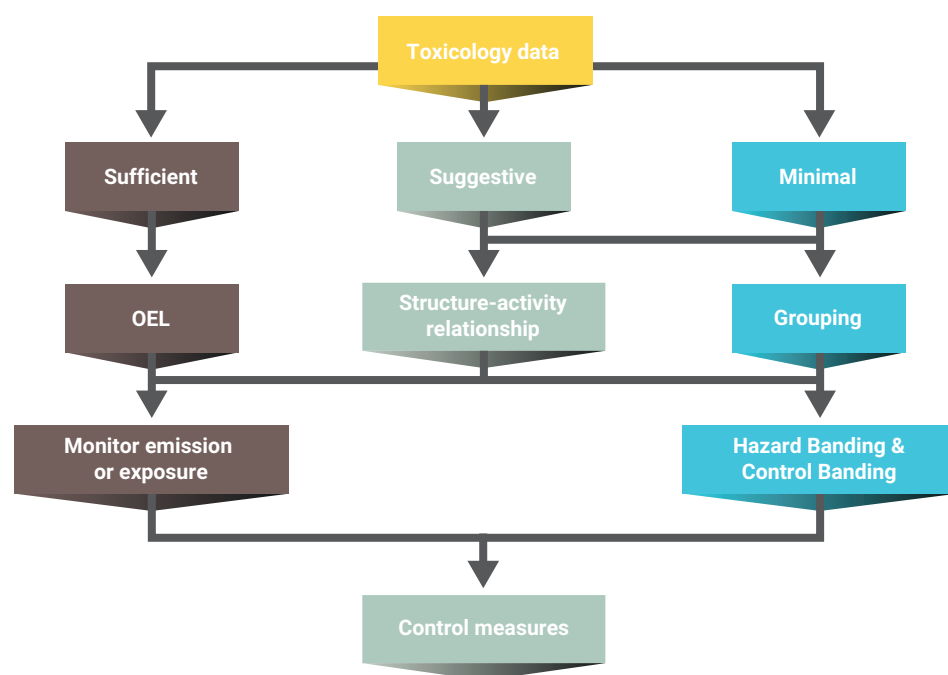
Dr Dimiter Prodanov from IMEC vzw shares his views on the fascinating world of nanomaterials including the governance of nano-related risk

Nanomaterials are fascinating for the wealth of modified properties that they possess, which can be used by the industry. On the other hand, they are not different materials per se, rather they are “nanoform” variations of ordinary materials: for example, silicon dioxide, which can be found in glass or quartz.

In a different nanoform, silica nanoparticles are used in certain polishing steps in chip manufacturing. The industrial processes, which use nanomaterials need to be comprehensively evaluated for their benefits and risks. This is the object of study of nano safety – it is a field which identifies the particular risks introduced by the use of nanoforms and nanomaterials in the product lifecycle.

Furthermore, a holistic view of the nano-hazard and the related process risk is crucial for successful integration of nano safety aspects into the overall risk management methodology. Material properties, health effects, the potential for release and occupational exposure are principal aspects of successful risk mitigation. In this article, I focus on the risk, which can arise in an occupational setting.

Traditional chemical risk assessment tools are based on the quantitative dose-response relationship, which is



augmented by a threshold defining the no-effect levels – that is the occupational exposure limit (OEL, see Figure). Such quantitative risk assessment is applicable in cases when sufficient toxicological and occupational exposure data are available. However, this is not the case for the majority of nanomaterials.

The main challenges are the size and shape-dependence of the toxic effects, which can be substantially modified by applied functionalisation or the interactions with the environment in the body. Therefore, the current expert opinion

tends to agree that conventional risk assessment tools have limited applicability to nanomaterials or nanoforms. Due to insufficient information, at present, there are no legally defined OELs for nanomaterials, which slows down industrial acceptance of nanomaterials and hampers consumer confidence.

These shortcomings can be tackled by using grouping principles for the novel nanomaterials. Such an approach can be implemented by the risk and control-banding risk assessment tools. Efforts in the direction of the grouping of nanomaterials and read-across

missing properties of nanoforms are encouraged by the stakeholders, such as the nanotechnology industry, national regulators and international bodies, like EU and OECD.

Identifying methodologies for risk assessment and governance of such situations is part of the work undergoing in the H2020 project *NanoStreeM*, which targets the semiconductor industry. The NanoStreeM consortium has taken up the challenge in defining "Roadmap Nanomaterials: Strategies For Safety Assessment In Advanced Integrated Circuits Manufacturing", where we identify the existing gaps in our knowledge and formulate a number of recommendations for their mitigation.

"In a different nanoform, silica nanoparticles are used in certain polishing steps in chip manufacturing. The industrial processes, which use nanomaterials need to be comprehensively evaluated for their benefits and risks."

To date, a total of 32 risk assessment tools have been identified under quantitative and qualitative methodologies. Based on the identified potential exposure scenarios, a detailed recommendation focusing on a key group of four risk assessment tools has been developed. At present, the efforts of the NanoStreeM project are focused on the evaluation of the proposed risk governance paradigms, starting with the ISO TS 12901-2:2014 standard. We have prioritised several common tools for the semiconductor industry scenarios. The consortium industrial partners evaluate so-identified risk assessment tools and compare them to the available emission measurements.

Although, the project has still about one more year to run, several key findings have come into view.

- The standard safety data sheets for chemical products do not contain information about the eventual presence of nanoforms and their characteristics. This makes the information easy to miss by the safety professionals.
- We have established a necessity for the grouping of nanomaterials to similarity groups (i.e. such as hazard bands or classes). The health and safety assessment can be empowered by the availability of international standards, such as the ISO/TS 12901-2:2014.
- There is a growing body of data related to potential exposure scenarios both to the worker and environment for nanomaterials currently in use in semiconductor manufacturing. Such information should be incorporated into appropriate exposure models to facilitate health and safety assessments.

To address challenges in nanomaterial risk assessments the H2020 projects *NanoStreeM* and *caLIBRAte*, with the support of the Royal Belgian Academy for Arts and Sciences, Flanders, organise a joint workshop entitled: "**Governance of emerging nano-risk in semiconductor industry**".

The workshop will take place in **Brussels on 26th April 2018**. The event will bring together regulators, policy makers, the growing risk governance community for nanomaterials, as well as industrial producers and end-user companies. The meeting will present how and where nanomaterials are used

in the semiconductor industry based on the findings of the *NanoStreeM* project.

The project *caLIBRAte* will present nanomaterials risk governance frameworks, which could be applied to the semi-conductor industry. The workshop will conclude with a panel discussion on the steps necessary to further enable the use of nanomaterials throughout the industry and appropriately govern the emergent risks. The meeting outcome will identify the challenges and regulatory issues in semi-conductor industry and how risk governance tools for nanomaterials can support effective business operation. More information is available on the event web-page.

Acknowledgement

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Innovative nanocapsules for skin care

Due to the unique properties achieved at nanoscale, nanotechnology has attracted an exponential interest, being the focus of numerous studies, developments and marketing actions in a full range of applications. Nanotechnologies and nano-enabled materials are already being used in several industries such as textile, pharmaceutical and cosmetic. Although the nanomaterials may bring many advances and benefits to society and the environment, it also poses new challenges and impacts in health, environment and safety, etc., thus being a thematic that needs to be handled in a responsible way.

Within this context, the project 'SKHINCAPS – Skin Healthcare by Innovative NanoCAPsuleS' is a research and innovation project funded by the European Union, under the Horizon 2020 research and innovation programme (grant agreement No 685909). It aims to develop the know-how and processes to manufacture novel, sustainable, safe, cost-effective and highly stable nanocapsules containing, at their core, different encapsulated active principles, for their incorporation into 'smart' skin care products such as textiles and cosmetics (creams, lotions).

The SKHINCAPS nanocapsules will be used to produce different demonstrator products for skin healthcare applications:

- First layer garments containing nano-encapsulated phase-change materials (PCMs) for thermal management and skin comfort;



- Anti-ageing creams containing a cocktail of nano-encapsulated vitamins and antioxidants to improve skin anti-ageing effect;
- Antimicrobial lotions and textiles containing nano-encapsulated natural essential oils to prevent or mitigate bacterial infections on end-users skin.

The project consortium comprises 8 partners from 5 different EU Member States, including 4 European research organisations – CENTI (PT, coordinator), UPC (ES), IVW (DE), VTT (FI) – and 4 industrial partners – Bionanoplus (ES), Devan-Micropolis (PT), TELIC (ES), Pro-Active (BE). The industrial partners involved in the project are all SMEs being key players in the value chain of high-tech textiles and cosmetics: a nanomaterials producer, a textile chemistry producer and distributor, a cosmetic formulator and a consulting company.

By combining the specific expertise fields, SKHINCAPS intends to bring the innovative technologies needed to increase the commercial potential of smart technical textiles and cosmetics, to improve the European competitiveness and create a new growth engine for economic development, and above all, enhance individual wellbeing and life quality, thus contributing to healthcare costs control. Furthermore, the project also intends to reduce the environmental impact related to the manufacturing process and the use of the novel nanomaterials.



Article 50 – one year on: Progress on research and innovation

Director of Science & Communities at the Royal Society of Chemistry, Jo Reynolds explores the impact of the EU exit on UK research and innovation one year on from Article 50

Thursday 29th March 2018 marked a year since the UK commenced the formal process of leaving the EU and one year on, our work has developed further as negotiations have progressed.

We are partnering closely with others across the research and innovation community to advocate for outcomes that support the scientific community in our three priority areas of funding, mobility and regulation. As part of this, Sir John Holman continues his role on the High Level Stakeholder Working Group on EU Exit, Universities, Research and Innovation – an opportunity for leading figures in science to share their insights directly with government ministers.

We have now seen the approval of a draft withdrawal agreement and the publication of the House of Commons Science & Technology Select Committee's report

on Brexit, Science and Innovation. As part of our evidence to this inquiry, I attended a summit organised by the committee to ensure the messages across our three priority areas were heard.

We will continue to work with our community to understand their needs and update our asks as negotiations progress.

Funding and collaboration

We welcome the news that UK researchers will continue to be able to participate in Horizon 2020 projects for the duration of the programme and the government has provided guidance on this for UK researchers.

However, we agree with the Brexit, Science & Innovation report that urgent clarity is needed on how the UK is going to participate in Horizon 2020's successor,



Medicinal chemistry – making an impact on the world

According to University College London⁽¹⁾, medicinal chemistry is concerned with the discovery, design and synthesis of new drugs for clinical use. In the view of the School of Chemistry at The University of Manchester, medicinal chemists contribute to finding out what happens to drugs in the body and modifying drugs to make them more effective.⁽²⁾ In the view of the American Chemical Society, medicinal chemists are focused on drug discovery and development and with the isolation of medicinal agents found in plants, as well as the creation of new synthetic drug compounds.⁽³⁾

Today, we are increasingly able to understand the causes of diseases at the molecular level. Modern medicinal chemistry is said to be central to the discovery and development of new drugs. Drug discovery is certainly one of the main contributors to the dramatic impact on health and wellbeing, particularly evidenced in the developed world over relatively few generations.

Medicinal chemistry is a stimulating field for many because it links many scientific disciplines and allows for collaboration with other like-minded scientists in researching and developing new drugs, the American

Chemical Society says. We also learn that chemists work in collaboration with scientists from different disciplines, including biologists, pharmacologists, toxicologists, theoretical chemists and microbiologists. Together, such a team uses sophisticated analytical techniques to synthesize and test new drug products, as well as to develop the most environmentally friendly and cost-effective means of production.

In closing, there is still much to do, in the view of School of Chemistry at The University of Manchester when it comes to the exciting field of medicinal chemistry. Indeed, in the developed world, diseases of ageing are becoming key targets for study, along with other viral diseases, such as Hepatitis C. “In the developing world, malaria and HIV-1 remain all too prevalent. Perhaps more than in any other area, medicinal chemists are able to make a significant impact on the lives of the wider community”, we discover.

1 <http://www.ucl.ac.uk/prospective-students/undergraduate/degrees/medicinal-chemistry-bsc/>

2 <http://www.chemistry.manchester.ac.uk/study/undergraduate/courses/chem-med-bsc/>

3 <https://www.acs.org/content/acs/en/careers/college-to-career/chemistry-careers/medicinal-chemistry.html>

Framework Programme 9 (FP9). Whilst the UK government has recently published a [position paper](#) on FP9, we have yet to see a clear indication of how they envision the UK's involvement in the programme.

The EU is forging ahead with plans for FP9 and the UK government must articulate how and on what terms it

wants to be part of this. This is essential for achieving the government's vision of building an 'ambitious agreement on science and innovation' with the EU.

As a member of the European Association for Chemical and Molecular Sciences (EuCheMS), we have, alongside 21 chemical societies from across Europe, [called for](#)

Continued on page 167 →

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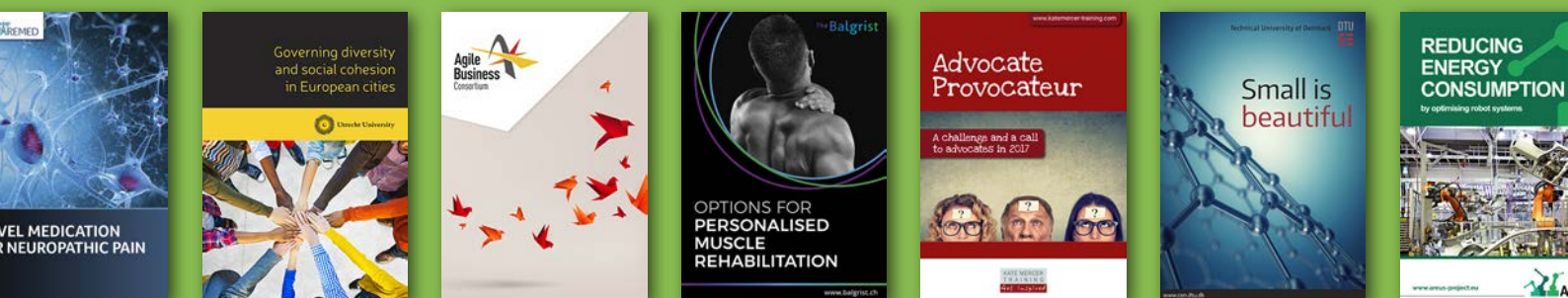
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continued collaboration between the UK and the EU after the UK's exit, including through continued UK participation in FP9.

Mobility

We have been clear that the UK needs to develop a flexible future immigration system to stay at the forefront of the global research community. At the start of March, we were one of over 40 organisations calling on the government to display this kind of flexibility, when we signed a letter to the Prime Minister calling for PhD level job roles and roles on the Shortage Occupation List to be exempt from the Tier 2 visa cap.

The Brexit, Science and Innovation report has recognised mobility as a priority, stating: 'It is imperative that the migration system for scientists, researchers and scientific technicians recognises the need for mobility.'

Regulation

The chemicals sector supports many other industries. It provides vital and sometimes irreplaceable materials in supply chains that are essential to developing everything from new therapies in the life sciences to materials for energy applications and inventions in aerospace and robotics. How the UK regulates chemicals post-Brexit will affect the entire chemical sector but is likely to have the greatest impact on small to medium enterprises (SMEs).

Regulation is also likely to impact the implementation of the government's Industrial Strategy, which was unveiled late last year. We welcome the proposal in the Industrial Strategy White Paper to convene a new 'Ministerial Working Group on Future Regulation' but in the near-term, businesses that translate scientific discoveries into products and services need to know what the UK's future regulatory framework will look like, particularly during the proposed implementation period.

At the start of March the Prime Minister, Theresa May, indicated that the UK wishes to negotiate a long-term agreement with the EU to become an 'associate member' of the European Chemicals Agency (ECHA), the agency that is currently responsible for setting the rules for regulation of chemicals in EU member states. This negotiation may or may not be successful. It remains uncertain which bodies in the UK would make



Jo Reynolds, Director of Science & Communities

regulatory decisions during the implementation phase and beyond and whether participation of UK scientists on ECHA committees and the required data sharing would be a part of future 'associate membership'.

As with all science, sharing data and expertise is essential to the development of aligned regulation across the world. Strengthened international cooperation on the development of regulation and policy, as well as the science that underpins it, helps to enable global innovation and trade, whilst providing responsible and consistent safeguards for human health and the environment.

We anticipate that the year ahead will be challenging, but we will continue to work together across our community to ensure the voice of science is heard during the continued negotiations. ■

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Treatment of *Clostridium difficile* associated diseases: One not so small step more... but still, more to come

Prof Colin J Suckling from the University of Strathclyde provides his seasoned opinion on a front-runner antibiotic for the treatment of *Clostridium difficile* associated diseases

As I write, the news has come through that our partner company, MGB Biopharma, has raised the necessary funds to carry out a Phase IIa clinical trial on our front-runner antibiotic, MGB-BP-3, for the treatment of *Clostridium difficile* associated diseases.

This compound designed and then synthesised at the University of Strathclyde on a scale of a few milligrammes ten years ago is now manufactured and formulated for human studies on a kilogramme scale. It is one of a family of compounds from our laboratories that bind to the minor groove of DNA, hence the shorthand MGB; we refer to our compounds as S-MGBs for Strathclyde Minor Groove Binders.

In our initial academic studies, we were able to reach proof of concept for the antibacterial action of MGB-BP-3 against Gram-positive bacteria in mouse models of disease with the help of Professor Curtis Gemmell, then at the University of Glasgow and Glasgow Royal Infirmary. That's about as far as one can reasonably expect to go in an exploratory research funded project based in university laboratories. The human and experimental resources and the necessary funds to support them are just not there in the normal academic environment.

That things have reached phase IIa is largely due to the determination and tenacity of our MGB Biopharma led by Dr Miroslav Ravic. MGB Biopharma has used a research and development model in which the company acts as the focus and management of the programme with a team of advisors, but the experimental work is carried out by trusted contract research organisations (CRO).

In this way, the infrastructure and employment costs associated with pharmaceutical development are avoided. Most of the time this way of working has led to good data in good time although there have been hiccups. The biggest challenge has been continuity of funding which is why the news that a phase II trial can begin is particularly significant. The phase I trial showed that MGB-BP-3 behaved exactly as expected in the healthy volunteer subjects: it was safe, non-absorbed (good for a *C. difficile* treatment) and killed only the Gram-positive bacteria of the gut flora.

In phase IIa, MGB-BP-3 meets patients for the first time. The qualitative data from the trial will provide the first evidence of how good a drug MGB-BP-3 might actually be in treating a real disease. This is a very big step on the way to market. Of course, as the title of



Prof Colin J Suckling OBE DSc FRSE,
Research professor of chemistry

this piece implies, there are many steps still to come and we must be patient and take each step-in turn.

MGB-BP-3 is a very important project for us at the University of Strathclyde. It has shown, through the partnership with MGB Biopharma, that the S-MGB class of compound can be manufactured and dosed successfully, outcomes that support the development of other S-MGBs for other applications.

In principle, S-MGBs can be used to treat many infectious diseases and we've worked with collaborators



Capsules of MGB-BP-3 used in clinical evaluation and a vial of MGB-BP-3 freeze-dried ready for redissolving

around the world to evaluate our compounds. We have identified compounds from our collections with profiles suited to the treatment of malaria and tuberculosis, for example, with the help respectively of partners in Australia and South Africa. However, the most promising are for antitrypanosomal and antifungal treatments; interestingly, similar compounds are of interest for each application, which may indicate some common features of their biology.

In the case of antitrypanosomal activity, the disease in question is African Animal Trypanosomiasis (AAT) and its South American relative, Chagas disease. For these, we have a number of very active S-MGBs, significantly different from MGB-BP3, that are capable of curing trypanosomiasis in mouse models of the disease. This brings us to the equivalent stage that MGB-BP-3 was before our partnership with MGB Biopharma began; we are now looking at the profiles of the most active compounds to decide whether they are suitable to propose for further development funding. Not only have our academic colleagues at the University of Glasgow, led by Professor

Mike Barrett, shown that S-MGBs are active *in vivo*, they are also making progress in understanding their mechanism of action. [The project website explains more.](#)

Most recently we have started to work with Dr Mike Bromley at the University of Manchester on antifungal activity. He has already shown that our collection of S-MGBs contains some significant compounds. One is notable because of its broad spectrum of activity and another is especially active against *Aspergillus fumigatus*, which is a serious pathogen for immunocompromised patients typically leading to invasive pulmonary aspergillosis. Particularly interesting is that S-MGBs show the potential to be treatments for a new fungal pathogen, *Candida auris*, that was first identified in Japan in 2009 and by 2017 had spread to Europe and the Americas. This fungus is characterised by multidrug resistance and therefore our S-MGBs, that operate by a new mechanism of action, could become really important.

Of course, all of these opportunities exist because of the remarkable flexibility of heterocyclic chemistry, which

is my core field of experimental chemistry and the molecular basis of a very large proportion of modern medicines as I have [described in detail before](#).

It is remarkable that the small S-MGB project begun in a university laboratory should have matured into one with such global significance and potential. There are a lot of dedicated and committed scientists around the world who have worked with us on the greater MGB project, each contributing to the individual small steps of the title.

Together we have shown what might be possible to defend the world against multi-drug resistant infectious pathogens in humans and animals using S-MGBs. We now need to take some big steps to bring these possibilities to reality and this will need the collaboration of strong commercial organisations.

Pictures courtesy of MGB Biopharma.



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Understanding the characterisation of sustainable materials

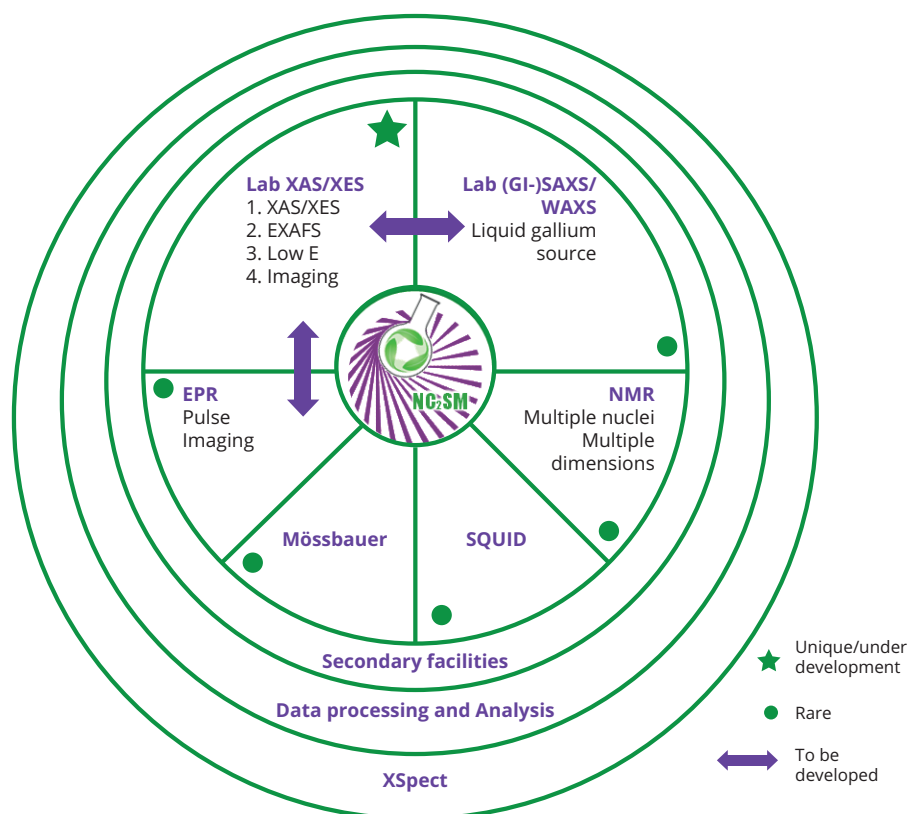
Moniek Tromp, Van t Hoff Institute for Molecular Sciences, Sustainable Materials
Characterisation sheds light on sustainable materials and their benefits

An integrated expertise characterisation centre providing a full set of advanced characterisation methods, some of which unique to the world, will enable sustainable materials scientists to characterise their materials and processes in all detail; using all eyes and ears to make pictures and movies of molecules and materials in action. This allows the rational design of novel materials and processes, which meet today's societal challenges, i.e. clean, requiring limited energy and using cheap and abundant resources.

Important ace of sustainability

Sustainability is important to accommodate the growth of the world's population and its future demand of resources for water, food and energy at a higher average standard of life. This requires a significant change of today's practice, including the minimisation of the manufacturing footprint of a material, but also the sustainable gains of its use during the life cycle and clever reuse of the material or its components. Integral sustainability must become a driver for new energy technologies, to produce durable systems to convert, produce and store clean energy.

Resources for energy (fossil origin) and raw materials (rare elements) are depleting and this requires a transition to sustainable energy production as well as the reduction, replacement, or recycling of rare elements and the



Overview of the facility, including embedding with full laboratory and computational facilities as well as data processing and analysis. Moreover, a commercial service for data acquisition and analysis will be set-up (XSpect)

further development of bio-based materials. The transition to a sustainable society will likely have a tremendous impact. While initial efforts are aimed at reducing the footprint by making existing technologies more efficient, the final goal is a (circular) society based on truly sustainable resources for energy and materials. In this transition to a sustainable society, advanced materials will play a crucial role; a sustainable society cannot be realised without the corresponding materials that enable it. These materials will have in common: less non-

renewable energy use and less greenhouse gas emission during the synthesis, construction, processing, packaging, transportation usage, recycling, and reuse.

Materials science

Materials Science is the discipline that engages with the design, synthesis, structure, dynamics and performance of materials. It is a multidisciplinary field that includes physics, chemistry, biology, and engineering, and studies materials in a broad range of length scales from the atomic scale, through

nano and micro, all the way up to the macro scale. In order to replace scarce raw materials, the functionality of materials needs to be understood much better, i.e. at all levels and in all its details. Further development and increased availability of the characterisation toolbox for this is a prerequisite in this domain.

Proper understanding not only means characterisation of the geometrical structure, from atomic to molecule and agglomerate /particle scale, but also the electronic structure. The latter determines, for a large part, the properties and reactivity of materials, but is also typically difficult to pinpoint, requiring a multitude of different and non-standard characterisation techniques. A radically different approach towards materials characterisation is thus required.

Most laboratories active in a specific materials research area specialise and invest in one characterisation technique only, which is most important or best available to them, and have experts in that one technique only. The problem with most techniques is that they only provide partial characterisation of the material under investigation. Combining several measurements of the same sample, under identical conditions, often leads to much more information than just the sum of individual data. Current challenges in sustainable materials, as described above, require detailed characterisation on multiple levels which can only be achieved with multiple techniques, i.e. 'all the eyes and ears one can have'. Groups or laboratories generally do not have the possibilities (staff, finances and expertise) to offer, develop and/or

execute all of these well. In addition to that, important X-ray techniques, allowing characterisation from atomic (Angstroms) up to inter-molecular information (micrometer) are typically performed at synchrotrons, with high oversubscription rates, severely limiting the accessibility. A radically different approach to materials characterisation is therefore crucial to ensure one can meet the materials science challenges we are facing today.

"Sustainability is important to accommodate the growth of the world's population and its future demand of resources for water, food and energy at a higher average standard of life."

National Characterisation Centre for Sustainable Materials

To unravel the novel chemistry displayed by these feedstocks and materials as well as their differing reactivity requires multiple advanced techniques, in an integrated approach. We are therefore in the process of setting up a National Characterisation Centre for Sustainable Materials (NC2SM) in which we bring important non-standard techniques together in one place, as well as develop novel and combined ones, by making x-ray absorption, emission, and scattering techniques available in the laboratory. Having access to all techniques in one place, thus making it possible to collect all necessary data in an unequivocal manner on the same sample under identical (operando) conditions, is key to fundamental materials understanding and subsequent rational design and development.

The suite of techniques will give detailed structural as well as electronic

information on the broad range of materials, at different time and length scales, from all different parts of the material/molecule. All techniques have their individual strengths and limitations, and only a combination of all can provide a full picture and movie of the sample and its reactivity. Moreover, the integrated centre will therefore not just act as a place to obtain data, but also as a sounding board and discussion platform for materials scientists, spectroscopists and theoreticians, which will catalyse novel and exciting science and advances in all fields.



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Getting to the truth about giving up plastics

President and technical advisor of the PMMDA and Managing Director of Sumitomo (SHI) Demag UK, Nigel Flowers explores the bad press plastics has been getting since the airing of Blue Planet II, the impact of Brexit on industry standards and the reality of giving plastics up for good

Plastic pollution is far from a new complaint. Yet, it's the environmental issue of the moment and public enemy number one. Rather than weighing in further on this debate and suggesting new ways to staunch the flow of plastic waste into our oceans, perhaps we should reflect on the impact if plastic left our world altogether.

What's undeniable is the impact on modern day living would be considerable and certainly not as comfortable. We're not just talking convenience packaging. Mobile phones, or any electrical device for that matter, would be virtually eradicated or uneconomical to produce. As the third biggest user of plastics, after packaging and construction, without it innovation would stall.

Examining the medical field, plastic has revolutionised patient care, increasing safety and making procedures simpler and faster to perform. Notably, plastics have contributed to a reduction in medical costs, infectious disease and improved pain management for millions of people.

Medical items we take for granted, such as disposable syringes, intravenous blood bags and heart valves are made of plastic. Disposable devices are proven to significantly reduce the risk of cross-infection among patients. Sterile plastic packaging and plastic medical disposables, in particular, contribute to keeping the rates of Staphylococcal infections low.

Modern-day prosthetic devices use high tech polymers to improve mobility for some 45,000 people in England alone. For those depending on prosthetic limbs, a number of components are now made from plastic to improve comfort and offer increased flexibility. Developments in 3D polymer printing technology will open the door to custom-made joints and limbs.

There are approximately 11 million people in the UK with hearing loss and by 2035, this is estimated to increase to 15.6 million people. Plastic remains a fundamental component of hearing devices and ear implants.

The UK is a nation of spectacle wearers, with over 70% of Britons now dependent on prescription glasses or contact lenses. In order to reduce the weight of glasses frames and lenses, plastic is now widely deployed. And for every disposable contact lens that's manufactured, a bespoke mould is created by injection moulding.

By 2030, most vehicles on the road will be electric. This phasing out of conventional petrol and diesel vehicles will lead to a greater reliance on plastic, due to its light weighting properties.

Alternative materials continue to be developed and although we could potentially reduce our dependence on plastics derived from the fossil-based resource, right now bioplastics represents around 1% of the annual plastics production.

Making a real difference requires a joint effort that requires industry stakeholders, manufacturers, suppliers and consumers being better informed and educated about the challenges and having legislative and regulatory frameworks that actively promote sustainable development and supports innovation.

No need for double standards

As Brexit looms and the announcement of the EU plastics strategy eight weeks after the UK's, the plastics industry is seeking assurance about what this means to standards, complexity and costs after we leave the EU.

Reassuringly, the positive impact on EU and international trade as a result of technical standards devel-

“Examining the medical field, plastic has revolutionised patient care, increasing safety and making procedures simpler and faster to perform. Notably, plastics have contributed to a reduction in medical costs, infectious disease and improved pain management for millions of people.”

oped by CEN and CENLEC, are uncontended. They have levelled the playing field by reducing technical barriers, ensured safe equipment and reduced production costs by simplifying product complexity. Over 30 years, this single harmonised standards model has delivered significant benefits. As testament, a 2015 Cebr¹ report summarised that 37.4% of UK productivity growth in 2013 was attributed to standards.

So, what happens after Brexit? Currently, every standard developed by the EU under CEN/CENLEC is adopted in all 34-member countries as a local standard. The UK will need to continue to support this single standard model in addition to integrating international standards into UK law. Also, the BSi and the PMMDA will continue to represent UK industry and shape the development of standards at EU, ISO and IEC levels.

The development process for standards under CEN/CENLEC is a robust one. It comprises technical expert groups, observed by shadow groups of stakeholders, with each standard subject to peer and open review before publication. Published standards are also regularly reviewed by a technical body to ensure they remain valid and meet current technical realities.

To put the scale of this industry commitment into context, 2,700 standards were published last year, each one overseen by a technical committee compris-

ing members from the 34 states. Given the extent of this workload, there is no rationale for redeveloping the standards for the UK. And if you factor in that industry experts volunteer their time to develop all the BSi standards, currently at 37,000, the time and costs associated with revising them for the UK would be unviable and an inefficient use of resources.

More importantly, this EU development model enables UK exporters access to European and international markets without technical barriers while ensuring that all equipment imported into the UK keeps our plastics workforce safe by meeting all essential health & safety requirements. When it works so well, why reinvent the wheel? ■

¹ <https://cebr.com/reports/standards-contribute-8-2-billion-to-uk-economy/>

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How to screen for endocrine disrupting chemicals (EDC)

Alberto Mantovani from Istituto Superiore di Sanità, Rome, Italy explains how to screen for endocrine disrupting chemicals (EDC)

Endocrine disrupting chemicals (EDC) are internationally recognised as a major issue for the regulation of chemical safety: for instance, the European regulatory framework requires that pesticides and biocides identified as EDC should be excluded from the EU market (but for exceptional derogations such as negligible exposure/risk). Thus, in principle, all new and existing substances should undergo a robust and consistent testing for their potential to act as EDC; a cost-effective testing strategy should concentrate on a first-step of screening.

The development of screening tests and/or batteries meet the current interest toward the increased use of non-animal assays in toxicity testing. However, the legitimate enthusiasm should not hide some of the critical considerations: EDC are substances whose endocrine activity is plausibly linked to an adverse effect; the endocrine system is a complex signalling network regulating development and all body functions.

Finally, screening for EDC should be part of a decision tree and decisions (for example, to proceed with additional testing) should be taken based on screening results. The complexity of molecular/cellular events that may be relevant to endocrine disruption can be managed with the help of pathophysiology, according to the current approach of Adverse Outcome Pathways (AOP).

For instance, the thyroid function is, in fact, a “thyroid axis,” which includes multiple targets and tissues. The pituitary gland regulates the thyroid function through the thyroid stimulating hormone-TSH. Within the thyroid gland, critical targets are enzymes deputed to hormone biosynthesis and to iodine uptake, as this trace element is all-essential for thyroid function. In the target tissues, like the developing brain, gene expression cascades are triggered through specific nuclear receptors (the TRs). The liver also acts as an “endocrine” organ, as hepatic metabolism regulates thyroid hormone levels. A less simplified scheme would include also the upstream hypothalamic signalling, the proteins transporting thyroid hormones in the blood and the cross-talk with other endocrine axes.

This rather long list of potential targets shows that efficient and standardised screening for thyroid-targeting EDC should include several assays that cover a representative sequence of events, such as TSH release, thyroid hormone production, iodine uptake, TR interaction and liver metabolism. Whereas it might be unfeasible to develop assays for each component of the thyroid axis, the components most likely to be targeted by chemicals and/or to lead to adverse effects (with the support of AOP) should be included in the battery.

A fast, robust and cost-effective (“high-throughput”) screening battery can

support and speed the evaluation of data-poor, high exposure substances (for example, some industrial chemicals or food additives), which are major concerns for regulators. Many in vitro assays are currently developed for EDC, thus regulators should ask toxicologists about scientific aspects, such as the prediction of potential adversity or the profiling of chemicals through the integrated evaluation of the screening battery results.

Other questions should pivot on screening optimisation: comparing candidate assays for concordance and/or redundancy; liability to automation; standard operating procedures and quality assurance criteria and so on. The use of case studies is of major value for such purposes. A screening battery for EDC should aim at the optimal balance between reducing complexity, as far as possible, and the capacity to cover an appropriate range of mechanisms.



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Assessing endocrine disrupting chemicals (EDC)

Alberto Mantovani presents the contribution of the Istituto Superiore di Sanità (ISS) to the international assessment of endocrine disrupting chemicals (EDC)

The Istituto Superiore di Sanità (ISS), as the reference scientific public body of the Italian Health Ministry and National Health Service, has a major involvement in the regulatory and risk assessment activities on chemicals at international level.

The experts at ISS contribute to the development of new toxicity testing guidelines, as well as to the updating of existing guidelines, which is the remit of the programme on guidelines for the testing of chemicals of the Organisation for Economic Co-operation and Development (OECD). The OECD guidelines are accepted internationally as standard methods for safety testing and are regularly updated with the assistance of national experts from OECD member countries.

The OECD provides specific attention to endocrine disrupting chemicals (EDC) as an emerging topic where many uncertainties still exist. For over 10 years, the ad hoc OECD advisory group on the testing and assessment of EDC has developed and updated a conceptual framework, as well as engaging in the validation work of new tests, with special emphasis on in vitro assays on mechanisms and in vitro/in vivo assays to assess EDC effects on environmental biota. In this vein, the ISS experts, on behalf of Italy as an OECD member country, have identified a potentially significant gap, that is the lack of guidelines for testing the effects on post-natal, pre- and peripubertal

development, as a life stage specifically vulnerable to EDC. As consequence, OECD is considering how to investigate hazards for post-natal development.

ISS also contributes to the EU expert group that supports the Advisory Group on Environmental Exposure and the Impact of EDC within the United Nations Environment Programme (UNEP). The current UNEP priority is awareness-raising among policy-makers, including developing countries or countries that currently have only a minor involvement in international programmes on EDC.

In the European Union (EU), the main fields where ISS toxicologists are involved are the European Chemical Agency (ECHA) and the European Food Safety Authority (EFSA).

Implement the EU legislation

The ECHA's task is to implement EU legislation on chemicals for the benefit of human health and the environment, as well as for innovation and competitiveness, by fostering the replacement of high-concern chemicals. The current priority of ECHA is the identification of high-concern substances: carcinogens, genotoxicants, reproductive/developmental toxicants, persistent bioaccumulative and toxic or very persistent and very bioaccumulative; in addition, EDC are considered as substances giving rise to an equivalent level of (high) concern, where scientific evidence indicates probable serious effects to

human health or the environment. The ISS experts have been active on EDC at ECHA, for example, by requesting additional studies to clarify whether the UV-screener octabenzene is an EDC.

EFSA is the first EU authority entirely devoted to risk assessment; due to its solid activity, established since 2003, EFSA is taking a spearhead role in the development of risk assessment methods and concepts. Accordingly, ISS scientists contribute their qualified and independent expertise to ECHA and EFSA activities. The contributions concern the assessment of substances (pesticides, plasticizers, nano-sized materials and so on), as well as novel approaches for assessing toxicological emerging hazards, such as EDC; for example, the use of adverse outcome pathways (AOP) in order to strengthen the potential of in vitro, mechanistic studies for predicting adverse effects on human health.



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Innovators race to find sustainable polymer-based materials

Jennifer Unsworth, Senior associate and patent attorney at Withers & Rogers LLP shares her expertise on the race for innovators to find sustainable polymer-based materials

Polymer innovation, a branch of materials science, has been instrumental in the development of many of the products and technologies we use every day. However, a recent global push to protect the environment has put polymeric materials, or plastics, in the spotlight.

In part, as a result of this increased scrutiny, there has been significant work going on in the field of polymer science in recent years. Innovators are reacting to negative messages in the media about plastic waste and packaging and are focused on finding solutions.

“Polymer manufacturing has for a long time now been intrinsically linked with the petroleum and fossil fuel industry. When crude oil is distilled, various by-products are made and these often find their way into plastic materials. From an environmental perspective, this process is not sustainable – it relies on the use of rapidly-depleting fossil fuels, releases carbon emissions into the environment and the end product is hard to recycle.”

Much of the innovation activity to date is focused on alternative methods for reuse and recycling and there are a number of interesting research projects being undertaken globally, seeking to alleviate some of the burdens of plastic waste. Among these projects, students at MIT – Massachusetts Institute of Technology in the US, are exploring the effects of exposing fine plastic flakes to small amounts of gamma radiation, before crushing them down and mixing them into concrete. This process helps to make concrete more durable at the same time as providing an alternative use for waste material that would otherwise have ended up in a landfill.

Indeed, many of the alternative uses for waste polymers

capitalise on the beneficial characteristics of plastics – their light weight, strength and rigidity. In many cases, these characteristics can be honed; allowing for the creation of bespoke materials with a wide range of potential applications.

An example of this is the growing popularity of wood-plastic composites (WPC), which are made from a mixture of wood fibre and thermoplastics, including polyethylene and polyvinyl chloride. These materials are used extensively for applications such as decking, railings, fencing and benches and are sustainable in that they can be made from recycled plastics. Although biodegradability is a consideration, a WPC reaching the end of its useful life can be re-fabricated into new materials, avoiding the need to dispose of it completely.

Polymer manufacturing has for a long time now been intrinsically linked with the petroleum and fossil fuel industry. When crude oil is distilled, various by-products are made and these often find their way into plastic materials. From an environmental perspective, this process is not sustainable – it relies on the use of rapidly-depleting fossil fuels, releases carbon emissions into the environment and the end product is hard to recycle.

In a bid to find a solution to this problem, innovation within the polymer materials space is starting to focus on drop-in or bio-plastics. These products are made from fermented starches, found in materials such as banana skins or peanut kernels.

One example of such a bio-plastic is Floreon, a specially-formulated compound that is added to standard bio-plastic polylactic acid in order to create a material that has a sustainable origin and a range of end of life options. The bio-plastic polylactic acid is produced

using renewable crops such as corn, tapioca roots, starch or sugarcane. A fully degradable and compostable polyester blend is added to this, to produce an environmentally-friendly plastic that can be used to manufacture drinks bottles and the like.

The developers of Floreon have protected their investment in research and development by filing patent applications that include claims related to the material blend, articles such as bottles made from the compound and specific methods of manufacture or polymer processing using Floreon, for example, injection moulding. To date, patents related to this technology have been granted in Europe, Australia, China and Canada.

In contrast to some bio-plastics, which are compostable and biodegradable, drop-in bio-plastics are fully-recyclable. This means that instead of requiring specialist dedicated recycling facilities, drop-in plastics can be fully-integrated into conventional recycling streams, requiring less investment in end-of-life processing facilities.

Compatibility with existing recycling facilities forms a key part of the polymer industry's push to drive innovation towards a circular economy, with closed recycling loops. Recycled plastic has a reputation for being lower-quality than virgin plastic and so its popularity with consumers has suffered. To tackle this, innovation in the area of bio-plastics is aiming to change this perception by creating an advanced material that once nearing the end of its life, can be recycled readily into something of equivalent quality.

With so much activity going on in this sector, intellectual property (IP) is bound to play a major role in protecting any innovation. Innovators around the world are competing to find viable solutions to the problems posed by widespread plastic use and multi-layered IP rights provide vital commercial protection.



*Jennifer Unsworth,
Senior associate and
patent attorney*

Growing public concern about the environmental impact of plastic waste is encouraging innovators to find new, sustainable polymer-based materials. Based on current trends, the solution lies in developing novel materials that meet consumer expectations as well as being easier to recycle. ■

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Self-reinforced gluten polymers: A step towards a true biocomposite

Prof Mikael S Hedenqvist and Dr Oisik Das from KTH Royal Institute of Technology in Sweden explain self-reinforced gluten polymers and why they are a step towards a true biocomposite

Bio-based polymer products are getting an increased amount of attention due to a paradigm shift in manufacturing towards sustainability. Wheat gluten (WG) is one such natural polymer that is a cereal-based protein produced as a coproduct of food industries. WG is attractive because it satisfies the growing need for polymers from renewable resources and exhibits acceptable mechanical properties. WG is a cohesive material with good oxygen barrier properties and can be moulded to various shapes such as films, foams and solids.

However, WG suffers from inherent disadvantages that hinder its widespread application. The mechanical properties of WG are inferior to that of the synthetic counterparts and they are also susceptible to moisture, microbes and fire. To remedy these issues, it is critical to identify reinforcements that are not only bio-based, but also to enhance WG's performance properties.

Biochar, which is a solid pyrolysis product of biomass, was found to be a potent reinforcing material for synthetic polymers ⁽¹⁾. During pyrolysis (heating at high temperatures, ca. 500-900 °C with limited O₂), the volatiles from biomass evolve, creating a porous and carbonaceous material (formed by gradual condensation of carbons into aromatic clusters). During processing, the molten polymer flows through the biochar pores – forming a

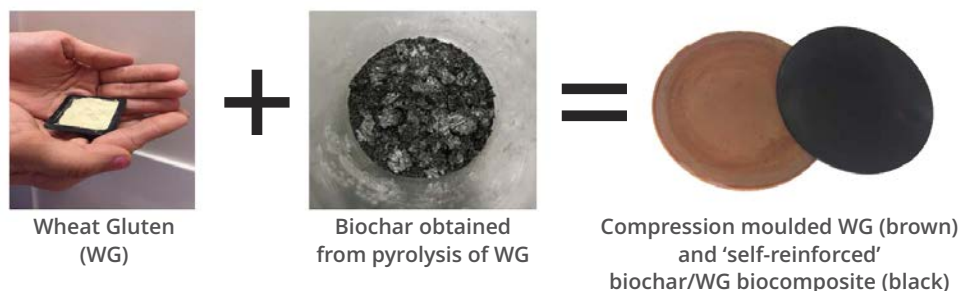


Figure 1: Wheat gluten plastic was converted into biochar through pyrolysis at 850 °C with a heating rate of 10 °C/min and 1 hr retention time. This biochar was then added to the gluten plastic itself and compression moulded to develop the 'self-reinforced' biocomposite.

mechanical interlocking like the 'Velcro effect.' The biochar, made at high temperatures also has remarkable fire resistance ⁽¹⁾. Hence, biochar is a reinforcement in polymeric materials which enhances both mechanical and fire properties.

Earlier studies have shown that it is possible to make biocomposites from various organic materials by utilising the fact that it can be converted to biochar that is retrieved from the material undergoing pyrolysis ⁽²⁾. Therefore, the application of the same method on materials from other sources is a possible approach to obtain innovative biocomposites. The polymeric materials division at KTH Royal Institute of Technology pyrolysed WG and the biochar obtained was added to the WG polymer itself to create a novel and a true homo-biocomposite (Figure 1).

This 'self-reinforced' biocomposite's components are derived from the same source but undergo different treatments for the same material to

reinforce itself. It is envisaged that this biochar/WG composite would be simultaneously mechanically strong, fire and moisture resistant giving rise to a new class of polymeric materials.

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The health effects of exposure to chemicals and other substances

Open Access Government details the work of the National Toxicology Program, a world leader in providing scientific information to help evaluate and better understand the potential health effects of exposure to chemicals and other substances

The National Toxicology Program is a world leader in providing scientific information to help evaluate and better understand the potential health effects of exposure to chemicals and other substances.

The National Toxicology Program (NTP) was established in 1978 to strengthen the science base in toxicology, support the development of improved testing methods and provide information about potentially toxic chemicals to health and research agencies, scientific and medical professionals and the public.

Based at the National Institute of Environmental Health Sciences (NIEHS) in North Carolina, the NTP coordinates toxicology and testing across the US Department of Health and Human Services.

Over the years, it has become a world leader in the development of techniques and testing regimes to evaluate the health-related effects of environmental and occupational substances. This includes short and long-term toxicology/carcinogenicity studies to address the gap in knowledge concerning the toxicity of substances in the environment, along with chemical disposition and toxicokinetic studies, which assess the absorption, distribution, metabolism and excretion of substances in laboratory animals.

The long-term goal of these studies is to gather data to better assess the structure-activity relationships that determine chemical disposition in the test subjects and, ultimately, better interpret the significance of this data to humans.

The NTP has also developed a range of genetic toxicology testing regimes to evaluate the potential of environmental and occupational substances to damage DNA,

as well as toxicogenomic studies to examine how chemicals can change the expression of genes, proteins and metabolites in living cells. Measuring genome-wide changes in affected tissues can help to identify markers of toxicity or disease and improve understanding how genetic variations between individuals can influence their sensitivity to substances.

In addition, the NTP has established techniques for testing the potential of substances to affect the development of and cause damage to, reproductive organ systems and tests to determine the toxic effects of exposure on the immune and nervous systems.

In recent years, a key focus for the NTP has been the development of new, alternative methods of toxicology research that will reduce, replace or refine the use of laboratory animals. Systems currently under development include computer-based predictive toxicology models, genetically engineered in vitro cell systems, microchip array technology, non-mammalian species and transgenic species.

In March, at the Society of Toxicology's 57th Annual Meeting and ToxExpo in San Antonio, Texas, the Inter-agency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), a committee under the NTP Interagency Centre for the Evaluation of Alternative Toxicological Methods (NICEATM), continued the rollout of a strategic roadmap for establishing new methods to evaluate the safety of medical and chemical products while reducing or eliminating the need for animal testing.

The roadmap, which was drawn up with input from 16 federal agencies, multiple interagency work groups and the public, aims to create a framework to support



the development of, foster confidence in and ensure the adoption of these new approach methodologies (NAMs). The implementation of the roadmap is currently focused on three areas: acute systemic toxicity; eye and skin irritation; and skin sensitisation.

Temporary, ad hoc work groups are playing a key role in implementation by undertaking specific tasks identified by the ICCVAM as being important for the development or validation of NAMs.

Chairs representing agencies that use or require data from an area of interest set their group's scope and charge. Once approved by the ICCVAM, member agencies and partners from the International Cooperation on Alternative Test Methods (the European Union Reference Laboratory for Alternatives to Animal Testing, the Japanese Centre for the Evaluation of Alternative Methods, the Korean Centre for the Evaluation of Alternative Methods and Health Canada) are invited to participate.

The work groups will develop detailed implementation plans to meet the roadmap's goals based on four key elements: definition of testing needs; identification of any available alternative tests and computer models; a plan to develop integrated approaches to testing and

assessment and defined approaches for interpreting data; and a plan to address both scientific and non-scientific challenges, including regulatory issues such as international harmonisation.

"This roadmap represents a coordinated effort by federal government agencies to proactively develop and adopt new approaches to toxicity testing, rather than having changes driven by external influences", says Warren Casey, PhD, director of the NTP Interagency Centre for the Evaluation of Alternative Toxicological Methods.

"If actionable progress in this area is going to happen, the agencies need to take the lead and that is exactly what they are doing with this roadmap." ■

For more information, please visit <https://ntp.niehs.nih.gov/>

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The potential long-term environmental health consequences of urban wildfire debris

Birgit Puschner and Pamela Lein from the University of California, Davis share their expert views on the impacts of urban wildfire on chemical contamination in small backyard agriculture

Worldwide, the frequency and severity of wildfires are increasing due to changes in temperature and precipitation patterns consistent with climate change and changes in land use, particularly at the rural-urban interface. The fire problem is particularly acute in Northern California, which has experienced a significant increase in wildfire frequency over the past few decades. In addition to the risk of injury, loss of life and destruction of property, there is increasing appreciation that wildfires pose significant environmental health threats.

Much of the research on adverse health impacts of wildfires has focused on wildfire smoke and recent reviews of this scientific literature conclude there is strong evidence that wildfire smoke exacerbates respiratory ailments, including asthma and chronic obstructive pulmonary disease and contributes to cardiovascular disease. What is less well understood, however, is the potential impacts of wildfire debris on human, animal and ecosystem health.

Debris from urban wildfires is particularly worrying because these fires involve the combustion of building materials, electronic equipment, chemicals and industrial equipment that contain toxic chemicals such as metals, pesticides and persistent organic pollutants (POPs).

POPs of concern include the polychlorinated biphenyls (PCBs) and polybrominated diphenyl ethers (PBDEs). PCBs are man-made chemicals that were widely produced for diverse industrial applications beginning in the 1930s until their production was banned in 1979 because of their carcinogenic potential and developmental neurotoxicity.

PCBs are found in older electrical transformers, capacitors and light ballasts still in use today and in caulking material, paints and sealants used to construct municipal buildings and homes prior to the 1979 ban. PBDEs are also man-made chemicals that were widely used as flame retardants in various consumer products including foam, plastics and textiles.

Due to health concerns, the state of California began prohibiting the manufacture, distribution and processing of flame-retardant products containing penta- and octa BDEs in 2006. However, human exposure continues because many households have products produced prior to the ban. Moreover, PBDEs are not chemically bound to materials and therefore, leach out of household products into the environment. Like PCBs, PBDEs persist in the environment and biomagnify up the food chain.

Pyrolysis results in the release of PCBs and PBDEs into the environment.

Increased PCB concentrations have been documented in air masses associated with fires. The ash from the September 11th 2001 World Trade Center fire in New York City was found to contain excessive PBDE levels. The combustion of man-made materials, particularly electronic equipment, is also associated with the mobilisation of metals. For example, ash debris from the California wildfires from 2007 contained toxic metals, specifically, arsenic, cadmium, copper and lead, at levels associated with long-term health effects in animals and humans.

Urban wildfires not only release toxic chemicals, but also generate hazardous compounds, such as dioxins and dibenzofurans, which are formed by the combustion of organic matter, such as paper and wood. Once the burning has stopped, re-volatilised chemicals distribute out of the atmosphere onto soils, vegetation and surface water, while non-volatile chemicals are deposited as ash. The increased environmental availability of these chemicals increases the risk of groundwater contamination, the uptake by plants and ingestion by animals, culminating in increased risk of human exposure for months to years. Thus, a question of growing concern is whether urban wildfires pose a significant long-term environmental health risk via chemical contamination of home-grown produce or animal-derived foods.



Wildfire aftermath on Cobb Mountain during the Valley fire in northern California

This concern is heightened by lay articles in the New York Times and San Francisco Chronicle and peer-reviewed publications reporting increased human exposure to lead (Pb) through consumption of eggs produced by backyard chickens. Eggs and eggs products are one of the most consumed foods worldwide. In the United States, individuals consume an average of 24 grammes of eggs per day. Backyard chicken ownership has grown in the United States in part because the eggs from backyard hens are perceived to be healthier than commercially produced eggs.

However, recent studies have identified concerning levels of Pb in eggs produced by chickens raised in areas with significant Pb contamination of the soil, usually as the result of the weathering of older buildings with Pb-based paints. The consumption of one average size 50-60 gramme egg from Pb-contaminated environment can exceed the safe threshold dose of 6µg of Pb per day from all combined

dietary sources. What about PCBs and PBDEs? These are very fat-soluble chemicals and egg yolk is rich in lipids resulting in an average fat content in an egg of 10%. Thus, the potential for significant contamination of eggs in regions with increased soil levels of these POPs is not unreasonable, as suggested by recent data reporting the detection of PCBs and PBDEs in milk from dairy cows of California.

The overwhelming majority of food safety research associated with backyard poultry and other home-produced food products has largely focused on microbial contamination. Human illness from most foodborne pathogens is limited to transient gastrointestinal symptoms; in contrast, human exposure to unsafe levels of PCBs, PBDEs or metals has the potential to cause long-term adverse health effects. Currently, urban and backyard farmers have no way of knowing whether eggs or other home-grown food products are contaminated with toxic chemicals unless they are lab

tested. There is, therefore, an urgent need to study environmental chemicals in home-produced food in geographic regions that have experienced urban wildfires to assess the potential food safety risk and to generate information needed to inform rational risk management.

In conclusion, the increase in wildfires has potentially serious long-term health consequences for communities and ecosystems. One important concern is the generation or release of chemicals into the soil and water environment and the risk for chemical contamination of home-grown produce, eggs and other animal-derived food products. To more accurately predict the risk to humans, it will be necessary to obtain data regarding the actual levels of toxic chemicals of concern in the environment before and after urban wildfires and to model the transfer of these contaminants through the food chain.



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From wheelchair to high heels: Realising the potential of stem cells

Dr Michael A Rudnicki, CEO & Scientific Director at the Stem Cell Network gives an expert view on a new era in health care, powered by stem cells

In 1996, a 21-year-old aspiring police officer, Jennifer Molson, was diagnosed with aggressive multiple sclerosis (MS). Within five years, Jennifer was unable to manage everyday tasks, including cutting her food and taking a shower. The prognosis was that she would live her life in a wheelchair and require constant care. Dr Mark Freedman from The Ottawa Hospital was Jennifer's neurologist. He and his research partner Dr Harry Atkins, a clinician/researcher, enrolled Jennifer in a clinical trial that took her stem cells, purified and fortified them and after extreme chemotherapy to knock out her immune system, returned the stem cells to rebuild a new, disease-free immune system. Today, with all traces of the disease eradicated, Jennifer has been cured. She has her life back – she works, enjoys family, skis and wears her high heels proudly. Jennifer's story is extraordinary and is a demonstration of what can be achieved through the application of stem cells.

Stem cells are powering a new and exciting scientific field – regenerative medicine – and this field is expected to have a global market value of \$53.7 billion by 2021. Stem cells are special, as they can make many copies of themselves and give rise to more specialised, or “adult” cells. We now know that most tissues contain their own rare populations of adult stem cells that help with maintenance and repair. One particular type of stem cell is especially powerful: known as the pluripotent stem cell, it is akin to a blank slate, capable of making any cell type in the body. Stem cells are invaluable to researchers for their ability to model development and diseases that may otherwise be difficult to study and have vastly expanded our understanding of how the body heals or succumbs to disease. This knowledge is fuelling the delivery of new ways to regenerate or repair cells, tissues and organs. The potential is extraordinary for fighting chronic diseases and illnesses that cost the Canadian healthcare system upwards of \$190 billion annually.

In Canada, stem cell-based treatments are being utilised to fight severe blood disorders such as leukaemia, as well as aggressive multiple sclerosis and some rare diseases. And this is just the beginning. With support from the Stem Cell Network, clinical trials are underway in British Columbia and Alberta that are testing a novel stem cell therapy for type 1 diabetes. The research from these trials may change the way those who have type 1 manage the disease by eliminating constant measuring of blood sugar levels and eliminating insulin dependence.

“Regenerative medicine is at a tipping point in Canada. It's time to build on our foundation of scientific excellence and harness the benefits of regenerative medicine for the health of Canadians and the economic prosperity of our nation.”

In Montreal, researchers and clinicians are working with a specialised molecule and state-of-the-art technology that allows stem cells found in cord blood to be expanded or grow. This is critically important work for developing a stem cell product that is not only affordable but safe and effective for the treatment of blood diseases, particularly for patients who are currently ineligible or do not respond well to current therapies.

Jurisdictions around the world recognise the benefits of investing in stem cells – economic, population health and individual patient outcomes. California, Japan and the United Kingdom are all fighting to lead the field that matters the most for health. Canada is well positioned to compete; in fact, it was two Canadians who proved the existence of stem cells in the early 1960s. And it was two more Canadian scientists who were behind the 2016 launch of BlueRock Therapeutics – a multi-national biotech supported with a USD\$225 million Series A investment. BlueRock is focused on bringing forward

Image: © Dwayne Brown Studio / The Ottawa Hospital



stem cell-based therapies for the treatment of cardiovascular and neurological conditions. Powered with Canadian ingenuity, we know this company will succeed.

“Stem cells are special, as they can make many copies of themselves and give rise to more specialised, or “adult” cells. We now know that most tissues contain their own rare populations of adult stem cells that help with maintenance and repair.”

It is just the beginning for stem cells and regenerative medicine. The challenge is to ensure the regulatory environment will allow for stem cell therapies to move through the clinical trials process effectively. We also require stable and predictable funding for research so that next generation therapies can be realised. Canada's small but growing regenerative medicine sector requires support to scale-up and commercialise its products. It also requires access to a skilled and talented labour pool. And of course, the healthcare system must evolve and be able to integrate innovative therapies as the new standard of care.

Regenerative medicine is at a tipping point in Canada. It's time to build on our foundation of scientific excellence and harness the benefits of regenerative medicine for the health of Canadians and the economic prosperity of our nation. ■

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The amazing spiny mouse, the champion of mammalian regeneration

Malcolm Maden, Department of Biology & UF Genetics Institute, Gainesville, Florida, USA shares his expert opinion on the amazing spiny mouse, the champion of mammalian regeneration

If you ask most people whether mammals can regenerate or not they would surely answer no. After all, many people have scars on their skin from wounds, burns or surgery, amputated limbs do not regenerate, tumour removal leaves large tissue defects and many people die from the fibrosis resulting from a heart attack. But if you scour the scientific literature for regenerative ability in mammals there seems to be quite a number of diverse reports. The annual replacement of deer antlers is surely one of the most conspicuous examples of regeneration and shows many features typical of complex tissue regeneration, such as limbs in lower vertebrates including the formation of a blastema (see [The Champion of Regenerative medicine – the Axolotl](#)).

The digit tips of children, mice, rats and monkeys also regenerate by the formation of a blastema. Holes punched through the ears of rabbits, cows, pigs, chinchillas, pikas, hares and bats are said to regenerate so this includes cartilage in the middle of the ear and skin over the top. Most impressively for a mammal, new-born mice can regenerate cardiomyocytes following a myocardial infarction, although this ability is lost by seven days after birth.

And of course, the mammalian liver regenerates (as the ancient Greeks in the legend of Prometheus knew), not by the formation of a blastema, but by

a process known as compensatory hypertrophy, such that if a lobe of the liver is removed the remaining liver lobes grow and expand to replace the lost function. This process involves the coordinated up-regulation of cytokine, growth factor and metabolic networks resembling true regeneration. Similarly, the lung can undergo compensatory hypertrophy after the removal of one or more of the lobes, in exactly the same manner as the liver.

Although tantalising, these regenerative abilities are too sporadic to provide us with a new model of mammalian regeneration which we clearly need for regeneration studies so that direct comparisons between the damaged organs (e.g. the skin or the heart) of an adult regenerating mammal and an adult non-regenerating organ (e.g. the lab mouse or human) can be made. We need these directly equivalent comparisons to eliminate differences due to developmental age or evolutionary distance to identify the molecules that are causing scarring and fibrosis in the typical mammal and may not be present in a regenerating mammal. We would then want to counteract these fibrotic molecules in a human with the intention of inducing regeneration and/or preventing scarring.

Excitingly, it now appears that we may have discovered an adult mammal which can regenerate many organs, namely the spiny mouse of the genus *Acomys* (Fig. 1A). There are several

species of these mice which inhabit desert areas in North Africa, the eastern Mediterranean and southwards into Kenya. Along with several colleagues (Ashley Seifert, Megan Seifert, Jake Goheen) we found that these species could frequently be trapped with large segments of skin missing from their backs and when these animals were kept the wounds regenerated perfectly and replaced the hairs, sebaceous glands, erector pili muscles of the hairs and the dermis without scarring (Fig. 1B).

“Excitingly, it now appears that we may have discovered an adult mammal which can regenerate many organs, namely the spiny mouse of the genus *Acomys*.”

In contrast, a similar wound in the lab mouse produces a scar covered by a hairless, glassy wound epithelium (Fig. 1C) just as humans do. In further skin experiments using full thickness thermal injuries rather than a physical wound, the *Acomys* skin regenerates perfectly with a full complement of hairs and no scar (Fig. 1D), whereas the lab mouse produces a hairless scar (Fig. 1E). Histologically these repairing skin tissues look remarkably similar in terms of the dermis. A section of *Mus* dermis four weeks after a burn injury is shown in Fig. 1F covered by a uniform epithelium.

In contrast, a regenerated *Acomys* burn injury at the same time point is

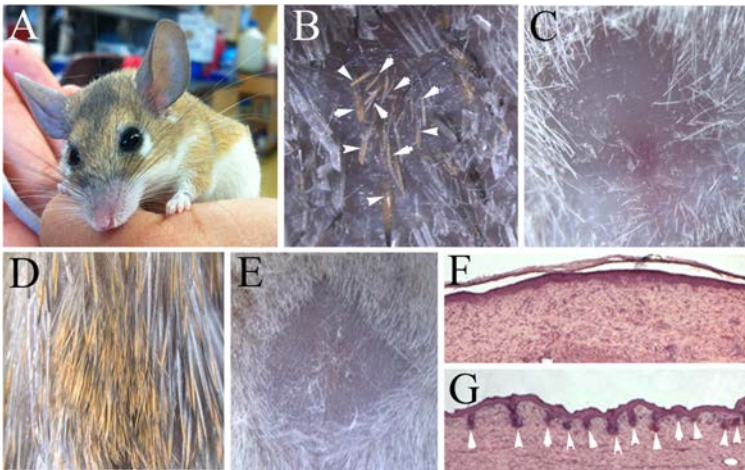


Figure 1

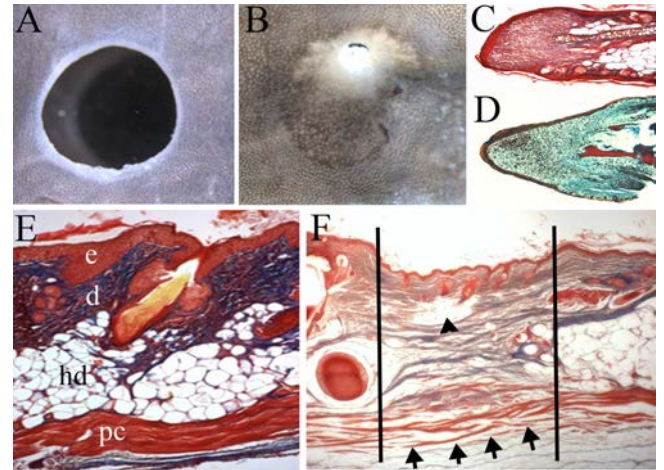


Figure 2

shown in Fig. 1G and many regenerating hair follicles spread across the wound epithelium can be clearly seen. However, there are molecular differences in the dermis of the regenerating and scarring dermis in terms of the collagens and other extracellular matrix molecules that are deposited, which may play an important role.

In the same series of experiments, we also showed that large 4mm holes punched through the *Acomys* ear could regenerate completely, replacing not only the skin but also the cartilage in the middle of the ear (Fig. 2A, B). This process of ear punch regeneration involves the formation of a blastema (Fig. 2C) which shows a remarkable similarity to the blastema of the regenerating amphibian limb (Fig. 2D and The Champion of Regenerative medicine – the Axolotl). This shows the truly epimorphic nature of this mammalian regenerative event.

An even more surprising result was seen in these skin regeneration studies because unlike the human skin, the rodent skin has a layer of skeletal muscle at the base called the panniculus carnosus (Fig. 2E). Normally, skeletal muscle cannot regenerate in mammals when a hole is made through the tissue. This is known as a volumetric muscle loss and frequently

occurs after injuries such as gunshot wounds. But when the spiny mouse skin regenerates the missing segment of the panniculus carnosus regenerates as well (Fig. 2F). This is a very exciting result and may lead to discoveries in how to regenerate missing muscle segments in humans.

In addition to the skin, the ear and skeletal muscle the *Acomys* heart also shows regenerative properties. In the lab mouse and humans after a myocardial infarction the damage immediately causes a huge drop in the ability of the ventricle to pump blood, known as the ejection fraction from which it does not recover. Heart cells at the site of the ischemia die and local fibroblasts proliferate and lay down a scar.

The reduced ejection fraction induces the ventricle to pump more blood and as a result, the ventricle wall thins dramatically. In adult *Acomys*, however, the immediately decreased ejection fraction caused by the myocardial infarction recovers over a period of 14 days to return to pre-MI levels. The missing capillaries are regenerated and there is a vastly reduced level of scarring. Future studies will be aimed at determining whether heart cells can divide and replace the ischemic tissue.

Our studies to date on the regenerative properties of the adult *Acomys* skin, skeletal muscle, ear and heart have revealed a striking lack of fibrosis in each tissue at the site of damage and this allows the natural regenerative abilities of cells and tissues to take place unhindered. We suggest that *Acomys* is a great candidate for an adult mammalian regeneration model for use in regenerative medicine with the ultimate aim of discovering why this genus can regenerate and extrapolating this knowledge to generate therapies for the benefit of humans.



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Evaluating multiple treatments within one study: Some practical considerations

Prof Thomas Jaki, Professor of Statistics at Lancaster University's Medical and Pharmaceutical Statistics Research Unit tells us about some practical considerations around evaluating multiple treatments for patients

In a multi-arm study, several experimental arms are evaluated within a single trial. The different arms can be different experimental treatments, different doses of the same agent or different combinations of treatments. Most commonly, such designs include a common control group against which each of the experimental arms is compared to. This set-up has the advantage that only a single control group is required so that fewer patients need to be allocated to the control treatment, compared to separate two-arm evaluations. The resulting reduction in sample size for a trial with three experimental arms – versus conducting three separate two-arm trials – is about 15%.

At the same time, a patient's chance to receive an experimental treatment is increased, which can help with recruiting patients ^[1]. These studies undertake a contemporary comparison of different experimental treatments using a single protocol – meaning that important features, such as the population studies, are the same.

Interim analyses that allow early termination of the study, either because of the proven effect of one treatment or due to a lack of benefit, increase the efficiency of these designs further. In addition, the interim analyses can be used to select which treatment(s) warrant further study. Figure 1 illus-

trates such a design where treatments are eliminated from the study – should the corresponding test statistic be too small (or equivalently the p-value too large) – that is fall below the lower bound. If the test statistic of one treatment is high – in that it exceeds the upper bound – the trial can be stopped, and the superiority of that treatment is claimed.

In the case where no test statistic is above the upper bound and at least one test statistic falls between the upper and the lower bound, the trial continues with all remaining experimental arms in addition to the control

arm. In the schematic of Figure 1, four treatments are compared against a common control and up to three analyses undertaken. At the first analysis, the test statistics comparing treatment 1 vs control and treatment 4, against control fall below the lower bound and hence they are removed from the study. Since none of the test statistics exceeds the upper bound, the study continues with treatments 2, 3 as well as the control group. At the second interim, the test statistic corresponding to treatment 3 exceeds the upper bound and hence superiority of treatment 3 over control can be claimed and the study can be stopped.

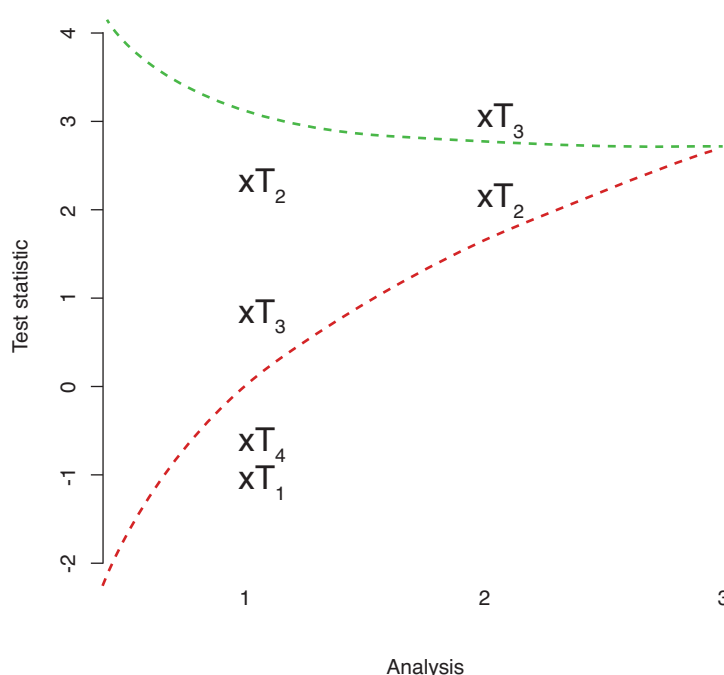


Figure 1 Illustration of a multi-arm multi-stage study following ^[2].



Multi-arm trials in practice

We illustrate above that multi-arm studies are efficient. They do, however, also require additional considerations. When comparing multiple arms, all treatments in the study need to be available at the same time to ensure a contemporary evaluation. Additionally, a multi-arm study implicitly assumes that all experimental treatments start on an equal footing – i.e. no treatment is believed to be better than any other before the study starts.

The analysis of a multi-arm study also requires special attention. Using standard analysis methods will result in an overenthusiastic (upward biased) estimate of the effect. Specialised methods for estimation and constructing confidence intervals [e.g. 3] are therefore necessary for analysing such studies.

For multi-arm studies with several analyses, one must note that the maximum sample size required will be larger than for a multi-arm study with a single analysis as the designs need to protect against an increased chance of claiming that a treatment is better than control when it is not.

Note, however, that the expected number of patients is typically notably smaller. Even though the increase in the maximum sample size is typically small (<10%), recruiting the maximum number of patients still needs to be possible. For (notable) reductions in the expected sample size, it is crucial that the endpoint used for treatment selection (primary endpoint or some short-term surrogate) is observed quickly since patients will continue to be randomised to each arm while the data to make the interim treatment selection are being collected.

Generally, the conduct of interim analyses must be efficient and to relatively tight deadlines as delays in the selection decision reduces the benefit of such a design. Consequently, the additional resource is often required to facilitate quick decisions and to ensure blinding and trial integrity. Efficient communication between investigators, data management and statisticians are essential.

Communicating the more complex design of multi-arm studies to both patients and investigators also requires some thought. The informed

consent procedure requires careful consideration as patients need to be fully aware of all possibilities.

Finally, planning and ensuring treatment supply needs careful thought before embarking on a multi-arm study that allows selection. The maximum amount of a drug required is uncertain as arms can be stopped prior to the end of the study. While the same issue exists for group-sequential designs, the additional arms make this challenge more pronounced. Accurate planning and precise estimation of recruitment rates are paramount.

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Developmental biology: Fulfilling the promise of Organoids

Professor of Developmental Mechanics at the Department of Genetics, University of Cambridge, Alfonso Martinez Arias shares his expert view on Organoids, within the field of developmental biology

A few years ago, a headline and a picture captured the imagination of the world: scientists had been able to grow a miniature version of a human brain in a dish in the lab. Understandably, such a feat unleashed the imagination and the hope of people, particularly those with disease. It did not matter that similar findings had been made and reported with the mouse before, the adjective 'human' always has an impact on anything science related. Soon the word was out that this would revolutionise the study of mental health, pave the way to cure disease and, of course, there were the inevitable claims to the cure of cancer.

These 'mini brains' were part of a menagerie of counterfeits of human organs and tissues grown in the lab including disembodied eyes, livers, intestines and pancreas that came to light with this finding. How was it possible? What does it mean? It is sometimes difficult to disentangle hype and hope in scientific research but, in this area, one needs to, as the potential gains are enormous but only if they are built on sound foundations and not on false expectations. For the moment, understanding mental health with mini brains is not on the cards, though understanding something about how cells make brains is. If you want to build tall edifices you need good foundations.

What are Organoids?

The structures reportedly grown in the lab are known as 'organoids', because they are imperfect replicas of real organs. They result from remarkable and still little understood, abilities of special cells, stem cells. Cells do not live forever, and most tissues of our body require a constant replenishment. This is what stem cells do. They manage to keep themselves going, while providing a constant stream of material to repair damage and keep organs functioning.

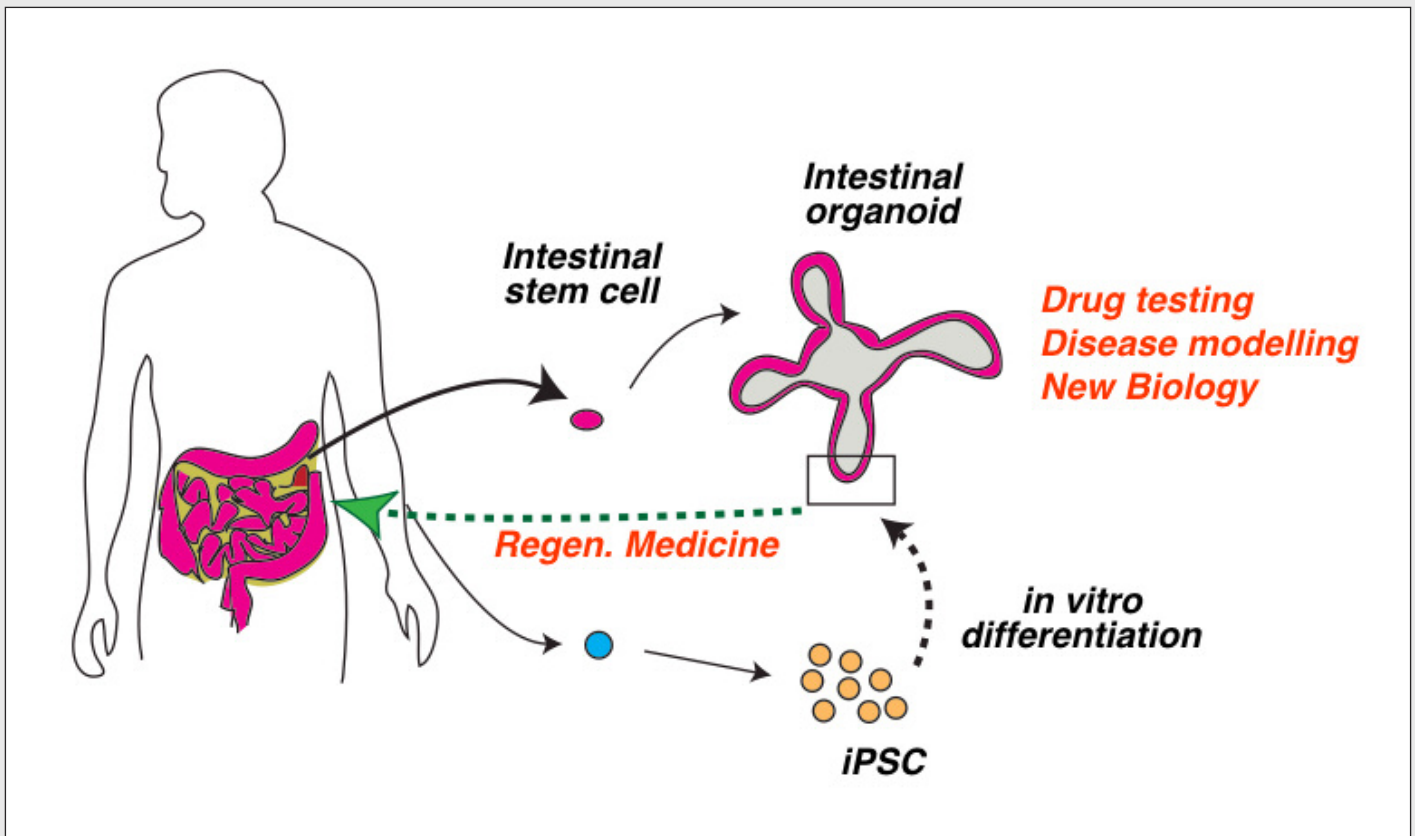
For example, every day your body produces 200 trillion red blood cells to keep you fit and stem cells in your intestine 30 billion cells to deal with your digestion; this is the awesome power of these cells. The ultimate stem cells are embryonic stem cells (ESCs), derived from very young embryos they can be grown almost indefinitely in culture and, at any time, any single one of them can generate a whole organism.

Organoids are the result of the potential of stem cells. It is not yet possible to grow blood in the laboratory, but intestinal and embryonic stem cells are paving the way for much of what we shall be able to do in the future. A single intestinal stem cell can produce a rough copy of the adult intestine, an intestinal organoid, *in vitro* and steering ESCs in defined environments with specific chemicals, can produce rudimentary kidneys and lungs. It is these ESCs that were used to build mini brains. However, for now, we cannot control these processes just watch them unravel.

The promise

It is early days. Organoids are, in most instances, too imperfect to be of use but the goal is to use these cellular contraptions to understand the disease, test drugs and even one day, create replacements for some tissues and organs.

One of the main problems of regenerative medicine, in which we can replace a damaged organ or tissue for a healthy one, is the matching of tissues between a donor and a patient. The work with organoids promises to solve this problem with the use of so-called induced pluripotent stem cells (iPSCs): ESCs generated by converting adult cells from an individual into ESCs which then, in principle, can be transformed into any tissue and organ.



Thus, iPSCs allow generating tissue matches for the patient as the donor is genetically the same. There is little question that this will happen in the future, but it will not happen faster because of ill-founded claims that it can happen, and we should avoid listening to siren chants that are so frequent in this field.

One of the roadblocks to progress is 'reproducibility'. In biology, when something works it is capable of making many good copies of itself; behold embryos building organisms. Unfortunately, most organoids now are low frequency, heterogeneous and not functional. To break this impasse, we need more basic research. Two fields will have an impact in progress: developmental biology – that teaches us how animals develop – and engineering – that tells us how to control processes and make them efficient.

The way to the promise

For now, however, while we realise the promise of iPSCs, intestinal organoids, probably the most advanced and reproducible in the field of human organoids, are providing a reference for some of the work that can be done. In a recent landmark study, scientists made intestinal organoids from cancer patients that were undergoing treatment and observed that the

in vitro avatars responded to the treatments as the individuals did. This opens enormous possibilities for the use of these organoids to rapidly test drugs and treatments highlighting the potential that lies ahead.

The emerging organoid field at the crossroads of stem cell, developmental biology and engineering will transform our understanding of how cells build organs and tissues and in doing so will pave way for significant applications in biomedical research. For this to fulfil its potential we should resist the allure of statements that promise much in a short-term present and investing in solid knowledge for a long-term future. ■

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Electrical activity as a regulator of induction and the maintenance of specialised tissues

The electrical activity as a regulator of induction and the maintenance of specialised tissues is placed under the spotlight by Graciela A. Unguez at the Department of Biology, New Mexico State University in the United States

It is increasingly clear that electrical impulses – action potentials – have profound effects on virtually all organs regulated through neurons that communicate through such impulses. One such target organ that is regulated by nerve-dependent electrical impulses is the skeletal muscle in vertebrate animals. In fact, the induction and maintenance of many properties of skeletal muscle are evident by the dramatic wasting and debilitating conditions that result in humans affected by genetic and degenerative diseases, trauma, injury and the ageing of the neuromuscular system¹.

Conversely, we know that the application of neuromuscular electrical stimulation evokes involuntary muscle contractions and supports muscle mass maintenance in conditions of muscle disuse². To date, research from many labs continues to uncover ways by which the phenotypic and functional properties of skeletal muscle respond to changes in innervation – under different environmental conditions from early development to ageing.

One fundamental question that remains largely unanswered is how do the amounts or patterns of electrical activation regulate the diversity of the many muscle fibre types? Specifically, how is neural input, coupled to the

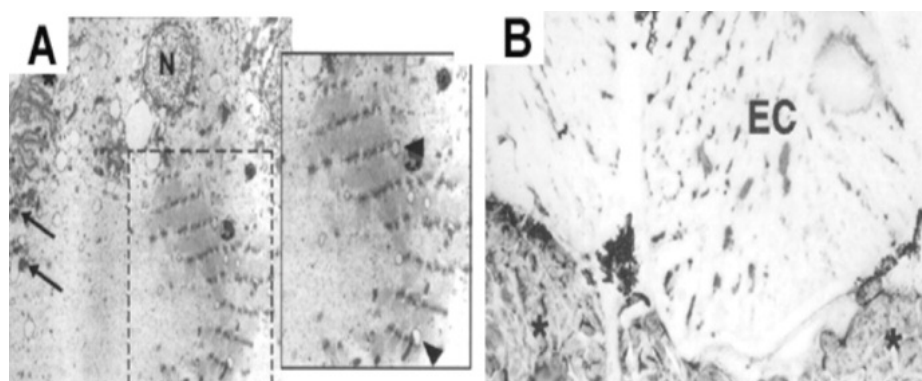


Figure 1. Electrically inactive electrocytes make new sarcomeres. **A:** Electron micrograph shows a sarcomere bundle in the electrocyte after spinal transection (see cartoon depicting inactivation of EMNs and SMNs). **N,** nucleus. **B:** Clustered anti-MHC labelling pattern inside electrocyte (EC), a pattern corresponding to sarcomeric clusters shown in electron micrographs. Mitochondria (arrows) are located peripherally near the cell membrane. (Unguez and Zakon, 1998b).

regulation of transcriptional and post-transcriptional changes of muscle genes that affect metabolism, morphology and contractility is unknown?

Moreover, the role that electrical activity patterns may play in the extreme transformation of skeletal muscle from a force-generating tissue to a specialised energy-producing, but not force-generating, tissue has only recently been addressed. Here, an evolutionary myogenic “novelty” is highlighted to raise interest in phenotypic outcomes of distinct nerve-myogenic tissue systems maintained by unique electrical impulse patterns.

In the electric fish *Sternopygus macrurus*, some skeletal muscle fibres exhibit an extreme phenotypic plasticity by

losing their contractility during normal development to give rise to electrocytes (ECs), the specialised cells that generate electricity and make up the electric organ (EO)³. ECs are also unique in that they are electrically driven by a population of spinal motoneurons called electromotoneurons (EMNs)⁴ at a continuous rate of 50-200 Hz⁵.

By comparison, somatomotoneurons (SMNs) in teleost fish innervate muscle fibres that are driven intermittently and at frequencies lower than 8 Hz⁶. We tested the idea that differences in activation patterns between SMNs and EMNs account for the differences in muscle and EO phenotypes in the adult⁷, by eliminating all motoneuronal activity to the muscle and EO tissues in adult fish.

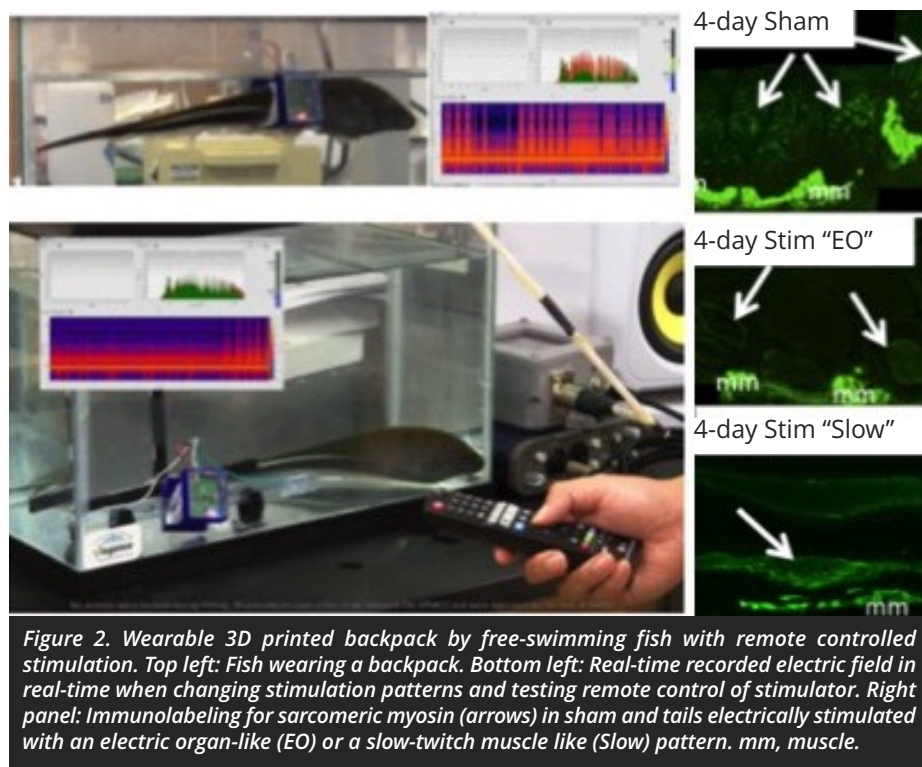


Figure 2. Wearable 3D printed backpack by free-swimming fish with remote controlled stimulation. Top left: Fish wearing a backpack. Bottom left: Real-time recorded electric field in real-time when changing stimulation patterns and testing remote control of stimulator. Right panel: Immunolabeling for sarcomeric myosin (arrows) in sham and tails electrically stimulated with an electric organ-like (EO) or a slow-twitch muscle like (Slow) pattern. mm, muscle.

Interestingly, this treatment resulted in the re-expression of sarcomeric contractile proteins and formation of sarcomeres de novo within mature electrocytes (Fig 1). Furthermore, in the absence of neural input the muscle-to-electrocyte conversion does not take place⁸.

To directly test the role of electrical activity on EC and its myogenic properties, we have pioneered a 3D-printed wearable backpack system that allows underwater chronic in vivo electrical stimulation (Fig 2)⁹. The stimulation pattern can be remotely controlled using infrared light with a TV remote controller. The stimulation pattern is adjustable by programming a micro-controller. The stimulator circuit is placed on a printed circuit board, which is placed in a waterproof circuit case attached to the backpack⁹.

Immunolabeling experiments of tails receiving different activity patterns suggest an upregulation of sarcomeric myosin heavy chain in ECs in sham controls (spinal transected only; Fig 2)

and stimulated (spinal transected and stimulated; Fig 2) tails. The ability to impose a wide range of electrical activation patterns will further our knowledge of how specific features of electrical stimulation may affect differentiation, maintenance and trans-differentiation of the skeletal muscle program.

Other myogenically derived tissues with unique non-force producing functions such as the heater organ in billfishes¹⁰ and sound organ in toad-fish¹¹ also receive neural input, that is different from that of skeletal muscle fibres. Whether specific electrical impulse patterns induce and maintain the muscle-to-heater cell and muscle-to-sonic muscle cell phenotypes in these tissues will be interesting with respect not only the degree of plasticity of the skeletal muscle phenotype, but also the evolution of “novel” vertebrate tissues. Learning more about the electrical activity patterns in a wide range of nerve-target organ phenotypes is particularly relevant in the current interest in the development

and use of electroceuticals – the use of electrical impulses to modulate the function and repair of body tissues¹².

Funding source

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Biology: Enabling discoveries for understanding life

The mission of the Directorate for Biological Sciences (BIO) at the U.S. National Science Foundation (NSF), is to enable discoveries for understanding life, as Open Access Government discovers

The clear mission of the Directorate for Biological Sciences (BIO) at the U.S. National Science Foundation (NSF) is to enable discoveries for understanding life. BIO-supported research furthers the frontiers of biological knowledge, increases our understanding of complex systems and provides a theoretical basis for original research in various scientific disciplines.

BIO supports research to advance our understanding of the principles and mechanisms that govern life itself. The research studies of BIO extend across systems that encompass biological molecules, cells, communities, tissues, organs, organisms, populations and ecosystems up to and including, the global biosphere. In addition, it is worth noting that BIO is divided into five divisions, which are:

- The Division of Biological Infrastructure (DBI);
- The Division of Environmental Biology (DEB);
- The Division of Integrative Organismal Systems (IOS);
- The Division of Molecular and Cellular Biosciences (MCB) and;
- The Emerging Frontiers (EF) Division.

To deal with ecological questions that cannot be resolved with short-term observations or experiments, NSF established the Long Term Ecological Research Program (LTER) way back in 1980. This research is located at specific sites chosen to represent major ecosystem types or natural biomes. It places focus on the study of ecological phenomena over long periods of time. According to the NSF, long-term studies are crucial to arrive at an integrated understanding of how populations, communities and

other components of ecosystems interact, as well as to test ecological theory.

One recent example of LTER's work can be found concerning scientists at the National Science Foundation (NSF) Bonanza Creek Long-Term Ecological Research (LTER) site in Alaska, one of 28 such LTER sites. Here, they are working to understand interactions between changing tree lines and plant-eating animals, like the snowshoe hare.

"This study is a reminder that there will be winners and losers as climate changes and that species' interactions with their environments will play a critical role in how the landscape changes," said Colette St. Mary, an NSF LTER programme director.¹

Another example of LTER's research is when scientists wanted to find out where the greatest risk of a mosquito bite is if you live in Baltimore, Maryland. Studying in Baltimore neighbourhoods where residents have low, median or high incomes, the scientists concluded that people are most at risk in areas with median incomes.

Providing insight into this fascinating area of research, Doug Levey, a director of the National Science Foundation's (NSF) Long-Term Ecological Research (LTER) program says: "Nature is all around us, including in downtown Baltimore. In this case, urban landscapes provide excellent habitat for rats and mosquitoes. Understanding how they live can help protect us from diseases."

Shannon LaDeau, a scientist at the Cary Institute of Ecosystem Studies in Millbrook, New York and co-author of the paper, explains that: "Mosquitoes are a global threat to public health. We're interested in knowing how



urban landscape features and social patterns influence mosquito biting behaviour.”

“Our findings suggest that median-income areas are where people are most at risk of being bitten,” adds LaDeau. “There are plenty of people for mosquitoes to bite and residents may be more likely to spend time in community gardens and shared green spaces, which makes them available to mosquitoes.”²

Staying on the subject of ecology, it’s worth looking at another example of NSF’s Long-Term Ecological Research (LTER) Program’s recent research. It concerns a study which ties phosphorus loading in lakes to extreme precipitation events. Going into more detail, the study shows that April showers contribute to toxic algae blooms, dead zones and declining water quality in U.S. coastal waters, reservoirs and lakes.

“This is an important example of how changes in one aspect of the environment, in this case, precipitation, can lead to changes in other aspects, such as phosphorus load,” says Tom Torgersen, director of the National Science Foundation’s (NSF) Water, Sustainability and Climate program, which, along with NSF’s Long-Term Ecological Research (LTER) program, funds the research.

David Garrison, chair of NSF’s LTER Working Group, comments: “This study’s findings, which depend on

long-term data, are important to maintaining water quality not only today, but into the future.”³

The above examples tell us about the guiding principles of LTER, in that long-term studies are vital to gain an integrated understanding of how populations, communities and other components of ecosystems interact. They also bring us back to the fundamental point that BIO research always aims to increase our understanding of the principles and mechanisms that govern life on earth. ■

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Next steps to the Moon: What role for Europe?

Sebastien Moranta, coordinator of studies at the European Space Policy Institute (ESPI) sheds light on Europe's potential to explore the Moon in co-operation with other great world powers

With an extension of operations beyond 2024 under discussion and promising opportunities of partnership with the private industry under development, the long-term future of the International Space Station (ISS) is not yet written.

Notwithstanding, the preparation of the post-ISS era is a central topic for the partners (U.S., Russia, Europe, Japan and Canada) who, despite multiple exchanges of ideas, declarations and precursor programmes, had been, so far, struggling to build a steady, robust and commonly-shared vision for the future of human spaceflight and space exploration. Recent events and announcements suggest, however, that the state of affairs is now progressing as agencies seem to be

converging toward a shared enthusiasm for the Moon and moving ahead with preliminary steps.

In *ESPI Brief n°12 "Making Exploration Great Again"*, ESPI highlighted the important step forward made by the American administration in the field of space exploration with the signature of NASA's Transition Authorization Act by President Donald Trump in March 2017. The document underlined a strong willingness of the U.S. to engage more actively in human space exploration with the development of a Deep Space Gateway (DSG) in cis-lunar orbit as the next programmatic step to prepare the journey to Mars.

Although building on past projects (e.g. the Space



SPACE POLICY

Council directed NASA to develop a plan within 45 days to carry out that revised policy. This presidential declaration and the development of a plan by NASA further consolidate both political support and programmatic implementation of the rehabilitated U.S. strategy.

Secondly and perhaps more importantly, the DSG gained an official international dimension with the signature of a joint statement by Roscosmos and NASA on 27 September 2017 at the 68th International Astronautical Congress in Adelaide, Australia. Although NASA had already been discussing technical options for the DSG concept with ISS partners through the ISS Exploration Capabilities Study Team (IECST) and International Spacecraft Working Group (ISWG) during meetings in Japan, Canada and Europe in 2017, the joint statement, focusing at the moment on preliminary studies, marks a noticeable milestone in the development of an international cooperation structure around the DSG project.

Regardless of the U.S.'s considerable financial and technical resources, international cooperation will be critical to achieving ambitious objectives, to secure programme stability and to consolidate U.S. leadership on the global scene. From this perspective, the acceleration observed recently suggests that the DSG provides a more fertile environment for international partners to contemplate a financially and technically conceivable contribution to the programme, than previous plans developed under the Obama administration did.

This being said, it is important to recall at this stage that, despite a strong political support, the programme still has to face major hurdles before becoming a reality. This includes the definition of an architecture meeting various objectives from different partners, the allocation of an appropriate budget (which may be challenged by the willingness to also expand ISS operations) and eventually an official endorsement by U.S. and international partners' establishments.

Nevertheless, partners can now build on an existing and robust multinational cooperation framework, such as the one of the ISS, which will undoubtedly simplify future political and programmatic progress. Overall,

Launch System and Orion capsule), U.S. plans marked a turn from the Obama administration's "Low Earth Orbit-Asteroid-Mars" path and a come back to the former "Low Earth Orbit-Moon-Mars" Constellation programme, supported by the Bush administration. Two major announcements recently highlighted a solidification of this renewed U.S. posture and confirmed the emergence of an international cooperation dimension.

Firstly, during the meeting of the re-established U.S. National Space Council on 5 October 2017, Vice-President Mike Pence delivered an engaging speech calling for a return to the Moon in cooperation with international and commercial partners under American leadership. The

in a context where drivers seem to outweigh barriers, the DSG seems particularly close to becoming the next stage of international cooperation in space exploration.

Another interesting factor that will certainly have to be closely looked into is the role that China may play in the future. As of today, with the Chinese programme ramping up toward the Moon and multiple legal and political constraints for NASA to engage in cooperation with China, the situation suggests that, following Cold War competitive era and ISS cooperation era, the third era of space exploration will very likely give way to a mix of cooperation and competition for leadership.

Regardless of the U.S.'s considerable financial and technical resources, international cooperation will be critical to achieving ambitious objectives, to secure programme stability and to consolidate U.S. leadership on the global scene.

What role for Europe?

Europe is already engaged, through ESA (The European Space Agency) and at a national level, in technical discussions with NASA and other partners and organised various consultations about the DSG. Maintaining such active dialogue will be essential to get an informed understanding of the evolution of the project and of European industrial and scientific communities' interest and to secure an active participation in the concept definition. Assuming that Europe intends to play a prominent role in the DSG, as it did for the ISS, the acceleration of the project on both the American and international scene now requires Europe to bring the topic to a higher level and to reach a political momentum.

As a partner, European decision-making process obviously depends on the progress of programme approval by U.S. institutions; yet, reaching a shared European position will require a preliminary effort to build a political consensus, if not unanimity, among the Member States. Achieving this consensus shortly is a necessary condition to secure Europe capacity to react timely to future evolutions on the American and international scene and to already position Europe as a key partner.

When looking at the rehabilitated Moon objective and taking into account that current DSG plans foresee robotic and human Moon landings, one cannot overlook the renewed light that is shed on ESA Director General's Moon Village vision. Indeed, the current dynamic of the international space exploration scene could offer an interesting springboard for Europe to implement, at least partially, this ambitious vision.

With the declared objective to prepare a journey to Mars, the deployment of a Moon Base as a potentially European-led component of an international DSG programme would certainly offer a relevant test bed for the development and validation of key capabilities for future Mars mission such as in-situ resource utilisation, robotic-human cooperative operations or ground base assembly among many others. In general, the role that Europe will hold within the next international partnership framework will be first and foremost framed by the financial and technical resources it is ready to commit. ■

Available for download from the ESPI website at:
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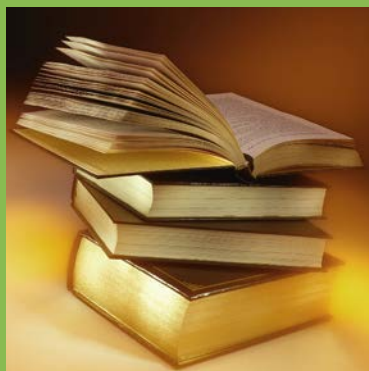
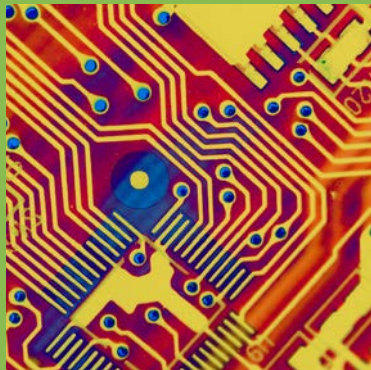
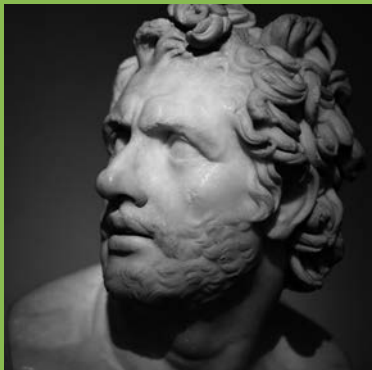
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Space: Reaching out to new heights to benefit mankind

Open Access Government reveals the exciting mission of the National Aeronautics and Space Administration (NASA) and how the United States aims to reach out to new heights to benefit mankind when it comes to exploring space and beyond

The National Aeronautics and Space Administration (NASA) prides itself in the collaboration of technology, science and unique global Earth observations to provide societal benefits and strengthen the United States. NASA's succinct vision for the past and present has always remained the same. "We reach for new heights and reveal the unknown for the benefit of humankind."⁽¹⁾

Leading the way back to the Moon

In February 2018, NASA Administrator Robert Lightfoot spoke about the Fiscal Year 2019 agency budget proposal and remarked how it reflects the US administration's confidence that through the leadership of NASA, America will lead the way back to the Moon and take the next giant leap from where they made that first small step almost 50 years ago. Firstly, he explained how the budget focuses NASA on its core mission and how it will help to place a renewed focus on the U.S.'s human spaceflight activities.

"This budget focuses NASA on its core exploration mission and reinforces the many ways that we return value to the U.S. through knowledge and discoveries, strengthening our economy and security, deepening partnerships with other nations, providing solutions to tough problems and inspiring the next generation. It places NASA and the U.S. once again at the forefront of leading a global effort to advance humanity's future in space and draws on our nation's great industrial base and capacity for innovation and exploration.

"This proposal provides a renewed focus on our human spaceflight activities and expands our commercial and international partnerships, while also continuing our pursuit of cutting-edge science and aeronautics breakthroughs at the core of our mission."

Lightfoot then went on to explain how the United States is once again on the path to return to the Moon, also with an eye towards Mars. He said that NASA is called to refocus existing activities towards exploration, by redirecting funding to innovative new programmes, as well as support for new public-private initiatives. Here, he expands on these ambitious goals in his own words, as well as explaining how the International Space Station (ISS) will be the cornerstone for pushing human presence further into space.

"Webb is the highest priority project for the agency's Science Mission Directorate and the largest international space science project in U.S. history. All the observatory's flight hardware is now complete, however, the issues brought to light with the spacecraft element are prompting us to take the necessary steps to refocus our efforts on the completion of this ambitious and complex observatory."

"We are leveraging multiple partners both here at home and internationally in developing a sustainable approach where the Moon is simply one step on our truly ambitious long-term journey to reach out farther into the solar system to reap the economic, societal and expanding knowledge benefits such an endeavour will bring.

"We've used the International Space Station (ISS) as the cornerstone for pushing human presence farther into space, with a horizon goal of humans to Mars. This includes learning about the human physiology of spaceflight and enabling new industry partners to bring to bear their capabilities and emerge as leaders... to help us on this journey. The commercial cargo and crew work continues through the life of the International Space Station in the budget."⁽²⁾

Lightfoot adds that while the Fiscal Year 2019 agency budget proposal does not provide funding for an Office of Education, NASA's mission successes will nevertheless continue to inspire the next generation to take up studies in science, technology, engineering and mathematics. Lightfoot believes that the next generation will become the diverse workforce of the future, where aerospace careers are concerned. He went on to develop this point, adding that NASA will help the United States lead the way in the space sector, despite the hard choices that have had to be made.

"We will use every opportunity to engage learners in our work and the many ways it encourages educators, students and the public to continue making their own discoveries.

"We can't do everything and as always, we've had to make hard choices, but we will continue to forge new paths and partnerships that strengthen our industrial base and our engagement with other nations to achieve challenging goals that advance our capabilities and increase our security and economic strength. NASA will continue to deliver on the promise of U.S. ingenuity and proven leadership in space."

In other interesting news, we also find out that NASA's James Webb Space Telescope is undergoing final integration and test phases that will require more time to ensure a successful mission. Following an independent assessment of remaining tasks for the highly complex space observatory, the launch is now targeted for around May 2020.

Lightfoot comments more on this ambitious aspect of NASA's work: "Webb is the highest priority project for the agency's Science Mission Directorate and the largest international space science project in U.S. history. All the observatory's flight hardware is now complete, however, the issues brought to light with the spacecraft element are prompting us to take the necessary steps to refocus our efforts on the completion of this ambitious and complex observatory."

Also, worth noting is that Webb has already completed extensive tests to make sure it reaches its orbit safely,

at almost one million miles from Earth. As with all NASA projects, rigorous testing takes time, which of course, increases the likelihood of the mission being successful. Thomas Zurbuchen, an associate administrator for NASA's Science Mission Directorate, comments on this point: "Considering the investment NASA and our international partners have made, we want to proceed systematically through these last tests, with the additional time necessary, to be ready for a May 2020 launch."⁽³⁾

NASA believes that the James Webb Space Telescope will be the world's premier infrared space observatory and the biggest astronomical space science telescope ever built, complementing the scientific discoveries of NASA's exciting missions, such as the Hubble Space Telescope. Webb will explain the mysteries of the solar system, look beyond to distant worlds around other stars probe the mysterious origins and structures of the universe, as well as our place in it. This fits in perfectly with NASA's mission to: "reach for new heights and reveal the unknown for the benefit of humankind." ■

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Rediscovering blockchain and bitcoin in Europe

Antanas Guoga MEP shares his views on why 2018 is an important period for rediscovering blockchain and bitcoin in Europe

Beyond the power of Bitcoin, 2018 is an important period for rediscovering blockchain technology beyond the massive craze over bitcoin and other cryptocurrencies. Beyond the race of ICO projects, this is going to be the winning year for everyone in the blockchain industry as business and governments are looking for effective ways to implement this revolutionary technology. The falling cryptocurrencies market will cool down those who are looking only for profit and will reveal the real hard-workers. This is where both national and European, governmental, business and non-profit players can step in and embrace the innovative technologies for the growth of business and the empowerment of citizens.

Europe should invest more

Here, at the European Parliament, we are having series of discussions on innovative technologies, especially artificial intelligence (AI) and blockchain technology. It is now obvious that Europe wants to lead the way in these areas, however, today we are far behind others, even Asia. These innovations create enormous opportunities for many traditional industries. However, we need to separate the bitcoin madness from other potential applications of blockchain technology. I truly believe in it and the goals behind it, including transparency, decentralisation and security.

Although the technology has many future-oriented applications, there is speculation about it. I do not support the latter. For blockchain investors, I would always suggest considering the projects that create value. I am hopeful we will allocate enough resources and funding from the governmental level for research into and the massive application of blockchain. To the maximum extent – I believe that this is essential for our future – that is the synergy of artificial intelligence (AI) and blockchain technology. This is where the major invest-

ment needs to go, starting from the government up to the corporate level. I believe that everybody in Europe should invest. Moreover, everybody should invest in both knowledge and skills to become successful.

Clear signs from the European Commission

I strongly support the European Commission's direction to consider the usability of blockchain technology. In this vein, the Fintech action plan has already been presented. The European Blockchain Observatory and Forum – have just been launched. I hope that this is going to be a very progressive engine that is going to take blockchain to new European heights. In addition, it is a clear sign from the European Commission that they care about blockchain in Europe. I strongly support, and I hope to contribute towards this. I encourage everybody to contribute their expertise, sharing events and other initiatives via <http://eublockchainforum.eu>.

Status quo: self-regulation

I have noted that one of the most popular discussion topics in Europe concerns the question of regulation – or lack of it, to be more precise, particularly related to ICOs and cryptocurrencies. We see regulatory measures in China, South Korea, the US and by some European governments and central banks – all of whom are taking a cautious approach towards the technology. As a member of the European Parliament, my policy objectives are to have a wider viewpoint, before deciding on whether regulatory measures are necessary, especially when it comes to innovation.

Every European will be using blockchain and will understand its benefits and opportunities in the future, in spheres such as national registers, health insurance, financial projects and so on. The enabling of a regulative approach is taking the lead now and this is how we can attract innovative investment into



Antanas Guoga MEP

Group of the European People's
Party (Christian Democrats)

Europe. The longer we have non-restrictive regulation – the better. I think the status-quo is self-regulation. We saw Google, Facebook, Twitter taking down ads about cryptocurrency, ICOs and in the end, I think, this area will self-regulate.

Education – a priority

Education in blockchain technology is crucial for everyone to succeed and benefit from what the technology offers. It is important to unite our efforts and invest our knowledge into changing the world for good. Significant actions have already been taken with the first international Blockchain hub in Europe – Blockchain Centre Vilnius – in January. These are some of the reasons for founding the Blockchain Centre Vilnius.

It is the first facility of its kind on the continent. The global network of blockchain centres includes Melbourne, Shanghai and now, Vilnius. It is a not-for-profit knowledge-hub, co-working space and incubator for blockchain technology companies. The chain started with Australia's Melbourne Blockchain Centre. Drawing on the experiences of the Melbourne location – which brands itself as a community of more than 2,000 blockchain technology entrepreneurs, experts, mentors and investors – the new facility's founders say they hope to benefit from Lithuania's favourable climate for digital businesses. Lithuania is a great place to invest in and there is a growing recognition in Europe that the country has gained an edge in terms of financial and digital innovation, as well as an innovation-friendly regulatory climate.

The first mover advantage

As a Lithuanian MEP, I am glad that the Australian and Asian blockchain communities selected Lithuania as the network's first location in Europe due to its political and economic stability and relationship with the European Union, as well as having favourable business and regulatory environments. It is in line with the overall

positive attitude of the European Union institutions, who are all ready to embrace the new technology.

Here in Lithuania, we are pulling out the stops to bring the world's top blockchain talent, ideas, investors and regulators together to create value for both the private and public sectors. Lithuania, for the last three years, has strengthened its reputation in this area – in our central bank and our investment community has been actively developing fintech industry, introducing LBChain, a sandbox to test blockchain initiatives. This has provided us with a lot of information and know-how.

I think Lithuania has many opportunities to bring different businesses and start-ups into the blockchain area. And initiatives like the blockchain centre in Vilnius will help people to deliver on projects and promises. I think we are delivering and empowering. I hope that Lithuania is going to lead the forefront of blockchain projects because we have the first mover advantage.

Witnessing the future

In conclusion, we are witnessing a completely new technology emerging that will revolutionise the way governments, companies and people access information. It has demonstrated how trust is created on a massive and global scale – so, blockchain technology enables people to feel safe, secure and confident. It is a very transparent system. Moreover, it just keeps expanding. I believe that several world-changing start-ups will emerge. I know there will be much activity coming from the blockchain centre in Vilnius, the first international blockchain centre, connecting both Asia and Australia. ■

MEP A. Guoga was elected for top 200 fintech influencers. You can find out more at www.lattice80.com/top-200-fintech-influencers-europe/

Antanas Guoga MEP, Blockchain Centre Vilnius and the diplomatic representations to the European Union cordially invite blockchain industry stakeholders to a high-level Intercontinental Blockchain Conference: "Blockchain - The Game Changer of the 4th Industrial Revolution", on the 24th May, at the European Parliament, Brussels, Belgium. Admission is free. Register at: <https://goo.gl/Lykwo2>.

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How trusted data is helping to liberate the power of medical cannabis

Bradley Moore, CEO of GCAC discusses how artificial intelligence and blockchain (trusted data) solve the paradox of limited medical cannabis data and anecdotal user information

Jane Carter is an active young woman in her 30s who works as a software engineer, likes the outdoors and is planning to raise a family. Jane also has epilepsy.

As someone who has dealt with the condition her whole life, Jane is accustomed to maintaining control over her seizures. However, when her usual medication started to feel less effective, Jane confessed her concerns to a friend, who suggested medical cannabis as a potential treatment. Jane had never considered this possibility, but when she tried to learn more about it, she struggled to find trustworthy sources. Therefore, she turned to her physician, Dr Lisa.

Dr Lisa told Jane that although the benefits of cannabis have been discussed among doctors for a few years, she herself hadn't yet seen any evidence from reputable studies showing clinical benefits of cannabis. The doctor explained that as a practitioner and a scientist, she liked to have solid evidence and clinical experience before she prescribed medication to her patients; therefore, she would not prescribe cannabis to treat Jane's epilepsy.

Jane's story is not unique and illustrates the medical cannabis paradox.

The medical cannabis paradox

The medical benefits of cannabis – including pain management, seizure

remediation, muscle spasms management and others – have been well known for centuries. However, over the past century, cannabis has become a proscribed substance and treated as a law-enforcement challenge. As a result, it has become difficult for researchers to get approval and funding for properly controlled cannabis studies and users are unable, or unwilling, to share their experiences. Consequently, doctors and other practitioners lack trusted information on which to base clinical decisions.

Altogether, these factors have led to significant under-prescription of medical cannabis, there has been a large, unfilled demand for quality research, new product delivery methods and consumer information on the uses and effects of this substance.

The Citizen Green community

In an effort to bring together the global medical cannabis community and motivate its members – including patients, practitioners, scientists, cultivators and manufacturers – to share their knowledge of and experiences with medical cannabis, Global Cannabis Applications Corporation (GCAC) has developed the Citizen Green platform. This cutting-edge platform will facilitate the sharing of information between consumers, caregivers and researchers, as well as regulators and members of other

industries, such as healthcare and cosmetics.

The Citizen Green platform is powered by the following technologies: CannaCube database, artificial intelligence (AI), mobile apps and blockchain.

AI, Chatbot and CannaCube

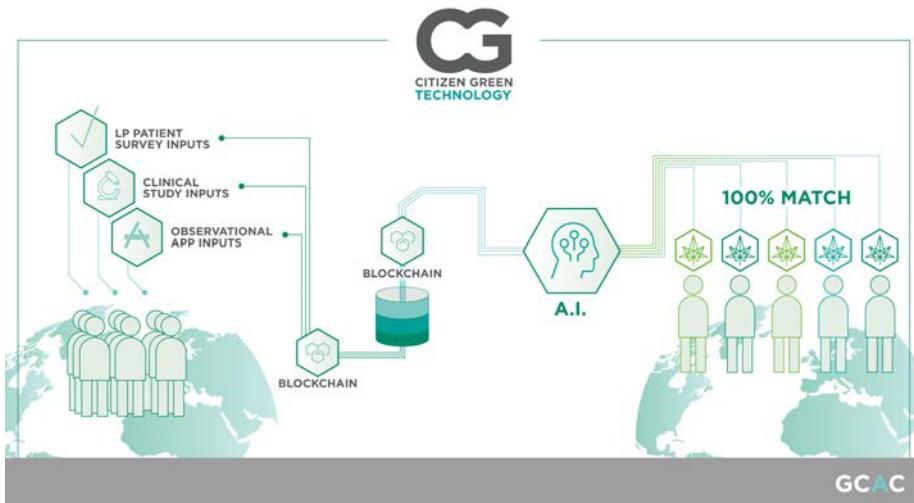
Artificial intelligence provides GCAC with the ability to bring to life all of the data collected and managed.

AI is used for multiple applications in our platform: chatbot, advanced analytics, predictive analysis and machine learning tools. And its capability to integrate observational and clinical research findings allows us to offer deeper insights and better outcomes for patients and the entire community.

The AI models the relationship between patients' demographics and medical conditions, medical cannabis features and treatments effectiveness, thereby closing the loop between "pain and strain". (TM pending)

Sanna, GCAC's proprietary chatbot, facilitates stronger engagement with its adaptive user experience and personalised recommendations via our apps, CannaLife and Prescriptii. The chatbot will grow smarter over time as it will bridge missing information in users' profiles.

CannaCube is GCAC's medical cannabis database. Equipped with



world-class data encryption and storage, this database curates ‘noisy’ data aggregated from CG apps, doctor references, social listening and various industry inputs against thousands of clinical study reports for validation and expansion of the data sets.

Mobile Apps

The client-facing components of Citizen Green are two easy-to-use mobile apps: CannaLife and Prescriptii. Connected by the CannaCube database, these apps collect and share 360-degree data relating to medical cannabis production, research, prescription and usage.

CannaLife is an app for networking, sharing peer-to-peer feedback and searching experiential user data related to cannabis consumption and consumer behaviour. Using screen capture technology, users can find information on medical cannabis, create a post and share it with other like-minded users. Then, when seeking information, users can call upon Citizen Green’s chatbot, Sanna, who, coupled with the world’s first cannabis-specific Google search engine, helps them find answers to specific health and cannabis queries.

Prescriptii is the first consumer-facing app for medical cannabis license holders. It takes users through an ailment-related questionnaire and

based on CannaCube analysis, recommends the appropriate products to the condition described. An interactive map helps users to find nearby retailers that offer the recommended products.

Sanna, the chatbot, encourages users to evaluate their experience with the cannabis prescription. Fed back to CannaCube this information optimises further recommendations and can help patients and their practitioners to assess.

Blockchain

The GCAC blockchain gives medical cannabis users ownership over their data in a secure and encrypted environment. Unlike centralised applications, blockchain uses a distributed, decentralised digital ledger to record all transactions. GCAC recently released a White Paper discussing the digital token it is introducing on the blockchain to incentivise users.

How CannaLife Changed Jane’s Life

When Jane saw a news report about the CannaLife app, she was intrigued enough to install it and as she familiarised herself with the Citizen Green community, she found many stories from other epilepsy sufferers. This made her reconsider how cannabis might help her own condition.

Jane presented Dr Lisa with CannaLife, showing her the large database of anecdotal patient information, as well as research studies and manufacturers’ results. After reading a large number of consumer testimonials and some of the research, Dr Lisa felt confident enough to prescribe Jane a medical cannabis license, using the Prescriptii app as a guide. Three months later, Jane’s epilepsy symptoms had decreased considerably, and she very rarely had seizures.

As she works with Jane on her progress in Prescriptii, Dr Lisa is getting a feel for what other treatments work best with medical cannabis. She will definitely be using the app as part of her diagnostic toolkit going forward.

Jane, meanwhile, has returned to a much-improved quality of life. She is back to coding, rock-climbing and considering with her husband whether it is time to try for a baby.



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Reinventing the collaborative economy with blockchain

The ERC research project P2P Models aims to use blockchain-driven Decentralized Autonomous Organizations (DAOs) to boost a collaborative economy which is decentralised, democratic and where profits are distributed, as the university's researcher, Professor Samer Hassan reveals

The collaborative economy is not what we were promised. Inspired by Wikipedia, it emerged from the idea of a peer-to-peer networks of citizens, sharing and collaborating for the common good, in every field. However, today we can observe how digital monopolies concentrating data, resources and power are the new normal. Instead of decentralizing the power of traditional institutions, we can see how the platform economy is creating larger than ever monopolies: Uber is larger than any taxi company, Airbnb than any hotel chain, Google than the traditional providers of infrastructure and Facebook governs more than 2 billion users.

This market dominance has, of course, some benefits of the services they provide, but it is not without serious drawbacks, in a context where scandals are common. For example, the terrible labour practices in Uber or Deliveroo, privacy-hindering services by Google, regular collaboration in mass surveillance programmes by most major companies as revealed by Edward Snowden, or Facebook's Cambridge Analytica mess. Even worse, any new start-up aims to either be absorbed by these giants or become the new monopoly in a non-platformed field. Is this science-fiction pseudo-dystopian scenario all we can expect? What would it take to change the rules of this nasty game?

P2P Models is a €1.5 million, five-year interdisciplinary research project, funded by the European Research Council (ERC) and awarded to [Samer Hassan](#), a researcher at both the [Berkman Klein Center for Internet and Society at Harvard University](#) and [GRASIA at the Universidad Complutense de Madrid](#) in Spain. The growing Madrid team comprises of computer scientists, social scientists, activists and hackers.

The P2P models vision

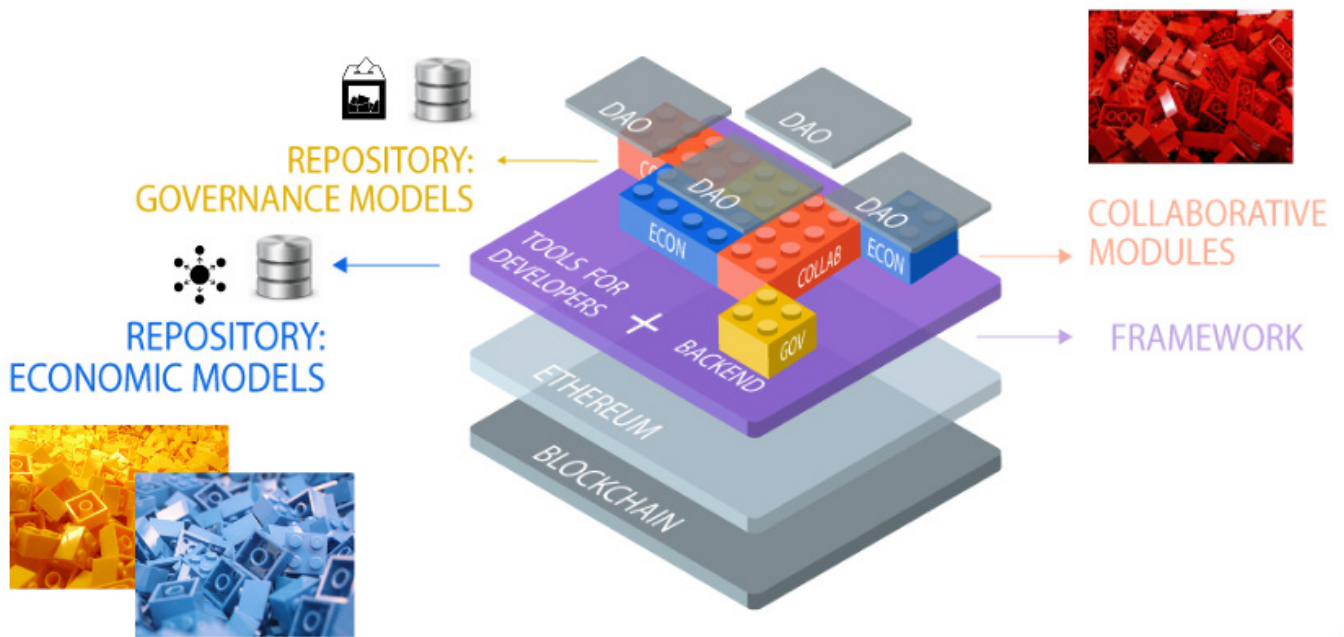
A new research project has the ambitious aim of facilitating the emergence of a different ecosystem. [P2P Models](#) has a simple yet challenging research question: can we build online platforms in a different way? Can we build collaborative economy platforms which are decentralised, so there is not a single owner of the whole infrastructure? Can we build platforms where the decision-making is democratic, involving their users, which may become empowered? And yet, can we make such platforms in a way in which the profits are distributed across the users?

The project will harness the potential of the blockchain to tackle these issues. However, instead of focusing on finance and crypto-currencies, the project will explore the potentials of Decentralized Autonomous Organizations (DAOs). The idea is to replace the traditional online platforms like Airbnb, which rely on a centralised server infrastructure controlled by a single actor, with the serverless DAOs hosted and executed

in a decentralised blockchain network. Such DAOs may embed the rules for the users to interact with each other in a peer-to-peer manner.

Thus, we can easily imagine a decentralised Airbnb developed in that way. Moreover, users could vote for which changes they would like to see in their DAO-platform, thus empowering them in the process. Then, we could see an ecosystem of multiple decentralised Airbnb's, with different features depending on what their community has decided, for example, some totally anonymous, others with a high insurance in case something goes wrong, or others adapted to a local culture.

Without the strong dependency on platform owners, profits could be more distributed, and users rewarded in multiple forms (for example, cryptocurrency, votes, reputation, shares). In such an ecosystem, interoperability provides a competitive opportunity, since the users and even their reputation, are shared across the ecosystem (sharing the same



blockchain), instead of locked in a single platform... allowing new start-ups to reach a faster critical mass, sharing users and even components with other companies. In such an ecosystem, barriers to entry are lower, competition is higher and dominant positions are harder to maintain.

New governance & economic models

If that vision is to be realised, at least partially, the building of DAOs is critical. Thus, the project will build both a framework and tools to enable the modular construction of DAOs, especially those providing collaborative economy features. Therefore, the project will build "lego's" or building blocks, embedding different features, so that developers may combine them to deploy their new platform. By being a fully free/open source platform, anyone could build their own building blocks for their specific needs and if desired, contribute them for others to use.

In the same way, other series of building blocks will embed governance models and economic models, focusing on democratic and redistributing

approaches. The characteristics of blockchain and smart contracts enable the automated execution and enforcement of rules in a decentralised context. Thus, the project will allow user communities to be governed, at least partially, by explicit rules embedded in the code. This may allow democratic rules that make these communities more inclusive and equal, for example, considering gender, minorities or low-income profiles.

Furthermore, blockchain, through its tokenization, facilitates the distribution of value. However, tokens may be much more than cryptocurrencies, alternatively representing equity, decision-making power, non-transferable reputation, or even property ownership digital certificates. This may enable the emergence of new business models, where user participation is rewarded.

P2P Models will perform social research, codesign pilots with communities, build a testbed for researchers... all with the aim of moving from an ecosystem controlled by Silicon Valley centralised monopolies – to an open interoperable ecosystem.

Today, with the help of blockchain, there is a window of opportunity to change the rules of the game. Will the project manage to avoid the dystopia?



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The bitcoin and cryptocurrencies market

Olivier Forgues, CEO of the EUROPEAN CRYPTO BANK Project explains the first bank and trading platform protecting its investments in the bitcoin and cryptocurrencies market

EUROPEAN CRYPTO BANK launched its Initial Coin Offering (ICO) on the blockchain on February 15th, 2018 to build the first bank and trading platform protecting its investments in the bitcoin and cryptocurrencies market. Faced with the observation of a lack of regulation, financial and tax specialists, computer scientists, mathematicians, blockchain engineers have partnered to build a European bank and thus meet the expectations of investors by providing banking and trading services, secure, flexible and scalable. The Artificial Intelligence Research Laboratory will be in Paris, the tax assistance department in Milan and the exchange and trading platform in London.

Today, one of the biggest problems crypto investors face is the difficulty in converting their investments into traditional assets. And clearly, the banking system is hostile and unfriendly.

Cryptocurrencies look like the serious competitor to the traditional process of banking and a lot of financial institutions stop accepting crypto exchange money and try to give a hard time to crypto owners and investors.

European Crypto Bank wants to reply to the growing requirements of Crypto holders and the market that we want to disrupt is a massive one, with over €8 trillion being circulated daily in the financial sector alone. If you consider the close to \$500+ billions that make



the cryptocurrency market, you realise that the first fintech ICO that will have a viable product has an immense opportunity. Today, most of coins and tokens holders need to declare their profits and need assistance to manage their wallet with financial advisors who master markets volatility.

From the investment side of our business, ECB will include an exchange and trading platform and leveraged services on cryptocurrencies and FIAT. Furthermore, ECB will provide portfolio management, wealth management and financial analysis on crypto-currencies, will help people for life planification with crypto-assets and finally will create gateways to all investments universe (real estate, art, gold, traditional financial assets (stocks, bonds and managed funds), private equity and alternative investments...)

From the tax side of our business, ECB will provide services to calculate the benefits people will have to declare to their tax administration and will give to them a tax reporting and a tax guide.

Furthermore, we will carry out tax optimisation and will provide a crypto expert tax lawyer in their country in case of tax litigation.

In that case, the blockchain will help ECB to transfer a payment in ECB Tokens to lawyers, in respecting the right to stay anonymous when a customer need lawyer assistance (a worldwide human right).

The team behind European Crypto Bank already has the KYC and AML software and they've been using it for the past nine years in their wealth management business. ECB will be

the platform that allows anyone in the world to make crypto investments and benefit from the same services traditional banks offer for fiat money.

The approach taken by European Crypto Bank is quite unique. Indeed, the token associated with the project (ECB) is a swap between two different tokens: One for investing and one for tax defending.

ECB TOKEN I, is for investments (access to the research, trading, etc...) and private bank services. Token I is non-anonymous. Token holders will enjoy, every year, a buy back with 6% of ECB annual turnover. Token I will be tradable and convertible to token S or usable.

ECB Token S for tax services and tax litigation on cryptocurrencies and anonymous. Token holders will get, every year, 5% reward program. Token S is tradable and convertible to ECB token I or usable.

All ECB Tokens selected by the token holder at the end of the ICO will be tradeable and listed in several exchanges.

ECB's main target is to become a fully regulated Crypto Bank in Europe over the next four years. This will act as a gateway between owners that want to exchange crypto and owners of traditional assets (shares, bonds, real estate, art, ...) - providing an easy and secure way to do these conversions.

Since 20th March 2018, EUROPEAN CRYPTO BANK partners with ARCHOS to distribute the ARCHOS Safe T mini under the brand name of EUROPEAN CRYPTO BANK. As per the terms of this partnership, holders of more than

600 ECB Tokens, whose current ICO finalised on May 1st, 2018, will receive a hardware wallet, which will then be available for purchase at a price of €49.99. In addition, the European Crypto Bank will transfer 150,000 ECB Tokens to ARCHOS, as part of its R&D investments.

“Cryptocurrencies look like the serious competitor to the traditional process of banking and a lot of financial institutions stop accepting crypto exchange money and try to give a hard time to crypto owners and investors.”

This wallet provides secure management and storage of crypto-active, safe from cyber threats:

- Identification by PIN;
- Offline private key generation;
- Management of operations on the device, offline;
- On-screen display of information about each transaction for an easy verification before approval;
- Physical authorisation with buttons;
- The creation of a recovery code (consisting of 24 words), essential in case of breakage, loss or theft;
- Support for ECB and major cryptocurrencies and;
- Compatibility with Electrum, GreenAddress/Greenbits, MyCrypto and Mycelium.

In addition to these functionalities, ARCHOS will also provide all the EUROPEAN CRYPTO BANK's multilingual platform services, accessible at

the end of its ICO from May 1, 2018: portfolio statements, research notes, investment advice, conversion of crypto-assets into traditional currencies and generation of corresponding tax declarations according to the various regulations in effect in Europe.

EUROPEAN CRYPTO BANK and ARCHOS join forces to facilitate access to Blockchain's cryptocurrencies, products and services, by the greatest number, whatever the level of experience, in the respect for the rules established taxes.

The easiest way to contribute to the European Crypto Bank ICO sale is to pay directly to cryptocurrencies. You can also purchase via wire transfer and by sending a cheque. For details on what information to put when doing a wire transfer/check visit their site: www.europeancryptobank.io.



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Crypto winter, or blockchain spring?

After a stunning rally at the end of last year, cryptocurrencies have lost almost two-thirds of their value. This is not necessarily bad news for the blockchain industry, says the Crypto Valley Association's Tom Lyons

What a difference a few months make. In 2017, we experienced a rally in the value of cryptocurrencies the likes of which had rarely been seen before. Bitcoin, which began the year trading at \$1,000 ended it close to \$20,000. Ether, the second-largest cryptocurrency by market cap, went from just under \$8 to nearly \$1,300. The story was similar for many, if not a majority, of the other 1,500 or so cryptocurrencies currently in existence.

This rally meant huge windfalls for anyone lucky enough to have bought in early. For those of us who work in blockchain – the technology that makes Bitcoin and other cryptocurrencies possible – it was hard not to see the rally as a validation of what we were doing.

For example, one of the factors driving the crypto rally had been a concurrent boom in initial coin offerings, or ICOs – a way for blockchain-based projects to raise money by creating their own cryptocurrency or token on a blockchain and selling it directly to investors. In 2017, more than 300 ICOs had come to market raising some \$5 billion for projects covering a vast array of use cases, from financial services, health records and supply chains to aiding refugees and combatting human trafficking.

As we popped the champagne on New Year's Eve, we could be forgiven for interpreting the ICO boom as a public vote of confidence in this nascent industry.

Yes, there were problems – as in any endeavour involving significant sums of money, ICOs have had their share of scams and cons – but overall it seemed clear that not only the ICO model, but the basic blockchain paradigm, was working. Then overnight, it seemed, the wind changed.

Reversing course

Through the end of March, bitcoin had lost almost two-thirds of its value, dropping back down to \$6,000. Ether dipped to around \$400. The market capitalisation of all cryptocurrencies shrank from \$800 billion to just under \$250 billion.

And while the ICO market continues its impressive growth, with a number of headline successes, behind-the-scenes we were seeing increasing numbers of token sales failing to meet their targets, or simply failing. Among investors and others, a general sense of doubt and unease set in. What happened?

One factor has been a regulatory clampdown on ICOs in several important jurisdictions, particularly the US. That has sent a chill through the industry. You could also rationally argue that the dramatic price spikes of 2017 were simply not sustainable. As crypto naysayers have maintained, this did look like a classic bubble that was bursting.

Whatever the reason, the icy winds of the 'crypto winter' have been bracing. Suddenly, we could wonder if the price of bitcoin, as some had predicted, might not just fall to zero. Perhaps crypto, in general, was destined for the same fate as past bubbles like tulips or the South Sea Company – a wild speculative ride based on little of sustainable value.

Just as well

Such a view, of course, is as irrationally pessimistic as the view that bitcoin would never correct was irrationally exuberant. While blockchain-based cryptocurrencies get all the headlines, as many of us have been at pains to point out, blockchain has many other important uses besides money. The price of bitcoin is therefore

not a very good proxy for the overall health of the industry.

Quite the contrary, the frothy speculative phase we have just been experiencing can be taken as a sign of progress: just think of the dotcom bust of the early 2000s, which seemed like a death knell at the time but in hindsight proved to be the starting bell for the rise of the global Internet and all the wildly successful enterprises associated with it.

We can see something similar at play today. Despite the crypto bust, for instance, governments remain largely committed to blockchain technology. Here in Switzerland, the regulator recently published [ICO guidelines](#) designed to foster innovation by providing some regulatory and legal clarity for blockchain projects and the Swiss Economics minister reiterated the country's determination to become "[crypto nation](#)".

In Europe, the EC just started a major two-year initiative called the [EU Blockchain Observatory and Forum](#) to support this technology throughout the bloc. And even the US regulators, while taking a tough stance on crypto-speculation, have made it clear that they are [keen not to squash innovation](#) in this space.

Perhaps more importantly, all over the world development of blockchain technology and its application to a wide number of problems goes on, a sign that [a major industry](#) is indeed coming to life here.

A necessary update

This is important not just for business but, in my opinion, also for the world.

A technology for creating consensus on information among large groups without the need for central authorities, blockchain supports trust, fairness and transparency while also protecting privacy. With it, we can build what many are calling the Web 3.0 – an Internet in which information can be trusted and individuals can better control and protect their data.

Considering the major data and propaganda scandals we are experiencing in today's Internet, this would be

a radical – and highly necessary – improvement. It is also likely to mean big business.

As in many other locations, at the [Crypto Valley Association](#) in Switzerland, we are working hard to look beyond the cryptocurrency hype to foster the sustainable industries, as well as jobs, that will grow out of blockchain.

On this, we remain quite bullish. If we have learned anything from the bracing winds of the crypto winter it is that this work will be difficult and will likely take longer than many had originally thought. But that too, as [Amara's law](#) reminds us, is typical of truly transformative technologies.

I, therefore, like to think of the present moment not as a crypto winter, but as more of a blockchain spring.

Even if we look at our somewhat flawed cryptocurrency bellwether, the forecast looks bright enough. As of this writing, the price of bitcoin seems to have stabilised in the \$6,000-\$7,000 range and ether in the \$300-400 band.

A disappointment perhaps compared to the heady days of last November and December, bitcoin still returned 600% over the past 15 months. Ether, close to 5,000%.

By any measure that's a remarkable achievement. For me, it is also a sign of rude health. ■

Tom Lyons
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AI & blockchain to empower 1 billion entrepreneurs by 2040

The ORS GROUP explains to us their expertise in delivering sophisticated AI-based optimisation software solutions to a large international client base, including how AI & blockchain will empower 1 billion entrepreneurs by 2040

In its simplest terms, a blockchain is a new means of structuring and distributing data. The technology enables financial companies and other institutions to create a digital ledger guarded by cryptography, which can be shared among participants during transactions. This allows authorised participants to alter the ledger without awaiting approval from a central authority, often resulting in faster and more secure transaction that saves financial institutions time and money. Since the mysterious origins of Bitcoin in 2009, numerous cryptocurrencies have been thrust upon the marketplace, allowing transactions to take place directly between users and can be exchanged – as regular currency can be – for goods and services.

So why is there such on-going hype around cryptocurrency and is it masking the power behind blockchain technology?

This year has commenced with a lot of turmoil in the cryptocurrency world. However, that has been necessary to preserve the long-term health of the market. Bitcoin is already amidst the throw of a turbulent year, with the recent ban on cryptocurrency advertising from the world's biggest search engine Google and social media platform Facebook to proceed in June 2018. There are also rumours that Twitter will soon follow suit. Despite the industry currently in overdrive, key

observers of the blockchain say the technology is bound to not only survive but thrive.

The general outlook for blockchain in 2018 looks to be increasingly positive: Fiat service provider, Robinhood, of which over 1 million people have signed up for, announced their zero-fee crypto trading on February 22nd; March 15th saw the official release of Lightning Network's first beta implementation for the Bitcoin mainnet, securing \$2.5 million in seed funding; and one of the most important Polish cryptocurrency exchanges, Bitbay, has decided to add support for Ripple (XRP) and Infinity Economics Token (XIN), impulsing the internet of things (IoT) to the mass market. It is clear that the production of mass-market-focused products will finally be launching this year, making it a lot easier for the wider public to start building on and using the blockchain.

What does this imply about the future of work?

As widely proposed in recent news, the future is autonomous. We are already moving towards a workforce that could be purely operated with the combined use of artificial technology and robotics. The study of 46 countries and 800 occupations by the McKinsey Global Institute found that up to one-fifth of the global workforce will be affected by robot automation.

According to the report, 39 to 73 million jobs may be eliminated by 2030 in the US alone, but about 20 million of those displaced workers may be able to easily transfer to other industries.

But what if there was a way that the inevitable influx of automated workforces didn't have to affect the world's rate of human employability? What if there was a solution that could effectively convert the masses into fully equipped entrepreneurs, by applying one straightforward concept?

Meet the man on a mission to change the world, one entrepreneur at a time

President and Executive Chairman of ORS GROUP, a leading Artificial Intelligence software company, Fabio Zoffi is on an incredible mission to empower 1 billion small entrepreneurs by the year 2040.

In the words of Fabio Zoffi: *"The future doesn't have to be dystopian."*

How will he do it? By making the algorithms his company currently uses for the world's largest companies (which until now have been extremely protected) available to small businesses and entrepreneurs by connecting them with the blockchain technology.

ORS GROUP's innovative new concept of **Hypersmart Contracts** will provide



the mechanism by which they will do this: connecting Artificial Intelligence and blockchain together to make use of big data and powerful algorithms for turning businesses of all sizes highly competitive on a global scale.

President Zoffi says: *"We are creating a global community of like-minded developers, entrepreneurs and crypto enthusiasts, who want to embrace the new digital alphabet "ABC – AI, blockchain and cryptocurrency", to create and successfully run a business in almost every possible industry sector."*

The power of algorithms

Founded in Italy, ORS GROUP is a leading global supplier of cross-industry software solutions for optimising and automating business processes. For over 20 years the company has delivered sophisticated solutions using proprietary Artificial Intelligence, machine learning and big data analytics algorithms.

ORS GROUP's large international client base includes that of Fortune 2000 enterprises and span industries including retail, energy, finance and manufacturing. ORS GROUP's soft-

ware solutions save their clients over \$1 billion yearly.

Small entrepreneurs' new digital alphabet empowering a global decentralised network – it's easy as ABC

Imagine the possibility of a future decentralised network of small companies on a planetary scale, empowered by technologies which enable the "little guy" to put their big ideas into action and to be competitive against the "big boys". For example:

A farmer living in a small village in Southeast Asia, running a family business that has carried on for generations. In light of increasing competitive pressure from global farming companies and distributors, the farmer is now struggling to make the necessary business decisions needed to survive and thrive in his industry. Thanks to ORS GROUP's new digital alphabet, he would be given the power to successfully compete and grow his business:

Hypersmart contracts can act as intelligent connectors, which activate AI algorithms (off-chain) to solve com-

plex efficiency/optimisation problems utilising data stored on-chain. They can also release instant crypto payments. Together, these technologies can lead to significant improvements in global value chains, which even small farmers can benefit from. For example, algorithms can be used to predict crop yields and for dynamic price optimisation, blockchain can be used for providing transparency about the whole food chain and cryptocurrency used for receiving immediate payments. As an end result, small farmers can regain negotiating powers against distributors and compete globally.

Individual entrepreneurs will become empowered once they are provided with the technology to educate themselves, resulting in the establishment and growth of fully optimised and successful businesses. ORS GROUP continues to dedicate itself to ensure that any entrepreneur with a dream will be able to compete on a global scale and in an autonomous world.



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Building a digital Europe: Seamless access to data and the role of blockchain technology

Markus Hautala, Head of Blockchain Solutions at Tieto argues that the public sector holds the keys to building a digital Europe, including why seamless access to data is essential for a thriving economy and the role of blockchain technology in the region

Any thriving economy depends on the availability and free movement of skilled labour, products and services. Data has for centuries been an integral element in facilitating the movement of these assets. For the casual observer, it might seem that – thanks to the internet, API economy, cloud services and data platforms – we have largely managed to solve the issue of free movement of data. But as the EU Commission initiative, “Building a European Data Economy” illustrates, this is not the case. There are still major barriers to free movement of data and competition, due to localisation restrictions and lack of rules for data portability.

The European Commission has sought to remove these barriers by issuing regulations such as GDPR and the recent proposal for a regulation on a framework for the free flow of non-personal data. Whilst these initiatives are major steps in addressing the issue of data portability, they fail to tackle one of the biggest challenges prevalent in the modern internet: the verifiability of data.

Trusted interactions require verifiable data

As anyone who has ever bought anything online knows, the main issue with data is not its availability, but instant access to trusted data. Can I trust the

merchant to deliver the purchased goods? Can I trust that the goods are not counterfeited? These are just some of the concerns for consumers and e-commerce is but one of many use cases. The W3C Verifiable Claims Working Group has identified many more in domains such as finance, education and healthcare. As more and more of our personal and business activities move to the internet, we need to make various kinds of claims as part of our everyday activities in transactional interactions. For example, we use a driver’s license to prove that we are capable of operating a motor vehicle, a university degree to prove our education status and government-issued passports to grant us travel between countries.

From centralised platforms to a distributed trust

As the amount of digital data has exploded, new platform-based business models have emerged. Due to network effects, this has led to a situation where a relatively small number of platforms control our data, as well as continue to grow and gain more influence. European Union initiatives related to data portability aim to address some of these concerns. Yet whilst doing so, the European Commission takes the former network, infrastructure and trust models as given. The trust and data sharing

paradigms present in platform-based business models rely on the existence of trusted counterparty (“the platform”).

As instant access to trusted information is becoming increasingly vital for our everyday interactions, a new type of approach for exchanging the data is needed. During the past couple of years, a new network and trust model based on distributed infrastructure – namely blockchain – has emerged. One of the reasons why blockchain technology has received significant interest is that it has the potential to transform existing trust models – including how personal data can be handled. Instead of relying on centralised trust platforms, we now have the means to establish new types of trust infrastructures without vendor lock-in.

Decentralised identity helps guard personal data whilst improving customer insight

Until recently, the prevalent way to share identity information has been through a centralised platform with a single point of control. The problem with trusted middlemen is that when compromised, they pose a massive security risk to a large number of people.

As global digitalisation moves forward, we have witnessed a tremendous

increase in hacks and personal data breaches that cripple businesses. Recent examples include the Equifax breach, where more than 145 million people were exposed to identity theft and the Facebook leak in which more than 50 million user profiles were handed to Cambridge Analytica.

Handling customer data is clearly a huge risk for organisations, but at the same time, it is the cornerstone of customer relationships and business critical operations. How can organisations then maintain a holistic view of their customers without exposing themselves to increasing risks and regulatory pressures? This is actually one of the goals of GDPR: to make organisations rethink how to handle customer information. And this is exactly what solutions decentralised identity networks, such as Sovrin, allows them to do.

Decentralised identity networks can deliver the internet's missing trust layer

In decentralised identity networks, the identity holder forms secure digital connections with entities (organisations, individuals or things) that can provide information about the identity holder. This information can literally be anything such as a name, government ID, address, power of attorney, drivers licence, health information, university degree etc. This verifiable data can then be shared by the identity holder to a party that requires these proofs. This provides for all kinds of rich digital interactions: Know-Your-Customer, contract and transaction signing (B2B, B2C, G2C), permits, insurance claim, job application and so on. Storing identity data on blockchain would naturally be problematic for various reasons, including adherence to GDPR compliance and risk of data hacks. In a decentralised identity network, actual identity

data is not stored on the ledger. Instead of identity data, the decentralised ledger only contains pointers to the data. These uncorrelatable pieces of information are related to an identity holder and stored on the ledger to allow entities access, share and verify identity data when authorised.

What should the European public sector do?

Whether we realise it or not, technology choices always also carry choices of ideology. This is rarely as evident as in the context of identity data. By supporting centralised platforms, we are essentially supporting a business model which leads to a situation where a relatively small number of operators remain in control of our data and – due to network effects – continue to gain even greater influence over our lives.

The European public sector holds the keys to changing the course of this path. In the context of verifiable data, public administration maintains base registries such as citizen, company, land, vehicle and others. Due to the trust held in public authorities, these are the most reliable sources of basic information. Seamless access to this data is essential in digitalising not only the government but in all interactions (B2B, B2C, G2C). To drive the adoption of distributed identity networks, private and public sector participants should jointly and iteratively prototype, pilot and develop new distributed infrastructure concepts to demonstrate their value for citizens.

Conclusion

Competitive economies depend on the availability and free movement of labour, products and services – and data is the fuel that drives the movement of these assets. Despite the ubiquity of the internet and related technologies, barriers remain in access

to verifiable data needed in transactional interactions. EU initiatives related to data portability aim to tackle some of the problems concerning access to data and the dominance of data platforms. These initiatives, however, fall short in responding to issues related to instant access to data needed in transactional interactions. The cause for this is that these initiatives do not address trust, data sharing and infrastructure issues caused by platform-based business models.

During the past couple of years, blockchain-based distributed platforms have emerged, providing us means to establish new types of trust infrastructures without vendor lock-in. The public sector has a pivotal role in digitalising society, as it maintains the base registries containing verifiable identity data needed by both public and private sectors in transactional interactions. The public sector needs to actively drive the adoption of the new distributed platforms in collaboration with the private sector to ensure a wide market take-up. It is now time to make the EU's single market fit for the digital age and ensure that the European economy remains globally competitive – bringing benefits to both businesses and consumers.



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How is blockchain disrupting health and wellness?

Distributed and open technologies are bringing new business models, personalisation, prediction, motivation, collaboration and trust in healthcare, in the view of Sari Stenfors from the ReCon Blockchain Research Project, at Aalto University in Finland

In a forward-looking research project at Aalto University's Business School in Helsinki, we are studying blockchain technologies and how they will impact our society. Much media attention is given to blockchain and its best-known use case, Bitcoin. However, the most impactful business and societal implications of blockchain are still in their early stages or yet to come. One of the important industries that will be disrupted by blockchain technology is healthcare.

“Different types of blockchain technologies and other decentralised ledger technologies are important building blocks of our future. When they are combined with AI, AR/VR, IoT and Robotics they provide completely new ways to set up the societies we live in.”

The future of health and wellness

The number of people aged 60 years is now 962 million and by 2050 it is projected to reach 2.1 billion. The rising life expectancy, together with an ageing population is creating high demands on our health care systems. Not only is there a strong need for rapid innovation in the biopharmaceutical industry, but also the way healthcare is delivered in our societies will need to change. Thus, the healthcare sector is under rapid innovation cycles to embrace new therapies (such as immuno-oncology, gene ther-



apies, personalised medicine) and emerging technologies (for example artificial intelligence (AI), augmented reality, wearable technologies and blockchain).

To provide affordable quality care for an ageing population, healthcare systems will need to focus on effectiveness, and home and preventive care. Wearables and different types of sensors will monitor your genealogical weakness points already before you fall ill and artificial intelligence (AI) applications will analyse the data streams together with your doctor. You will be guided by an application, which generates a personalised patient path for you. The enabler of this disruptive change will be blockchain technology.

New ways of healthcare

Blockchain technology will enable placing the patient at the centre of the

healthcare ecosystem. It will increase the security, privacy and interoperability of health data and it will make health records more efficient, disintermediated and secure. Also, it will allow for the addition of wellness records (such as a fitness tracker data stream) to supplement your health records for the AI systems to more accurately analyse your health.

Some examples of how exactly blockchain is changing healthcare:

Value-based care

Blockchain-based smart contracts are used for focusing on patient outcomes. The patient pays for the result and not for the medical process (Robomed Network).

Patient wellness motivation

A user of the wellness platform is rewarded with crypto tokens for engaging in healthy activities (Clinicoin).



Provider collaboration audit trail

Providers are reimbursed for care depending on how extensively they worked with other providers (ConnectingCare).

Prescription medication provenance

Bringing together competing pharmaceutical manufacturers and wholesalers to improve traceability of medicine (MediLedger Project).

“The number of people aged 60 years is now 962 million and by 2050 it is projected to reach 2.1 billion. The rising life expectancy, together with an ageing population is creating high demands on our health care systems.”

Why is blockchain technology so powerful?

Blockchain technology is a new type of a data-architecture and that makes it powerful as we live in the data-driven era. The most important businesses, such as Google and Amazon, are about data. Blockchain technology stores data in a decentralised way in

multiple computers to make sure it is not tampered with. There are hundreds of different decentralised ledger technologies today and their governance structures ensure that a single computer cannot decide what data are stored. This way, we can trust that the stored information will not be corrupted by a party that would benefit from the change. The system creates programmable trust.

Different types of blockchain technologies and other decentralised ledger technologies are important building blocks of our future. When they are combined with AI, AR/VR, IoT and Robotics they provide completely new ways to set up the societies we live in. They hold the potential to disrupt not only the Internet but the way our societies are governed and what we know of as the current way of doing business. The impacts could be vast. Blockchain technologies are also being applied to the fields of finance, government, energy, accounting, logistics, insurance, education, record keeping and governance.

Our research

These are the types of questions we at the ReCon research project are elaborating and experimenting on. We engage in pilot projects, hackathons, studies, workshops and keynotes. Our mission is to describe, analyse and experiment on the potential societal impact and new business models of blockchain-like technologies. More information regarding the ReCon research team and our partner organisations can be found at <http://recon.site/>.



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Blockchain and initial coin offerings: Switzerland as an attractive location for digital innovations

Switzerland's Federal Department of Finance (FDF) explains the country's position as an attractive location for digital innovations, focussing on blockchain and initial coin offerings (ICOs)

A blockchain/ICO working group in Switzerland is investigating the legal framework for the provision of corresponding services and pointing out any need for action. The focus is on financial sector-specific applications using blockchain technology.

As a small and open economy, Switzerland is dependent on continuous innovation if it wants to maintain its appeal as a business location in the longer term. Blockchain technology¹ has great innovation potential and applications based on it can be used in many economic sectors. Aside from the financial sector, examples include energy trading, supply chain management and land register management. Switzerland has excellent conditions for playing a leading role internationally in this

area. These include the strong financial centre, leading universities, an existing Fintech and blockchain ecosystem and stable framework conditions. Consequently, Switzerland is an attractive location for digital innovations already today.

However, blockchain technology also raises questions about risks and the legal framework. Due to the rapid developments in recent times – including those in Switzerland, for example, around initial coin offerings (ICOs)² – the clarification of such issues has become very important and urgent, especially in the financial sector. The industry has a considerable and understandable need for a greater legal certainty: it wants to know which activities are possible under which condi-



BLOCKCHAIN INNOVATION

Swiss Civil Code, etc.). In the longer term, the legislator or regulator will be responsible for making legal adjustments, if necessary, to ensure a competitive framework and technology-neutral regulation, as well as to address any risks.

“As a small and open economy, Switzerland is dependent on continuous innovation if it wants to maintain its appeal as a business location in the longer term. Blockchain technology has great innovation potential and applications based on it can be used in many economic sectors.”

The FDF has established a working group (together with the FOJ and FINMA, among others) for this reason. It is to report to the Federal Council by the end of 2018 and point out any requirements for action. The sector should be consulted and involved in this process. The aims of this work are to increase legal certainty for companies in the blockchain area, maintain the integrity of the financial centre and ensure technology-neutral regulation. ■

References

- 1 Blockchain is a decentralised register in which all types of transactions are processed in a network of distributed computers.
- 2 With this special type of crowdfunding, bitcoins, ether tokens or other cryptocurrencies are collected under the term “ICO” (initial coin offering) for project financing and new, project-specific tokens are issued. These tokens are designed differently. Some contain only rights and values on the blockchain (e.g. bitcoin), others represent values (e.g. gold) or rights (e.g. shares) in the real world. Depending on distribution and acceptance, all these tokens can also have characteristics of a currency.

tions. However, any risks must also be addressed. The integrity of the Swiss financial centre may not be adversely affected by the new technology.

In the short term, the Swiss Financial Market Supervisory Authority (FINMA) is tasked with applying the existing financial market law considering technological developments. In February 2018, for example, it published guidelines on the practical design of ICOs. In addition, it conducts strict enforcement in the case of fraudulent projects.

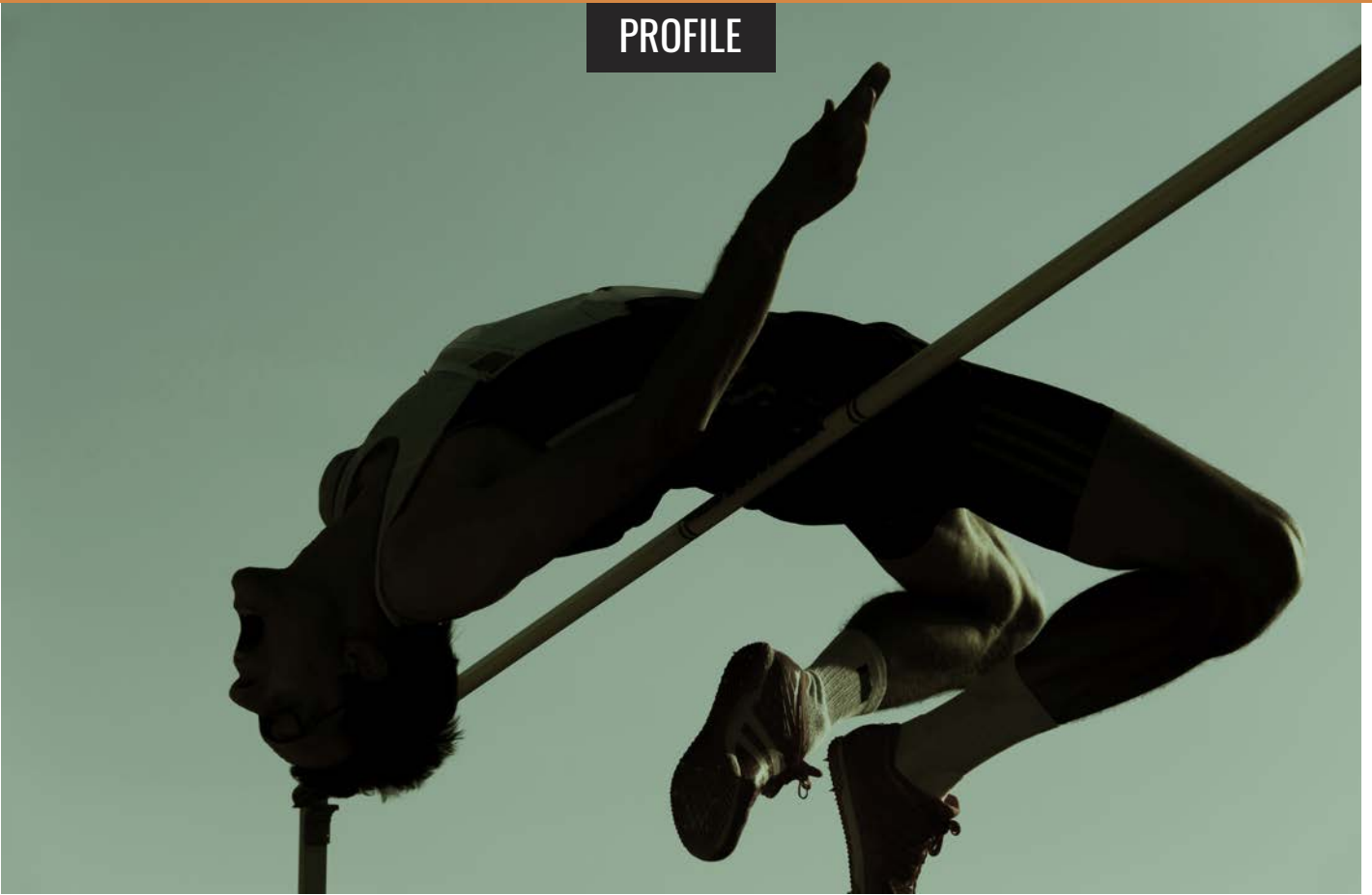
However, blockchain technology also gives rise to fundamental legal issues concerning both financial market law and general pieces of legislation (Code of Obligations,

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Blockchain – a “Fosbury flop” for the insurance industry?

Jags Rao, from Swiss Re explores how a maverick mentality can turn the tables on tradition and have a global impact

Mexico City, 1968. The Summer Olympics. And the scene is the men’s high jump final. The whole stadium was stunned when a 21-year-old lanky American called Richard Douglas Fosbury took Gold that day with a record-breaking jump of 2.24 meters. That in itself wasn’t so much the point but the manner in which he did it was. Fosbury jumped with his face to the sky. Until then, everybody did what was called “straddle” jumping facing the ground. His technique has since been famously called the “Fosbury flop”.

The athletics coach for the American team announced at the time that

those who followed Fosbury’s method risked breaking their necks. The only things that were broken were high jump records and the Fosbury flop has been almost universally adopted.

Uniquely, Fosbury challenged the status quo and adopted a style that contradicted the established convention. Decades later, his innovation is still discussed. And yet all he did, in fact, was to seek a better way of jumping over a high bar.

Fast-forward to January 2009 when a peer-to-peer electronic cash system called bitcoin network came into existence. This offered a unique way of

moving currency from point A to B without any intermediaries. It demonstrated that “trust” could be generated digitally from within the system. It contradicted the traditional process of building trust externally through intermediaries such as correspondent banks, clearing houses and sidestepped legal and regulatory oversight.

Much like the Fosbury flop, blockchain, the underlying technology behind bitcoin, challenged the status quo by offering an alternative that was fundamentally opposed to the traditional way of building trust. After over nine years the market capitalisation of Bitcoin continues to

soar to billions of US dollars, while the underlying blockchain technology continues to unravel its latent potential for the financial services industry and beyond.

So, what can blockchain do for insurance? In fact, the industry is financially healthy, but could operationally improve. It relies on multiple layers of counterparties generating “trust”, but with high frictional cost through their interactions. Over time, counterparties have improved operational efficiencies, but gains have been confined to “silos”. And the reality is that there still exists noise, friction, duplication, excessive paperwork and bureaucracy, with shared and common business processes leading to huge reconciliation costs and contract uncertainty. It is no surprise that this has contributed to the insurance industry’s not-so-customer-friendly reputation!

However, with the advent of cryptography, smart contracts and distributed ledger technology (blockchain), there are clear opportunities to tackle inefficient processes. The potential exists for commercial entities to track all their data-driven interactions securely on a smart-contracts resident on a blockchain without having to build different systems. Blockchain can enable the transaction flow across multiple layers of counterparties from original insured to brokers to reinsurers and all the way to capital markets. It could feasibly redefine the standard for digital transaction processing and deliver significant efficiency gains.

There are a number of experiments going on in the industry to test the hypothesis, validate the benefit and

convert prototypes into production-ready states. B3i, the Blockchain Insurance Industry Initiative, remains at the forefront of approaching this innovative technology with a clear purpose to bring real business change to our industry. This spirit around rethinking insurance is brought to life by some B3i members and captured on [video](#).

The formation and success to date of B3i is in itself breaking moulds. Formed initially by 15 insurers and reinsurers and later expanded to 38 market participants including brokers, the project has shown that where there is a common sense and purpose across the whole value chain, genuine collaboration is possible.

The project is an innovation and not just a dream. It has delivered hard results. In its first year, it moved from small in-house prototypes to an industry-wide global proof of concept and on to a market-tested property catastrophe excess-of-loss application in the largest industry-wide distributed ledger network to date. In 2018, B3i aims to transfer this into a self-sustaining entity to further develop and run the platform to settle legally binding contracts.

Nevertheless, there are a number of challenges ahead. Key issues such as collective standardisation, systems integration, legal and regulatory frameworks, privacy and confidentiality need to be addressed. However, the expected benefits in the form of reduced cycle time, cost and friction, as well as enhanced transparency, are hard to ignore as they are expected to create significant material savings.

Sharing these savings with the ultimate insured could help to drastically reduce the global protection gap.

The fact that over 7.5 billion people on our planet have no or limited access to insurance or cannot afford it, as much as anything else, provides an incentive to close this gap especially when the untapped premium could be as much as USD 800 billion. So, it is not just about increasing margins or improving service but providing an opportunity for social good and for a just cause. Let’s not forget that our role is to share the misfortune of the few across the many.

Much like the Fosbury flop, blockchain technology is once-in-a-generation kind of innovation, which if applied with clear sense and purpose as postulated in a [blog](#) by Paul Meeusen of Swiss Re, can make insurance more affordable, accessible and attractive for millions of underprivileged across the globe and make our world more resilient.



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Regulation within cryptocurrency markets

Alexander Larsen from the Institute of Risk Management (IRM) provides an in-depth look at the state of play concerning regulation within cryptocurrency markets

According to Reuters: "Japan's financial regulator said on 2nd February it had ordered all cryptocurrency exchanges to submit a report on their system risk management, following the hacking of over half a billion dollars of digital money from Coincheck."

Whilst the whole premise of blockchain technology and cryptocurrencies revolves around it being essentially unhackable, the exchanges that trade these currencies are vulnerable. The introduction of system risk management (which we assume to be risk management of the software/operating systems and servers) checks is a step forward for the cryptocurrency space, although it only covers one area of exposure linked to the cryptocurrency market.

History of incidents

Cryptocurrency has been a booming market with increases in some major coins in the high 1000's of percent during the last year. This rise, coupled with a lack of regulation, has seen the cryptocurrency world being hit with a number of negative incidents from Ponzi schemes to fraud, scams and hacking incidents.

Bitconnect, which as of the writing of this article, is trading at roughly \$8.60, a huge fall from its height of over \$300 in January, is an example of a potential major Ponzi scheme which has lost \$2.4 billion worth of value over 10 days.

The subpoena by US regulators of crypto exchange

Bitfinex and its relationship with Tether is another concern to the cryptocurrency market, with many claiming Tether to be a scam. Tethers are tokens backed by US dollar deposits, with each tether always worth one dollar. These tokens should be backed by dollars, but thus far the company has yet to provide evidence of its holdings to the public and has not had any successful audits as of yet.

There have also been a large number of Initial Coin Offerings (ICO's), used to raise money for start-ups by issuing tokens/coins, which have raised vast sums of money only for the owners to disappear with all the money, whilst others have been less deliberate but have been just as devastating to investors. A cryptocurrency called Tezos, raised \$232 million last year, but suffered internal power struggles which have left the project in disarray.

This brings us to the current concern in Japan of cyber-attacks of exchange platforms. Cyber-attacks and hacking attempts of exchanges have been frequent with Bitfinex, coinbase and kraken amongst others having been closed down for days at a time during 2017 due to a number of hacking attempts. It is the successful hacking incidents which are the most worrying, however, with successful hacks such as MT Gox, which cost almost 350 million and two attacks on Yobit which led to its bankruptcy. The most recent Coincheck hacking was worth 500 million, a record, and it is this which has caused Japan to act.

Regulation

Last year, China took a definitive stand on regulation on cryptocurrencies which sent shockwaves through the market. Some feel it was perhaps heavy handed with ICO's being banned, bank accounts being frozen, Bitcoin miners being kicked out and nationwide banning on the internet of cryptocurrency trading related sites. Others, however, believe that it has been a positive step and has encouraged other governments to take regulation seriously and hopefully take a more balanced approach. It certainly isn't in the interest of governments to stop ICO's, which provide many positives including innovation, but they should certainly regulate them from a consumer protection, taxation and organised crime standpoint.

Implementing regulation also removes uncertainty for investors as well as the companies who are involved in ICO's. Uncertainty is the source of many risks and often a negative certainty is better than uncertainty as it allows a focus within set parameters. It's important to remember that too little regulation doesn't offer protection and too much stifles innovation.

How to regulate

There are a number of ways to regulate cryptocurrencies and the following are just some examples:

1) Framework for ICOs

New ICO's are currently not subject to much in terms of regulation globally. One of the problems is determining how they should be treated with some being considered securities. As a fund-raising vehicle, there could certainly be a framework that lays out key requirements of an ICO such as a company needing to be registered in order to issue a token, transparency in terms of individual members of the registered company as well as perhaps introducing a few requirements that regular IPO's require such as implementing risk management. Currently, in the USA, ICOs are expected to adhere to Anti Money Laundering (AML)/Know Your Customer (KYC) practices.

2) Regulate exchanges

Exchanges, which is where much of the transactions take place in terms of trading coins, is a logical area of focus when it comes to regulations.

South Korea's financial services commission, for example, has stated that trading of cryptocurrencies can only occur from real-name bank accounts. This ensures KYC and AML compliance. According to the FSC, the measures outlined were intended to: "Reduce room for cryptocurrency transactions to be exploited for illegal activities, such as crimes, money laundering and tax evasion."

Regulators should, therefore, focus on regulation that encourages transparency and minimises anonymity.

3) Tax laws

Clarity needs to be brought into the tax laws in terms of when investors should pay capital gains. The USA

has been quite quick to ensure that crypto-to-crypto transactions are now taxable and not just crypto to Fiat currency transactions. This is not the case in the UK however, where things are less clear and will become even more so, once cryptocurrencies start to introduce dividend like behaviour.

4) Reserve requirements of exchanges

Most banks and stock exchanges are required to hold a certain amount in reserves in order to survive any major downturn or crash. This should most certainly be the case for cryptocurrency exchanges too especially considering the volatility which sees crashes of 60% several times a year, with some cryptocurrencies falling 90% before recovering. This is also known in part as a systemic risk, which could be what the Japanese financial regulator defines as system risk.

5) System risk management

As we have seen from this Japan story, one way of ensuring more protection and reliability is by ensuring there is regulation around system risk management on exchanges. There should be minimum requirements protecting against hacking, phishing and other cyber-related attacks. The requirements could be scaled against the value of the exchange and the number of users or number of daily transactions.

It's important to note that much is being done to reduce the risks of hacking incidents such as the concept of a decentralised exchange. This would essentially be a cryptocurrency exchange on the blockchain, much like the cryptocurrencies themselves. This would reduce hacking significantly and whilst it is not currently practical, it could be the standard of the future.

Self-regulation

The cryptocurrency market gets a lot of negative publicity and much of this could be rectified if there was more self-regulation. It would also reduce volatility within the market and bring about positive change. This refers to both exchanges and ICO's alike.

The Japan Blockchain Association (JBA) for example has established self-regulation standards which include the use of cold wallets amongst its 15 crypto exchange members (of which Coincheck was one of them) and

are now looking to strengthen the standards further, following this recent incident.

Risk management in the cryptocurrency space

Risk management, as with all organisations, plays a vital role in meeting and exceeding objectives whilst providing resilience and stakeholder confidence. Exchanges and companies that are raising/have raised ICO's should ensure that risk management is a part of their business. Identifying risks and opportunities, assessing them and implementing response plans should be standard. Cyber risks, reputational risks, operational risks, system risks and strategic risks should all be considered and prepared for, which would minimise market disruption and reduce the likelihood of financial ruin. At the very least they owe it to the investors who have funded them.

For investors, with volatility so high, the rewards are great but so are the risks. Investors should ensure that they only invest what they can afford to lose, do their due diligence on their investments which includes understanding the technology, the team and look for a prototype rather than a wild concept. Additionally, investors should always be on the lookout for phishing scams and suspicious emails.

Finally, even the most optimistic investor should at least consider that cryptocurrencies are a speculative bubble that could burst. ■

You can find out more about IRM's Strategic Insights into Cyber Risk Course and much more at: <https://www.theirm.org/training/all-courses/strategic-insights-into-cyber-risk.aspx>

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Blockchain technology for the public good: Design constraints in a human rights context

Tomaso Aste and Geoff Goodell from University College London's Centre for Blockchain Technologies share their views on why blockchain technology is for the public good and about the fundamental design constraints and digital identity protocols in a human rights context

Digital technologies offer great potential for the marginalised populations of the world in many dimensions of their lives, including communication, commerce, financial inclusion, disaster recovery and the delivery of aid. However, digital technologies can also play a divisive role. By enabling the powerful who can access key information and who have the capability to develop infrastructure, it often penalises those who cannot, especially the most disadvantaged. This is consequently increasing inequality and marginalisation. In this respect, technology is not neutral, and its design can strongly influence and shape our future society.

We argue that distributed ledger technologies present an opportunity for marginalised populations, by empowering them to manage their data and business practices and achieve demarginalisation by involving the community in a decentralised manner. Distributed ledger technologies allow cooperative actions for marginalised populations to refocus away from the most powerful gatekeepers and ease the conflicting interests between governments, non-government organisations and entrepreneurs. Here we present fundamental design constraints for digital technology services in a human rights context. We also

discuss an approach for decentralised digital identity that complies with these fundamental design constraints.

Centralised infrastructure is economically efficient and may create value, both financial and political, for those groups who authorise, build, operate and oversee the systems that use it. Often, the interests of such groups are not aligned with the populations they serve. Some service providers are drawn by the promise of operating a central hub that everyone must use, thus allowing them to collect economic rents on an indefinite basis. Other businesses are drawn by the promise of collecting, aggregating, analysing, or selling data about individuals for profit. State actors are drawn by the opportunity of controlling the behaviour of their constituent populations through surveillance.

Infrastructure with decentralised governance, by contrast, affords no such incentives for its development and relies on local actors to see the benefit of its value. Deploying infrastructure with decentralised governance is a particularly challenging task because it impacts existing business models based on asymmetry of information and disrupts local incumbents that may already benefit unfairly from existing centralised control points. To

create decentralised infrastructure, we must activate a multi-stakeholder process aiming at an agreement on standards and the mechanisms by which different participants can interact. A bottom-up process for deployment of infrastructure achieves legitimacy by rightfully involving the populations that it serves, each acting in their own self-interest.

Design constraints for digital technology services

Let us first identify eight key constraints that can serve to guide our thinking about information services in a human rights context. These foundational constraints set a base for the design of ethical digital technologies that respect fundamental human rights and promote social virtue:

1. **Minimise** control points that can be used to co-opt the system. A single point of trust is a single point of failure and both state actors and technology firms have historically been proven to sometimes abuse such trust.
2. **Mitigate** architectural characteristics that lead to surveillance. Surveillance is about control, as much as it is about discovery: people behave differently when they believe that their activities are

being monitored or evaluated. Incentives defined by powerful actors do not always serve the public interest and the opportunity to discover misbehaviour often does not justify such mechanisms of control.

3. **Do not impose** non-consensual trust relationships on beneficiaries. If a direct trust relationship with a third-party platform provider or certification authority is required, then that counterparty is facilitating coercion. Such coercion should be recognised for what it is and not tolerated in the name of convenience.

“By enabling the powerful who can access key information and who have the capability to develop infrastructure, technology often penalises those who cannot, especially the most disadvantaged. This is consequently increasing inequality and marginalisation. In this respect, technology is not neutral, and its design can strongly influence and shape our future society.”

4. **Disincentivise** economic rent-seeking on the part of solution providers. These models provide the opportunity to achieve status as de-facto monopoly infrastructure, with network effects that shut out prospective competitors and allow extraction of value over the long-term. Such opportunities are fundamentally abusive to the users of the infrastructure.

5. **Empower local businesses** and communities to establish their own trust relationships. The opportunity to establish trust relationships on their own terms is important for businesses both to compete in a free market place and to act in a manner that reflects the interests of their communities.

6. **Empower service providers** to establish their own business practices and methods. Providers of key services must adopt practices that work within the values and context of their communities.

7. **Empower individual users** to manage the linkages among their activities. To be truly free and autonomous, individuals must be able to manage the cross sections of their activities that are seen by various institutions, businesses and state actors.

8. **Resist creation** of potentially abusive legal processes and practices. Infrastructure that can be used to abuse and control individual persons is problematic even if those who oversee the infrastructure are genuinely benign. Once the infrastructure is created, there is only a matter of time before it is used for the wrong purposes.

Establishing meaningful credentials for individuals and organisations is a problematic task, even in developed economies with strong rule of law. In an environment in which the incumbent actors are widely accepted as unscrupulous, this presents an even greater problem challenging the viability of services based on hierarchical trust networks, such as all-purpose identity cards. In many parts of the world, legitimate trust relationships are not hierarchical, and a top-down approach will not work.

Decentralised design for digital identity

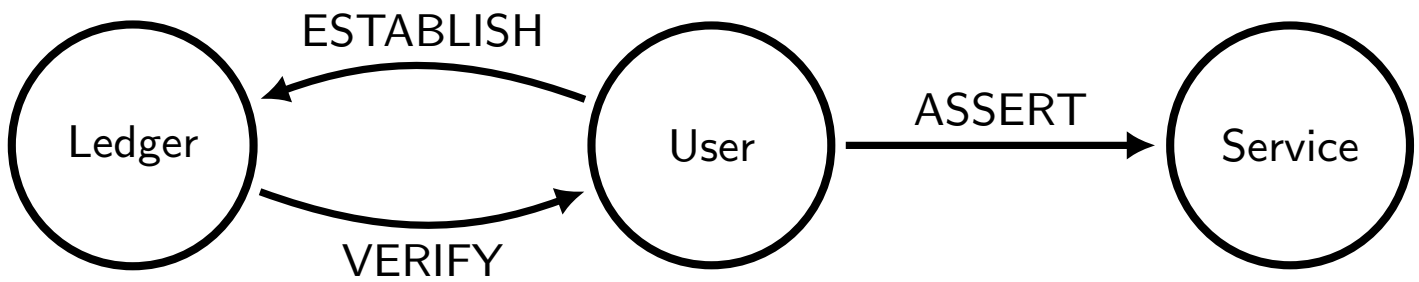
Modern digital technology infrastructure relies heavily on services that often require their users to establish accounts and assert their identities as they make use of the services. For this reason, the collection, aggregation and

analysis of personal data have become politically contentious issues, as the businesses that operate on such data often have little or no public accountability with respect to how the data is gathered and used. When marginalised communities are involved, the problem is exacerbated as weak public institutions are ill-suited to defend the interests of individuals and small businesses against the interests of those who seek control.

The current state-of-the-art in identity systems for social protection and financial inclusion impose non-consensual trust relationships on their users, including both the ultimate beneficiaries, as well as local authorities, service providers and others. Such trust relationships expose users to powerful central authorities with potentially corrupt or unscrupulous operators, poor security practices and the potential for coercion by politically or economically powerful actors. Identity systems that rely on a single technology, a single implementation, or a single set of operators have proven unreliable at best and in many cases, they represent a threat to human rights as well.

The alternative to imposing new trust relationships is to work with existing trust relationships. Distributed ledgers allow for system-level approaches that make it possible for existing businesses, community groups, cooperatives and service providers to continue to exercise self-determination, without forcibly requiring them to cooperate with central authorities (including governments, NGOs, operators and other institutions or service providers) or with specific platforms or implementations.

For users to retain control of their identities and to avoid the possibility that others might abuse their data, it must be possible to:



1. **Generate identifiers** on hardware that users own and trust. Conversely, general-purpose authentication tokens issued externally, such as all-purpose identity cards, as well as inalienable tokens such as biometrics, can be used to track the behaviours of users against their wishes.

“Modern digital technology infrastructure relies heavily on services that often require their users to establish accounts and assert their identities as they make use of the services.”

2. **Ensure** that authentication infrastructure operators never learn meaningful identity information about their users. Infrastructure operators are naturally positioned to exploit the data that they carry. To minimise the potential for abuse, such operators must not receive or carry exploitable information in the first place.

3. **Separate** operators of authentication infrastructure from service providers. Users must be able to exercise autonomy in making use of services, free of the concern that their various activities might be tracked and linked.

The figure above shows how such an identity system might work. An individual user can establish a credential representing an attribute or token by

writing to a distributed ledger. Later, the individual can use the distributed ledger to verify the credential and assert it when requesting a service or conducting a transaction.

The best way to eliminate control points is to decentralise control. The distributed ledger would serve as a layer of indirection between the processes of establishing and asserting identity, without itself being owned or operated by any single party. As long as the community of operators of the distributed ledger remains sufficiently diverse, there would be no particular point of control to be abused without establishing many separate control relationships.

By applying cryptography and community validation to remove third-party trust from business transactions, distributed ledgers hold promise as part of the solution. By facilitating decentralised control of a transactional system, their use can mitigate the threats to human rights posed by powerful intermediaries and, their use can empower the less powerful participants, such as small businesses, local cooperatives and the individual beneficiaries themselves.

It may not be easy to convince state actors and incumbent businesses to accept the development and use of

technology that disrupts current business and power models. However, with the rise of coercion and control through platform services and data aggregation, now is a fine time for those who believe in human rights to take a stand in favour of individual autonomy and dignity.



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The role of blockchain technology in Dubai

Smart Dubai Office lifts the lid on the role blockchain technology plays in Dubai, in this revealing interview

Smart Dubai Office lifts the lid on the role blockchain technology plays in Dubai, in this special interview, including their thoughts on the Dubai Blockchain Strategy and what it sets out to achieve. In addition, they explore how this aims to demonstrate an opportunity to deliver more seamless, safe, efficient and personalised city experiences.

Smart Dubai Office also explains how blockchain technology is shaping the future of the Internet with simple, safe and secure transactions. Finally, we are told about the role blockchain will play in the country's government, to be an example to the rest of the world, as well as driving Dubai's economy.

Firstly, can you introduce and outline your thoughts on the Dubai Blockchain Strategy? What is it and what does it set out to achieve?

The Smart Dubai Office launched the citywide "Dubai Blockchain Strategy" in October 2016, with the objective of executing all applicable government transactions using blockchain by 2020.

The strategy establishes a roadmap for the introduction of blockchain technology to Dubai and the creation of an open platform to share the technology with cities across the globe.

"In May 2017, the Smart Dubai Global Blockchain Challenge saw 21 start-ups fly into Dubai from 19 cities – to pitch their best and brightest blockchain ideas – several of which are now being piloted around the city. We are running the challenge for a second year in 2018 and will be announcing this year's winners in May."

We designed it essentially around three pillars that connect government, the private sector and the global community because of our strong belief in the power of collaboration. These three pillars – efficiency, industry creation and global leadership are detailed below.

Efficiency: To implement blockchain technology across all applicable government services.

Dubai aims to use blockchain to enable a paperless



BLOCKCHAIN INNOVATION

and will be announcing this year's winners in May.

Global leadership: The strategy aims to position Dubai as a global thought leader in blockchain, through both formal and informal cross-border collaboration.

“In short, we want to give people back time and money they would have otherwise spent on filling paperwork and travelling to government service centres. More importantly, at the core of this vision is a belief in the profound power of emerging technologies to dramatically improve city experiences. This is a belief we have put into motion with the launch of the Dubai Blockchain Strategy.”

How does this aim demonstrate an opportunity to deliver more seamless, safe, efficient and personalised city experiences?

To answer this, we need to look at the traditional governance model and the extent to which Dubai is different.

Traditional governance model: To understand why we are embracing blockchain and other emerging technology, we'll first state that governments have long existed to manage societal growth through the provision of trusted public services.

Historically, the delivery of these services involved frequent and time-consuming interactions between public sector agencies and constituents. If one wished to buy a property, the government's role would be to authenticate the transaction and record it for future reference.

The purchaser in this scenario would, therefore, be required to fill out and present several documents to ensure the government can do its “authentication and recording” role properly. The relationship between the two – government and individual – is purely transactional: Give and take.

Governments around the world have believed for centuries that they are achieving their objective by fulfilling

digital layer for all city transactions, converting millions of documents – covering everything from visa applications to bill payments to license renewals – into digital, blockchain-secured form.

In 2017, over 20 government use cases have been identified and designed, with many progressing into proof-of-concept phase. These cases include daily life experiences such as purchasing or renting a property, registering a student in school, obtaining medical treatment, and more. Dubai intends to first pilot these use cases on blockchain, before it proceeds to full implementation later in 2018 and beyond.

Industry creation: Support the creation of a blockchain industry by providing an enabling ecosystem that empowers start-ups and businesses.

In May 2017, the Smart Dubai Global Blockchain Challenge saw 21 start-ups fly into Dubai from 19 cities – to pitch their best and brightest blockchain ideas – several of which are now being piloted around the city. We are running the challenge for a second year in 2018



these traditional transactional roles – though this has been done through heavy reliance on manual processes and unnecessary labour work.

How Dubai Is Different

The Dubai government differs from others around the world in that it aims to make Dubai the “happiest city on Earth.” We aspire to touch the life of every individual to ensure that their everyday city experiences and interactions are efficient, seamless, safe and personalised.

In short, we want to give people back time and money they would have otherwise spent on filling paperwork and travelling to government service centres. More importantly, at the core of this vision is a belief in the profound power of emerging technologies to dramatically improve city experiences. This is a belief we have put into motion with the launch of the Dubai Blockchain Strategy.

How is Blockchain technology shaping the future of the Internet with simple, safe and secure transactions?

Fundamentals of blockchain: Due to the underlying fundamentals of how Blockchain functions, it acts as self-authenticating technology, guaranteeing the accuracy of the data on it, including transactions that have taken place. For this reason, blockchain is cutting off middlemen who act as ‘verification agents’ in today’s world.

Several industries will be disrupted once blockchain goes global including banking, insurance, government, transport, healthcare. This is the reason Dubai is embracing blockchain and other emerging technologies today, so the residents and visitors of Dubai can embrace the technologies benefits first and the city can act as a global benchmark for other cities around the world.

With Dubai planned to be the first blockchain powered government, driving the future economy, what example will this set to other countries?

This takes us back to the Industry Creation pillar. We are proud to say that due to our ambitious mandate, the world has recognised Dubai as a global hub for blockchain implementation and blockchain specialists from around the world such as ConsenSys and BitFury are setting up offices in this city. This is further backed by our recognition at the Barcelona Smart City Expo World Congress, where we received the City Award for our efforts towards blockchain implementation.

“The Dubai government differs from others around the world in that it aims to make Dubai the “happiest city on Earth.” We aspire to touch the life of every individual to ensure that their everyday city experiences and interactions are efficient, seamless, safe and personalised.”

Dubai is host to at least one blockchain conference every month, as the world has acknowledged Dubai for blockchain knowledge exchange as well. The Smart Dubai Office is hosting a major blockchain festival in May called the Future Blockchain Summit, where we are inviting global blockchain experts to share their experiences with all. ■

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GOVERNMENT

Bold decisions will take Finland towards the age of AI

Pekka Ala-Pietilä, Chair of Finland's Artificial Intelligence (AI) Programme reveals that Finland aims to be a leading country in the application of AI

Already, artificial intelligence (AI) is so commonplace that we hardly notice it. At the same time, it is so vital that it would be difficult for us to manage our daily lives without it. In the next few years and decades, its impact will continue to grow – for individuals, companies and the entire society.

Artificial intelligence is the new electricity. Electrification fundamentally changed society: it made everyday chores easier, influenced companies' competitiveness, made it possible to offer new kinds of public services and replaced some human labour.

The effects of AI will be similar. Working life will never be the same again, as AI will take over many tasks. Few jobs will disappear entirely, though. For the most part, AI will serve people as assistive tools.

Finnish AI programme: the race to be among the forerunners

According to a study by Accenture⁽¹⁾, Finland has the second greatest potential of benefitting from AI as a nation, only preceded by the USA. This is because of our country's capital goods-intensive economic structure, high level of education and the advanced digitalisation and considerable data resources of the public sector.

Now is the time to purposefully set out and become a forerunner in the utilisation of AI. We are not late, but there is no time to waste. This is the goal set by Minister of Economic Affairs, Mika Lintilä, when he founded the AI programme in May 2017: Finland is to be a leading country in the application of AI.

As a result of our network-based work, we specified eight key questions which will help us to take Finland successfully into the age of artificial intelligence. We have already made progress with many of these issues, but all of them need an extra boost.

1. How can we enhance the competitiveness of businesses through the use of AI?

We will create internationally competitive, business-driven innovation ecosystems for sectors that are advantageous for the utilisation of AI, such as energy, healthcare, transport and industry, as well as promising emerging sectors. On the other hand, companies in their early stages must be activated and concrete support must be offered to help get them started. In the AI Growth Group currently being established, companies encourage and stimulate each other in applying AI.

2. How can we utilise data effectively in all sectors?

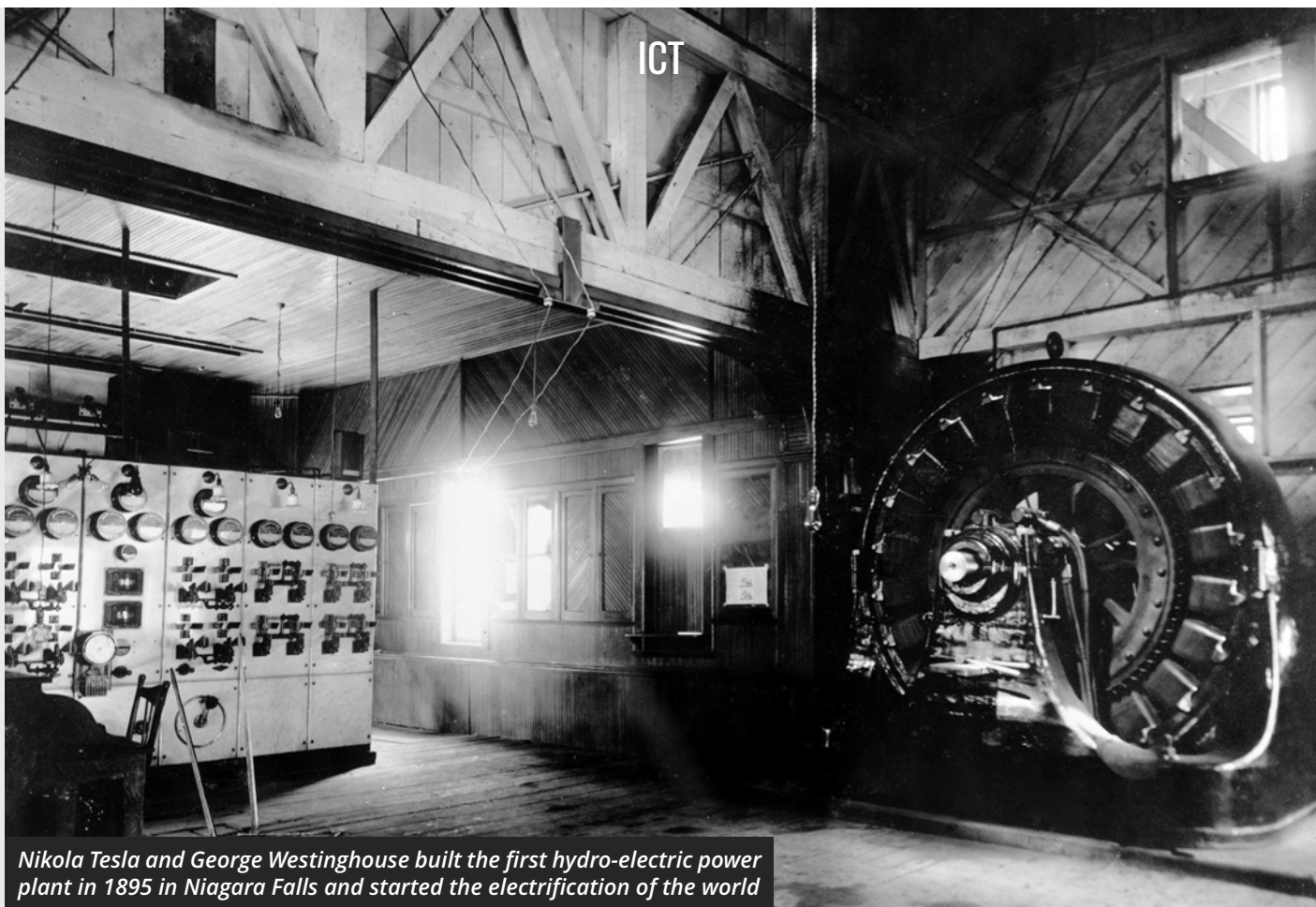
We must make sure that Finnish data resources are enriched. At the same time, we must make the accumulation of citizens' so-called MyData possible and also offer them opportunities to take advantage of it. The work launched by The Finnish Government to create a comprehensive information policy promotes these goals.

3. How can we ensure quick and easy adoption of AI?

A new AI Accelerator programme is being created to give companies, universities and research institutes the opportunity to work together to advance quickly in this field and to test how AI works in various situations.

4. How do we ensure top-level expertise and attract top experts?

We must ensure excellent competence in applying AI at all levels of education. Working peoples' skills must be updated so that they have the ability to use AI tools. Additionally, Finland must attract AI experts from the rest of the world. The new Finnish Center for Artificial Intelligence (FCAI) was established to serve the needs of top AI research.



Nikola Tesla and George Westinghouse built the first hydro-electric power plant in 1895 in Niagara Falls and started the electrification of the world

5. How do we make bold decisions and investments?

Finland must use its limited resources wisely and allocate them boldly. The steering group of the programme proposes an investment of €100 million in research and innovation projects that support the advancement of AI in 2019 and another €100 million in 2020.

6. How do we build the world's best public services?

AI makes it possible to disconnect public services from time and place and to target them at citizens based on their life events and at companies based on their business events. The citizens' virtual assistant Aurora, which is currently under development, will be a network of bots designed to meet these needs.

7. How do we establish new models of collaboration?

Difficult ideas are often located on the fringes of areas of responsibility or just outside them. When this is the case, you have to open-mindedly agree on new ways to proceed together into areas where no one has yet been.

8. How do we make Finland a forerunner in AI?

Successful utilisation of AI is a vital issue for Europe.

Finland is participating in leading the changes on the European and international forums where AI is being promoted.

The work continues

In addition to the promotion of the above-described aims, the programme will continue to work with other themes, in particular, the labour market and working life, ethical questions and security. The work on the Finnish AI programme continues at www.tekoalyaika.fi.

1 Purdy, Mark & Daugherty, Paul (2016) Why artificial intelligence is the future of growth. www.accenture.com/lv-en/_acnmedia/PDF-33/Accenture-Why-AI-is-the-Future-of-Growth.pdf

Pekka Ala-Pietilä

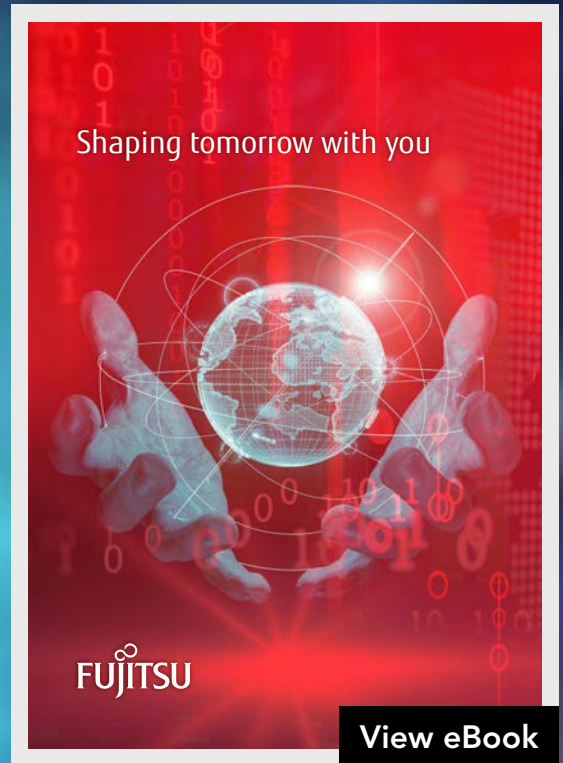
Chair of Finland's Artificial Intelligence Programme

www.aiera.fi

#tekoalyaika

The background is a vibrant, abstract digital composition. It features a central bright blue and white light source that radiates outwards, creating a sense of depth and energy. Overlaid on this are various digital elements: vertical columns of binary code (0s and 1s) in red and white, some of which are slightly blurred to create a sense of motion. There are also green and blue rectangular blocks, some of which are connected by thin lines, suggesting a network or data flow. The overall color palette is dominated by blues, greens, and reds, with a high-contrast, futuristic aesthetic.

FUJITSU



Shaping tomorrow with you

Andrew Cowling at Fujitsu Scanners explains how local government can benefit from document management technology, as well as his thoughts on GDPR-compliance.

Empowering pathologists with artificial intelligence (AI)

Anna Knuuttila, Senior Scientist and Kaisa Helminen, CEO of Fimmic explain how artificial intelligence (AI) empowers pathologists when it comes to cancer care

By 2030, nearly 22 million new cancer cases are expected and the burden on the healthcare system to quickly and accurately analyse the tissue samples to diagnose them and develop lifesaving drugs is immense. To help address the growing number of samples from cancer, as well as other diseases, Fimmic, a Finnish software company, has developed Aiforia™ Cloud. It combines deep learning artificial intelligence (AI) image analysis cloud solution and automatised pathology image analysis capabilities. With this Fimmic aims to improve the speed and accuracy of tissue-based diagnostics and thus enable efficient, precise and more personalised care.

Formerly known as WebMicroscope, Aiforia Cloud is already used by more than 6,000 pathologists, researchers and pharmaceutical R&D teams to manage and share digital slide collections. With the new Aiforia platform CNN (convolutional neural network) deep learning algorithms can be easily developed in just days or less, compared to the months needed for conventional machine vision approaches. Along with the algorithms being easy to create, the entire platform itself is simple, easily accessible and affordable with SaaS model. Users can deploy and use the platform through a browser.

For the first time, the Aiforia deep learning algorithm can mimic the human observer in understanding the



Figure 1: Segmentation of tumour epithelium from the stroma and quantification of Ki67 positive and negative cells within the epithelium

context in tissue and it can automatically and accurately perform laborious image analysis tasks in a fraction of the time. This gives users significant time back in their day for high-value work, such as analysing more complex or rare samples.

“Digitising the field of pathology has been an important step forward for healthcare, but we’re once again poised for real disruption in the space,” said Kaisa Helminen, Fimmic CEO. “An ageing population and rise in cancer prevalence, coupled with the radical innovation of AI technology, have created both a significant need and opportunity for digital pathology to evolve. At Fimmic, we are driven by the common goal of better and more

accurate medical analysis, diagnoses and treatments and we are proud to offer the first solution of its kind to bring deep learning AI to the fingertips of all pathologists and researchers, empowering users to explore and discover more with less time, money and effort.”

Application example: Quantification of Ki67 in breast cancer

Fimmic has developed deep learning algorithms for several different applications, for example, in drug development and in research on cancer, neurodegenerative diseases and liver diseases, but this technology can be applied to numerous other applications as well. One example of the

developed algorithms is epithelium segmentation and quantification of Ki67 positive and negative cells in breast tumour sections. Ki67 is a nuclear protein that is expressed in proliferating cells and may be used for the estimation of prognosis of breast cancer, prediction of responsiveness to therapy, estimation of residual risk and treatment efficacy¹.

“An ageing population and rise in cancer prevalence, coupled with the radical innovation of AI technology, have created both a significant need and opportunity for digital pathology to evolve. At Fimmic, we are driven by the common goal of better and more accurate medical analysis, diagnoses and treatments and we are proud to offer the first solution of its kind to bring deep learning AI to the fingertips of all pathologists and researchers, empowering users to explore and discover more with less time, money and effort.”

Unbiased and reproducible quantification of Ki67 positive and negative tumour cells is important both for breast cancer research, as well as in clinical practice. The Ki67 scoring methods are traditionally based on visual assessment¹. This is laborious and time-consuming and subject to human error. Since it is not possible to count all Ki67 positive and negative cells from the whole tumour area, the counting by eye is always an approximation. In the novel deep learning algorithm these problems have been overcome.

Furthermore, unlike algorithms that have been generated with conven-

tional machine vision, the deep learning algorithms can automatically segment the tumour epithelium from the stroma and count the Ki67 positive and negative cells in the right context, resulting in significantly faster and more reproducible results, with no hands-on-time. The Ki67 counting is performed from the digitised breast tissue sections. There is no need to acquire any local hardware for image processing, since the Aiforia deep learning algorithms are available as a service from a cloud platform, accessible with any modern browser. [See our video.](#)

The benefits are:

- Fully automated analysis from the whole tumour area;
- Analysis from the area of interest. No double-staining needed for epithelium/stroma segmentation;
- Fast, accurate and reproducible results and;
- No local hardware or software needed.

About Fimmic

Fimmic, founded in 2013, is a spin-off company from the Finnish Institute for Molecular Medicine at the University of Helsinki. Fimmic's unique Aiforia Cloud brings together deep learning-based image analysis and high-performance cloud computing. The SaaS solution enables fast, accurate and affordable analysis support for every pathologist and medical researcher in tissue-based image analytics through a zero friction cloud deployment and intuitive online user interface.

New algorithms can be ordered on-demand or with a self-service model where users can generate their own deep learning algorithms by training convolutional neural networks to learn, detect and quantify specific features of interest in tissue images. Aiforia is currently sold for research use. Please visit www.aiforia.com for more information.

References

- 1 Dowsett et al. Assessment of Ki67 in Breast Cancer: Recommendations from the International Ki67 in Breast Cancer Working Group. JNCI 2011;103: 1656–1664, <https://doi.org/10.1093/jnci/djr393>



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The Government Transformation Strategy: One year on

Kevin Cunnington, Director General of the UK's Government Digital Service (GDS) shares his thoughts on the progress of the Government Transformation Strategy, launched just over a year ago

The Government Digital Service (GDS) launched the Government Transformation Strategy just over a year ago.

Designed so that meaningful change could be delivered quickly, the strategy guides what the government should do and how it should do it, in order to deliver world-class services to citizens.

One year on, I'm pleased at the progress GDS has made to deliver the ambitions of the strategy. I'm especially pleased to see so many government services using our common components.

Driving the creation and use of common components across government is a priority in the strategy. Common components help departments to build excellent user-centred services quickly and with ease. The speed of delivery is even more vital as the government prepares for EU Exit. Common components help to minimise disruption to services and allow us to seize the opportunities that this change brings.

As I write this, there are more than 240 services across government using our common components. Over 60 million notifications have been sent through GOV.UK Notify, which allows service teams to send text and email messages to users. It's a cost-effective, reliable and easy-to-integrate solution. GOV.UK Notify may sound like a simple proposition, but it has a huge effect. For example, GOV.UK Notify is helping to keep our roads safe.

More than 30 million cars need an MOT every year in the UK and around 28% of cars are late for their test. Of those cars that are late, the MOT failure rate is 8% higher than average. This means that not only are they breaking the law, but that their vehicles are in worse condition, which makes them more likely to be involved in an accident.

Driver and Vehicle Standards Agency (DVSA) has developed an MOT reminder service using GOV.UK Notify and the service has over 500,000 users signed up. This is helping to keep unsafe cars off our roads.

And GOV.UK Notify is also helping to drive British trade around the world. The Department for International Trade (DIT) uses GOV.UK Notify to keep users informed about the new Overseas Market Introduction Service. This helps businesses enter new overseas markets.

DIT will also use payments platform GOV.UK Pay to process user's payments more quickly. And the department is also using GOV.UK PaaS (Platform as a Service) to host great.gov.uk, the 'front door' for its services.

PaaS allows departments like DIT to scale easily and deploy applications more quickly, so less time is spent on managing technical infrastructure.

We're also pushing forward with registers. Registers are live lists of data, each managed by a government custodian. They represent the government's approved version of that data. There are 34 registers ready and 36 are in progress. There are currently 13 government services using registers. The growth in registers is really exciting because they are managed by departments, not by GDS, so this is a true example of cross-government transformation work.

As well as our common components work, GDS will continue to facilitate cross-government DDaT capability through things like the DDaT workforce planning project and our work to upskill civil servants.

We will continue to build on the UK's position as a world-leading provider of public services. This means that GDS should adopt the role as innovators for government.



Image: © GDS

Kevin Cunnington, Director General of the UK's Government Digital Service (GDS)

We are working with departments to support existing and upcoming programmes, including using biometrics and artificial intelligence (AI) on services. We're working to make sure the things we build and run – including GOV.UK – can use innovative technologies like machine learning and voice control.

“Driving the creation and use of common components across government is a priority in the strategy.

Common components help departments to build excellent user-centred services quickly and with ease.

The speed of delivery is even more vital as the government prepares for EU Exit. Common components help to minimise disruption to services and allow us to seize the opportunities that this change brings.”

We are also responsible for the [GovTech Catalyst programme](#), a £20 million fund to help tech firms deliver innovative fixes to public sector challenges. Our team will help government departments and public bodies identify challenges they face that could be solved by new digital technologies. We will then act as a ‘front door’ to tech firms, giving them a clear access point where they can put forward innovative ideas. Once a finalised product is created, the public sector body can then choose to buy it from the tech company.

And of course, a big priority for GDS over the next 12 months is to support the government during EU Exit, by providing knowledge and expertise to departments.

We will be working with departments to support delivery through controls, boots-on-the-ground help in departments and consultancy.

There is a clear need for GDS to support and lead government in its transformation at this time. I am confident that the work that the organisation is doing in collaboration with other departments will help us to retain our reputation as a world-leading e-government. ■

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Kevin Cunnington
Director General

Government Digital Service (GDS)

www.gov.uk/government/organisations/government-digital-service

www.twitter.com/gdsteam

Breaking down boundaries with digital

Jason Fahy, CEO of Knowledge Hub reveals how the firm's feature-rich digital tool-set is breaking down boundaries in the public sector

With the year on year reduction in public sector spending unlikely to change any time soon, the ability to share knowledge, source rapid answers and to remove duplication is increasingly important if shrinking resources are to be focused on delivering front-line services.

With a fast-growing community of over 160,000 professionals, spanning every corner of the public sector, Knowledge Hub is helping to remove traditional, organisational and geographical boundaries and making it easier to deliver results through collaboration. International working groups, cross-government communities of practice, time-limited project groups and leadership development cohorts are just some examples of how the platform's community is exploiting its feature-rich digital tool-set.

Melissa Whittle, Engagement Co-ordinator at GeoPlace, describing the trusted online community they have built for local authority members to share best practice advice on addressing and street data said: "Knowledge Hub is about connecting and sharing in order to improve our knowledge and help us in our day to day work. It's improved our communications 100% and improved our relationships with our community."

The connected intelligence of the virtual community is where the strength

lays. This is attractive to organisations who can tap into a wider knowledge pool and crowd-source answers from subject matter experts, instead of expensive consultants and who can reduce travel expenses by supplementing physical meetings with online activities. And there are benefits to the individual too, who can further their professional development through connecting with their peers, wherever they may be based, to share experiences and to give and get help.

Barrie Minney, Senior Enforcement Agent at Brighton & Hove City Council, reveals how the Local Authority Civil Enforcement Forum (LACEF) has saved money through sharing advice and best practice on local authority debt collection. "The group regularly helps a lot of us to learn new ways of working. Using the latest debt collection technique is one example. Being spread across the country and knowing what working practices are happening elsewhere allows us to improve how we do things", he says.

Originated in the UK, Knowledge Hub now extends to 80 countries as the appetite to share knowledge and understand different approaches to common issues, grows. One such example is UDiTE, who use the platform to support the associations work in promoting relations between the professional associations of Chief Executives and Municipal Clerks rep-

resenting European local authorities, to develop exchanges of information, to share professional experiences, contribute to the enhancement of the role and functions of local authorities and to contribute to democracy and the European Union.

"With a fast-growing community of over 160,000 professionals, spanning every corner of the public sector, Knowledge Hub is helping to remove traditional, organisational and geographical boundaries and making it easier to deliver results through collaboration."

Membership growth, to date, has been largely driven by peer to peer recommendation. However, more recently organisations such as the Cabinet Office, Health Education England and Public Health England have followed founding partners at the Local Government Association and the Improvement Service in Scotland in establishing their own branded networks on Knowledge Hub, to support their business objectives and to tap into the connected intelligence of the wider community.

With the recent announcement of its appointment as a platform partner of 100 Resilient Cities – pioneered by the Rockefeller Foundation, Knowledge Hub seeks to increase its global presence by supporting cities in engaging local communities on resilience initiatives.

The image displays the Knowledge Hub website. The top section features a green header with the 'Knowledgehub' logo and a 'Sign up' button. Below the header is a large banner with the text 'Welcome to Knowledge Hub - join the global public service community'. The banner includes a sub-headline: 'Connect digitally with colleagues and experts, share knowledge, insight and best practice, learn from experiences and inspire innovation and new ways of working.' and a call to action: 'Sign up for free today.'.

On the right side of the banner is a 'Log in' form with fields for 'Email Address' and 'Password', a 'Remember me' checkbox, a 'LOG IN' button, and links for 'Forgot Password' and 'Sign up'. Below the form are three social login buttons: 'Sign in with Google', 'Sign in with SSAT', and 'Sign in with LinkedIn'.

The bottom section shows two screenshots of the Knowledge Hub dashboard. The left screenshot shows the 'Knowledge Hub' page with a navigation bar (MY HOME, LIBRARY, BLOGS, EVENTS) and a main content area with 'ALL ACTIVITY' and 'ANNOUNCEMENTS' sections. The right screenshot shows the 'My Groups' page with a search bar and a list of groups including 'KHub Connects', 'LG Inform and LG Inform Plus', and 'Public sector news'.

Arguably, the blueprint for building online communities to unite resources around common goals is the Scottish Public Services Network, facilitated by the Improvement Service in Scotland. With over 20,000 users across 800 groups of interest the network supports local, national and cross-sector projects ranging from migration resettlement and public health reorganisation to digital transformation. Sarah Gadsden, Interim CEO describes Knowledge Hub as invaluable in joining up the

many stakeholder bodies involved in the numerous initiatives supported by the Improvement Service.

“Originated in the UK, Knowledge Hub now extends to 80 countries as the appetite to share knowledge and understand different approaches to common issues, grows.”

Knowledge Hub is free to public service and not-for-profit organisations and their employees who can access the platform at www.khub.net/sign-up.

Knowledgehub

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Combining large corporations' market reach with start-up innovation power

Imec's programme manager Sven De Cleyn explains how imec.istart helps boost start-up innovation in large corporation markets

According to the Merriam-Webster dictionary, the first-known use of the word 'innovation' dates back to the 15th century. Yet, while the concept has been in place for more than six centuries and has become part of our daily vocabulary, it is becoming increasingly challenging for companies to continue to innovate / reinvent themselves in an environment of start-up innovation.

Larger corporations mainly struggle with the fact that the innovation land-

scape is very much scattered, making it difficult for them to keep a close eye on innovative, emerging technologies that might enrich their product portfolios and provide them with a competitive advantage. At the other end of the spectrum, lots of promising start-ups find it difficult to translate their market potential in a first big customer win or strategic partnership.

To bridge the gap between those two worlds, imec is introducing its 'Smart Brokerage' initiative. Set up under the

umbrella of the imec.istart business acceleration programme, the initiative aims at helping larger corporations and start-ups interact more easily, and create a mutual win-win.

Bridging the gap between large corporations and innovative start-ups

A smart broker is an organisation that bridges the gap between larger companies' requirements and start-ups' innovation capacity; a gap characterised by following mutual concerns:

- Large companies do not want to contaminate their IPR or disclose confidential data in their search for partners.
- They do not have the time to continuously scan the market for relevant start-ups in their domain.
- Start-ups, on the other hand, are typically reluctant to share their ideas and advances with bigger companies.
- Moreover, they lack the corporate contacts to translate their market potential into concrete business opportunities.

In such a setting, a smart broker can put in place the necessary (intellectual property) protection mechanisms and create a trusted environment in which both parties can discuss potential collaboration opportunities.

In general, smart brokers work along the following main principles:

- They have a fully confidential relationship with the large corporation, governed by means of an NDA or another legally-binding contract.
- They have insight into its strategic roadmaps or innovation plans.
- This input is used to identify relevant start-ups that the company could partner with.
- The smart broker helps the start-ups prepare a business case.
- Finally, the smart broker presents the start-up proposals to the larger corporation; this can lead to a variety of collaboration types:
 - Paid proof-of-concept/commercial deal;

- Joint business offering;
- Distributor/reseller type of deal;
- Licensing deal; and
- Any other type of mutually beneficial relationship.

Imec's 'Smart Brokerage' approach: lightweight, lean & results-driven

Imec's 'Smart Brokerage' initiative features a four-step approach that is lightweight, lean and results-driven:

- 1 In the first phase, imec focuses on getting to know the corporate partner, its activities and its requirements.
- 2 Building on those insights, imec proposes a longlist of start-ups it could partner with; an exercise during which imec calls upon its broad entrepreneurship ecosystem – ranging from the start-ups supported by the imec.istart business acceleration programme to iMacs portfolio of spin-offs, its EIT contacts and potentially even other (international) partners/sources.
- 3 Together with representatives from the corporate partner's various business lines, this long list then gets translated into a shortlist – featuring those start-ups that show the highest collaboration potential.
- 4 Prior to the final (half-a-day) pitching event, imec specialists coach the shortlisted start-ups on the topic of successful deal pitching – after which the corporate partner decides with which start-up(s), to embark on a business journey (resulting in business discussions with the right corporate executives and the kick-off of proofs-of-concept).

Everybody wins

"We saw a clear need for this type of initiative – as to avoid that larger companies and start-ups continue to work on their respective islands; after all, by combining forces, they get so much stronger," says Sven De Cleyn, programme manager of the imec.istart business acceleration programme. "The first cases we have gone through clearly show that imec's role as smart broker makes everybody win."

"Our corporate partners, for instance, get in touch with a line-up of innovative start-ups they would not be able to easily find themselves. For the start-ups, this is a unique opportunity to talk to the business executives they have been longing to see; and they can learn from one another during the pitching sessions. Finally, from an imec perspective, we can help our start-ups with what they need the most – i.e. making deals and facing customers."



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Govroam: The Wi-Fi network linking public services

Mark O’Leary from Jisc shares his seasoned opinion on govroam which provides the possibility of “zero-touch” access to Wi-Fi for public sector workers

Anyone who must travel to different offices and buildings regularly as part of their job will understand what a pain it can be to swap on to different Wi-Fi networks at every new destination.

Identifying the correct network, sourcing the password and logging on all takes both time and effort.

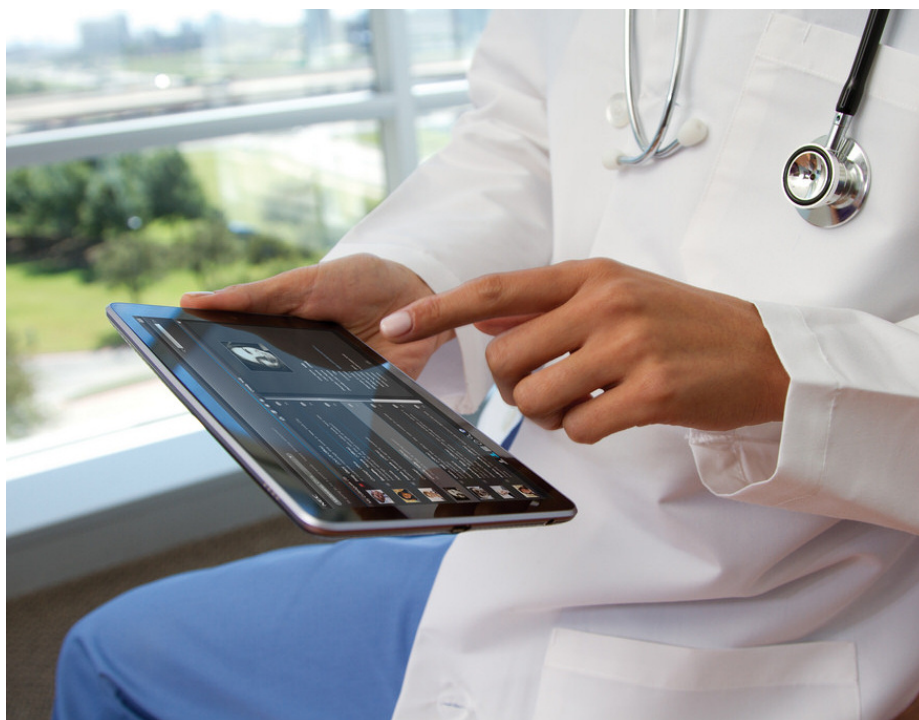
In the public sector, where partner-working across different sites and organisations is increasing, “zero-touch” access to Wi-Fi has become a possibility with the launch of [govroam](#).

It means that public sector employees across the UK can now travel between any participating public services’ building and connect to the network, without touching their laptop, smart phone or tablet. Once the profile is installed, the connection happens automatically.

How does govroam work in practice?

The introduction of govroam supports the trend towards multi-disciplinary activities, such as the convergence of health and social care.

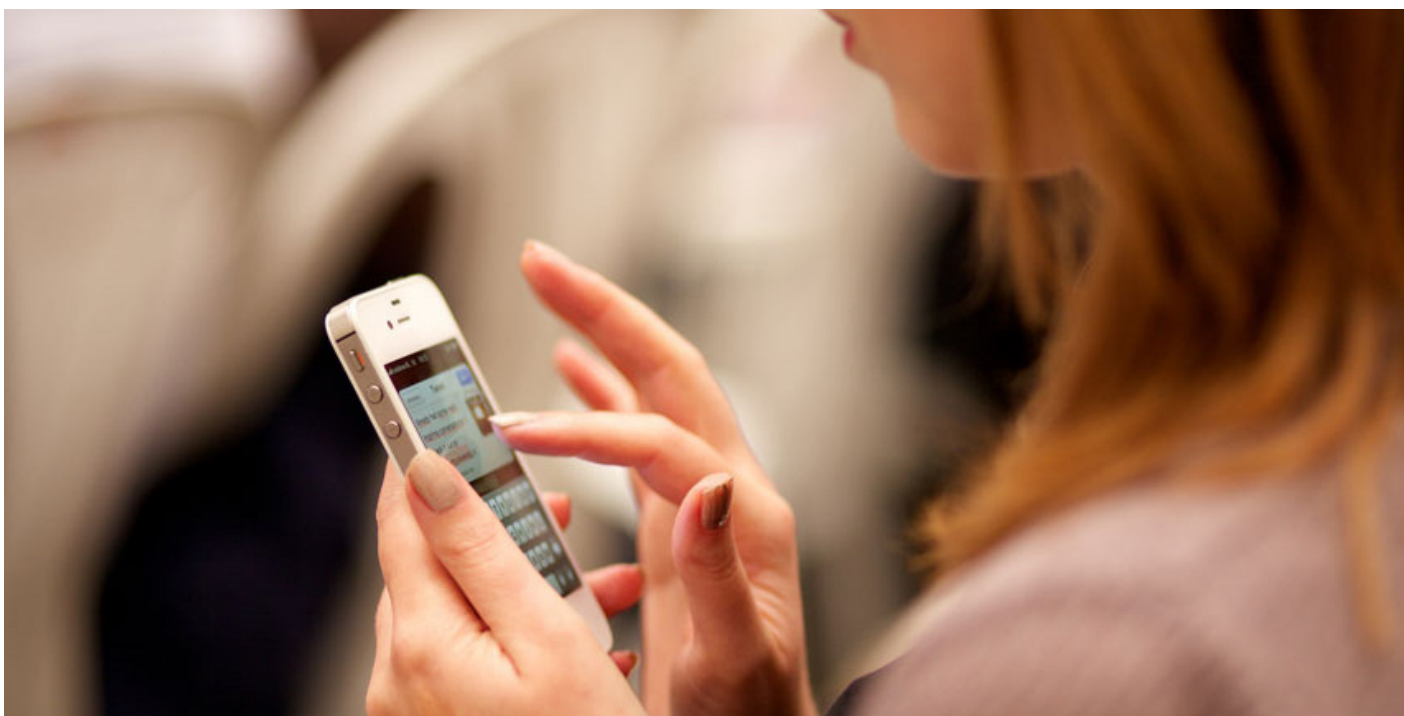
Site-sharing with govroam enables multiple organisations to share a physical location and connect over a single standardised network. Parts of a council office could be repurposed for community-based police or health workers, or spare space in police



stations made available for probation staff. This approach encourages collaborative working and has considerable cost-saving benefits, too.

Scenarios where govroam could prove useful include:

- A school where health visitors attend to immunise the children, police visit to teach road safety and council workers provide estate services and meal deliveries etc.
- An elderly person is recovering in hospital after an assault and, while there, needs contact with social services, community health workers and the police.
- Heavy snowfall prevents council workers from reaching the building they work in, but by prior arrangement, they can get to the local fire station and temporarily work from there.
- An international event like Tour de France comes to town and outdoor govroam coverage allows coordination between police, medical and council staff to manage the crowds.
- A health trust organises a conference for doctors from all over the country and doesn't have to budget or plan for networking, as there is already govroam in its conference centre.



- Council workers can use any room in the building for tasks that require connectivity, not just designated areas.
- A multi-disciplinary meeting is held to organise a university fundraising week, where police and ambulance staff, highways and other council workers, plus the local MP can all meet at the university to talk to the student union, all using their own online resources back at base to plan, schedule and research.

Who's using govroam?

The Public Services Network (PSN) for Kent has adopted govroam, where every local authority has rolled it out; govroam is now available at more than 400 sites and rising and work is continuing to connect the whole of Kent's PSN, which has more than 370,000 users across nearly 1,200 sites.

Such multi-tenanted sites are also being deployed across the Yorkshire and Humberside region, where gov-

roam is in place at more than 600 venues, by YHPSN and NYnet. This pattern is being repeated across the UK. The service is not, however, limited to PSNs: the fastest growing adopter of govroam to date is the NHS.

Govroam has also been deployed in parts of London and there's a lobby group, Connectivity Over London, which is looking to champion the use of both govroam and its sister service for the education sector, eduroam, across the capital. This would link hundreds of universities and public-sector locations.

Background and further info

Govroam evolved from eduroam – the established Wi-Fi service used by the further and higher education and research sector, which runs on the UK's national research and education network, Janet, and supports the roaming of 1.6 million unique devices each month. This network is operated by Jisc, the UK's education technology not-for-profit, which has used its experience of

eduroam to develop govroam. Jisc has produced a [podcast](#), a [film](#) and an [animation](#) about govroam and has [further information](#) on its website.

For more information, please email govroam@jisc.ac.uk.



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Cybersecurity and its role in delivering digital public services to citizens

John Swinney, Deputy First Minister of the Scottish Government shares his thoughts on the importance of cybersecurity and why it is an essential component of delivering digital public services to citizens

Across the globe, our ability to inform and interact with citizens is being transformed by digital opportunities and Scottish public bodies, businesses and charities are developing ambitious plans to embrace these opportunities. However, the scale and nature of the cyber threat is indisputably on the rise and this presents a risk to Scotland's ambition to be a world-leading nation in cyber resilience.

Worldwide, public services are being routinely and mercilessly subjected to low-level but high-volume attacks which capitalise on the complacency around basic cybersecurity measures, as well as more sophisticated and targeted cyber-attacks which in turn are impacting on the ability to provide essential health, social care and community services. This can also serve to undermine trust and confidence in the public sector.

The impact of a significant cyber-attack on any one organisation can be potentially catastrophic, but it does not necessarily stop at that one organisation. Cybersecurity must be viewed by the boards and senior management across all public, private and third sector organisations as an essential component of delivering digital public services to citizens.

In the wake of cyber-attacks in 2017, which affected some public services in Scotland, the Scottish Government committed to accelerating the development of an action plan on cyber resilience which would ensure that Scotland's public services are ready to deal with the emerging cyber threats. Published in November 2017, the Public Sector Action Plan on Cyber Resilience asks the public sector in Scotland to undertake a number of actions to further strengthen our cyber resilience.

In the short term, I want to see a common baseline of cyber resilience measures implemented across the

Scottish public sector, including a commitment from boards and senior management to having appropriate governance arrangements in place to manage the cyber risks. We want active membership of the NCSC's Cybersecurity Information Sharing Partnership to ensure better awareness of cyber threats, independent assurance of critical cybersecurity controls to help protect against the most common internet-borne attacks and implementation of the NCSC's Active Cyber Defence Programme. Furthermore, there should be training and awareness raising arrangements for individuals at all levels of the organisation and robust cyber incident response plans as part of wider response arrangements.

"A group of public bodies, the cyber catalysts, have committed to work towards becoming exemplars in respect of cyber resilience, helping identify common issues and solutions and sharing knowledge and learning with the wider public sector."

Looking to the medium term, we will aim to promote a common, effective, risk-based approach through the development of a Scottish Public Sector Cyber Resilience Framework, which will help make sense of the wide range of standards Scottish public bodies are, or will be, required to comply with, such as the NIS Directive, the GDPR and cross-government security standards.

The cybersecurity of any one organisation within the chain is potentially only as strong as that of the weakest member of the supply chain. We are therefore developing a proportionate, risk-based policy in respect of supply chain cybersecurity, aligned with GDPR requirements, which we will then encourage public bodies to apply in all relevant procurement processes.

A group of public bodies, the cyber catalysts, have com-



John Swinney, Deputy First Minister of the Scottish Government

mitted to work towards becoming exemplars in respect of cyber resilience, helping identify common issues and solutions and sharing knowledge and learning with the wider public sector.

The Public Sector Action Plan forms part of a suite of plans that we committed to developing in the Programme for Government, in order to drive Scotland towards our vision of being a world leading nation in cyber resilience by 2020. These plans are designed to create concrete actions which will help our citizens operate safely and confidently in the digital world, drive up levels of fundamental cyber resilience in the private and third sectors and support the economic opportunities that innovation and cutting-edge research in cybersecurity presents.

I often remark that “resilience is everyone’s business”. Nowhere is this more true than in the area of cyber resilience. The complex nature of the cyber threat, its lack of respect for any boundaries and our increasing reliance on interconnected digital networks means that we ALL have a stake in making our nations safer places to live and flourish online.

“The impact of a significant cyber-attack on any one organisation can be potentially catastrophic, but it does not necessarily stop at that one organisation. Cybersecurity must be viewed by the boards and senior management across all public, private and third sector organisations as an essential component of delivering digital public services to citizens.”

I also have no doubt there will be challenges as we take forward work together to develop and implement our action plans on cyber resilience. But I truly believe that, if we can create an environment where we work together, with a common goal and build on one another’s strengths and knowledge, the vision for Scotland being a world leading cyber resilient nation is within our reach. ■

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Cyber security: Making the UK safer

The National Cyber Security Centre reveals how they help to make the UK the safest place to live and do business online

The National Cyber Security Centre helps to make the UK the safest place to live and do business online. The NCSC was set up to help protect our critical services from cyber-attacks, manage major incidents and improve the underlying security of the UK Internet through technological improvement and advice to citizens and organisations. Our vision is to help make the UK the safest place to live and do business online.

We support the most critical organisations in the UK, the wider public sector, industry and SMEs. When incidents do occur, we provide an effective incident

response to minimise harm to the UK, help with recovery and learn lessons for the future.

More specifically, the NCSC:

- Understands cyber security and distils this knowledge into [practical guidance](#) that we make available to all.
- Responds to [cyber security incidents](#) to reduce the harm they cause to organisations and the wider UK.
- Uses industry and academic expertise to [nurture the UK's cyber security capability](#).

- Reduces risks to the UK by securing public and private sector networks.

Launched in October 2016, the NCSC has headquarters in London and brings together expertise from CESG (the information assurance arm of GCHQ), the Centre for Cyber Assessment, CERT-UK and the Centre for Protection of National Infrastructure.

By building on the best of what we already have, the NCSC provides a single point of contact for SMEs, larger organisations, government agencies and departments. We also work collaboratively with other law enforcement, defence, the UK's intelligence and security agencies and our international partners.

National Cyber Security Centre (NCSC) – a year on

A report marking the first anniversary of the National Cyber Security Centre (NCSC) has shone a light on the work the organisation has done to make the UK the safest place to live and work online.

The NCSC, part of GCHQ, brought together elements of its parent organisation with previously separate parts of government and intelligence to create a single, one-stop-shop for UK cyber security. While there is still much work to be done, in its first 12 months the organisation has prevented thousands of attacks, provided vital support for the UK's Armed Forces and managed hundreds of incidents.

The NCSC has also made an impact on the future of cyber security, helping to foster a talent pipeline of the next generation of experts and working with business and academia to create a culture where technology can thrive

Jeremy Fleming, Director of GCHQ, says: "In an increasingly digital world, cyber is playing an ever more important part in our daily lives and in the UK's approach to security. The threats to the UK are evolving rapidly as technology advances. Our response has been to transform to stay ahead of them.

"The NCSC is a pivotal part of that transformation. It is a critical component not only of GCHQ, where it benefits from the data and expertise it has access to as part of the intelligence community, but of how the government works to keep the UK safe.

"The NCSC has brought together unparalleled skills, capabilities and partnerships and in its first year has made enormous strides in increasing and improving our cyber capabilities. It is in the front line in protecting the UK against a growing number of cyber-attacks."

Ciaran Martin, CEO of the NCSC, says: "Cyber security is crucial to our national security and to our prosperity. We're incredibly proud of what we have achieved in our first year at the National Cyber Security Centre, bringing together some of the best cyber security brains in the country in a single place.

"But the threat remains very real and growing – further attacks will happen and there is much more for us to do to make the UK the safest place in the world to live and do business online. We look forward to working with our partners at home and abroad in the year ahead in pursuit of that vital goal."

While operational since October 2016, the NCSC's new London headquarters were opened by HM The Queen and HRH The Duke of Edinburgh in February 2017.

As well as co-ordinating the government's response to over 820 significant incidents, the NCSC has prevented waves of attacks through its Active Cyber Defence programme. The NCSC is proud to deliver vital work nationally and internationally as part of GCHQ and over the last year has worked with more than 50 countries across five continents, including signing NATO's ground-breaking cyber Memorandum of Understanding.

In closing, it is worth highlighting that the UK Government is fully committed to defending against cyber threats and address the cyber skills gap to develop and grow talent. The NCSC was created as part of the five-year National Cyber Security Strategy (NCSS) announced in 2016, supported by £1.9 billion of transformational investment. ■

The National Cyber Security Centre
www.ncsc.gov.uk
www.twitter.com/NCSC

Reskilling the cyber gap in the UK

Cyber security trainer at QA Limited, James Aguilan shares his expert opinion on the key issues around reskilling the cyber gap in the UK today

McAfee, security firm, states that UK education systems are providing minimal insight into careers in cyber security. Government bodies have addressed the skills gap with plans to triple the amount of computer science teachers in schools and introducing a National Centre for Computing. CWJobs found that 65% of employers thought the government had not invested enough in training the next generation of tech employees, which is causing a gap in the field of cyber security. Notably, with recent high profile cyber-attacks including Uber and NHS data breach, the importance of robust cyber security is clear, or at least it should be. Here, I discuss the concern with cyber security gaps.

Skill shortage in secure coding, cyber security and cloud migration are widespread

The main concern for the shortage in cyber security is the inadequacy in preparing for the demands of technology, specifically, within secure coding and cloud migration. 31% of cyber security professionals state that organisations have a shortage of application security skills. When you think about the whole digital transformation trend going on across all industries, it's easy to conclude that this mismatch can only result in a lot of insecure code being developed and deployed.

Additionally, 29% of cyber security professional state organisation has a

shortage of Cloud security skills. ESG research indicated that 42% of organisations currently use IaaS and/or PaaS services today and these percentages are poised to increase in the future. Beyond this, survey respondents point to a skills shortage in areas like penetration testing, risk/compliance administration and security engineering. The overall picture is bleak – many organisations may not have the right skills and resources to adequately secure new business and IT initiatives and may also lack ample skills to detect and respond to incidents in a timely fashion.

Lack of readiness for a cyber security attack

With numerous high-profile security breaches in recent years, UK businesses are facing greater pressure to ensure their security measures are up-to-date and in place. However, despite the increase in both attacks and warnings, many companies remain complacent as some believe they can't be hacked. As a result, they lack the right approach or plan to protect themselves against attacks.

With organisations confidence so low, it is unsurprising only 50% of small business enterprises (SME) are prepared for a cyber-attack. On the other hand, the other half of organisations are said to look for cyber security skills when recruiting new tech talent. Experis research found that 65% of employers thought the government

had not invested enough in training the next generation.

Beyond the recent budget, however, the government has taken steps to address the problem of a skills shortage. For example, the UK Government launched the National Cyber Security Strategy in 2016, part of which incorporates a plan to make sure there is a constant supply of home-grown cyber security talent. However, 80% of technology organisations stated that they are currently struggling to fill cyber security roles, with 30% believing this is due to an industry skills gap.

Educating the cyber skills gap

In 2017, GCSE/GCE/Degree grades have marginally improved. However, there are still systemic issues when it comes to cyber security. So, how can businesses address the skills gap? Organisations can deploy an innovative recruitment process in a bid to resource the skills that they can't currently find. An example and a good place to start is implementing gamification.

The National Cyber Security Centre's (NCSC) codebreaking exercise is a playing field for all applicants – in that the recruitment process can be used to find prospective candidates from all backgrounds. Not only did it enable NCSC to see how well potential candidates would fare on the job, it gave them access to a larger pool of raw talent. In turn, this results in a greater



diversity of skills – an essential asset for any business looking to contend with a threat landscape that evolves by the minute.

Introduction to apprenticeships and The CyberFirst Programme

As an alternative to the traditional education system, another route to bridge the security gap is for businesses to offer apprenticeship programmes for young people looking to get into the industry. A cyber security apprenticeship programme involves the hiring of raw talent, after having completed their GCSEs or GCE. Apprentices can work, develop new skills on the job while learning and earning at the same time. This way, apprentices can study for the certifications they require, with businesses also getting the exact cyber security skills they need to protect their organisation from threats.

What's more, apprentices don't have to attend a university or college to do apprenticeships. Taking on apprentices is the perfect way for businesses to nurture a robust cyber security team that is fit for purpose and has the technical and practical know-how to fend off cyber threats.

Introducing cyber skills and awareness early - is often key to encouraging the

next generation to consider cyber roles later. The CyberFirst Programme targets children from GCSE age onwards – CyberFirst is a collaboration between NCSC, QA and The Smallpeice Trust. It is a pivotal part of the UK Government's National Cyber Security Programme and aims to embed cyber skills to give talented young people the support, experience and exposure they need to become the cyber professionals of the future.

To prevent a worst-case scenario – technological change accompanied by talent shortages, mass unemployment and growing inequality – reskilling and upskilling will be critical. Every industry is being impacted by the rise in technology and an increased reliance on the Internet of Things (IoT). Thus, businesses are being forced to rethink the way they work and turn to new technologies to remain successful. The upsurge will see countless new roles created as employers seek digitally-savvy workers to help them master these technologies.

However, to thrive the modern employee will need to learn new skills and have some form of cyber awareness. Apart from a reform in basic education, it is simply not possible to weather the current technological

revolution by waiting for the next generation's workforce to become better prepared. In its place, it is critical that businesses take an active role in supporting their current workforces through reskilling and upskilling. This approach of cross-collaboration between business sectors, the government and the education system are mandatory if millennials and future generations are to become the sharp, aware and talented cyber defenders our societies need.



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European Commission: Tackling illegal content online

The efforts of the European Commission around tackling illegal content online are charted here by Open Access Government

The European Union, earlier this year said that they have responded to the challenge of illegal content online by means of both binding and non-binding measures, in sectoral and horizontal initiatives. Their ongoing work under sectorial dialogues with companies has shown positive results. For example, under the Code of Conduct on Countering Illegal Hate Speech Online, internet companies now remove on average 70% of illegal hate speech – and in more than 80% of these cases, the removals took place within 24 hours. However, illegal content online remains a severe issue with tremendous consequences for the security and safety of citizens and companies, thus undermining the trust in the digital economy.

European Commission reinforces EU response to illegal content online

In its communication back in September 2017 on tackling illegal content online, the European Commission promised to monitor progress in tackling illegal content online and assess whether further actions are needed to ensure the proactive and swift detection plus removal of illegal content online, including possible legislative measures to complement the regulatory framework already in place.

As a follow-up, the European Commission in March recommended a set of operational measures – accompanied by the safeguards – to be taken by companies and member states to further step up this work before it determines whether it will be necessary to enact legislation. These recommendations apply to all forms of illegal content, including terrorist content, incitement to hatred and violence, copyright infringement and counterfeit products.

The recommendation builds on the on-going work with the industry through various voluntary initiatives to ensure that the internet is free of illegal content.

Vice-President for the Digital Single Market, Andrus Ansip says: “Online platforms are becoming people’s main gateway to information, so they have a responsibility to provide a secure environment for their users. What is illegal offline is also illegal online. While several platforms have been removing more illegal content than ever before – showing that self-regulation can work – we still need to react faster against terrorist propaganda and other illegal content which is a serious threat to our citizens’ security, safety and fundamental rights.”

While progress has been made in protecting Europeans online, platforms still must redouble their efforts to take illegal content off the web more quickly and efficiently, the European Commission urges. Voluntary industry measures encouraged by the Commission are through the EU Internet Forum on terrorist content online, the Code of Conduct on Countering Illegal Hate Speech Online and the Memorandum of Understanding on the Sale of Counterfeit Goods have all been successful. Having said that, there is significant scope for more effective action, especially on the most urgent issue of terrorist content, where serious security risks are present.

Stronger procedures for more efficient removal of illegal content

The recommendations from March this year set out operational measures to reinforce the cooperation between companies, trusted flaggers and law enforcement authorities and to increase transparency and safeguards for citizens, include:

- **Clearer ‘notice and action’ procedures:** Companies must make easy and transparent rules for notifying illegal content, including fast-track procedures for ‘trusted flaggers’. To avoid the unintended removal of content which is not illegal, content providers should be informed about such decisions and be able to contest them.

- **More efficient tools and proactive technologies:** Companies must make clear notification systems available for users. They should have proactive tools to remove and detect illegal online content, such as child sexual abuse material or counterfeited goods.
- **Stronger safeguards to ensure fundamental rights:** To ensure that decisions to remove content are accurate, especially when automated tools are used, companies must ensure effective and appropriate safeguards are out in place, including human verification and oversight, in full respect of fundamental rights, freedom of expression and data protection rules.
- **Closer cooperation with authorities:** If there is evidence of a serious criminal offence or that illegal content is creating a threat to life or safety, companies must promptly inform law enforcement authorities. As such, member states are encouraged to establish the appropriate legal obligations.

“Online platforms are becoming people’s main gateway to information, so they have a responsibility to provide a secure environment for their users. What is illegal offline is also illegal online. While several platforms have been removing more illegal content than ever before – showing that self-regulation can work – we still need to react faster against terrorist propaganda and other illegal content which is a serious threat to our citizens’ security, safety and fundamental rights.”

Increased protection against terrorist content online

Terrorist content online poses a very grave risk to the security of Europeans and its proliferation must be treated as a matter of serious urgency. As such, the European Commission recommends more specific provisions to further curb terrorist content online, which are:

- **One-hour rule:** Considering that terrorist content is most harmful in the first hours when it is online, all companies should, as a rule, remove such content within one hour from its referral.

- **Faster detection and effective removal:** Internet companies must implement proactive measures, including automated detection, to effectively disable or remove terrorist content and stop it from reappearing again.
- **Improved referral system:** Fast-track procedures must be laid out so that referrals can be processed as quickly as possible, while member states must make sure they have the necessary resources and capabilities to identify, detect and refer terrorist content.
- **Regular reporting:** Member states should report to the European Commission on referrals, ideally every three months and their follow-up should ensure an overall cooperation with companies to hinder terrorist online content.

Next steps

The European Commission says they will monitor the actions taken in response to this specific recommendation and determine whether further steps, including, if necessary legislation, are needed.

https://ec.europa.eu/commission/commissioners/2014-2019/avramopoulos_en

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Working To Eradicate Global Cyber Risk

The World Economic Forum Global Risk Report 2018 cites cyber risk as one of the top risks we face today and is the number one risk that businesses are concerned about. The rate at which the threats are growing, combined with the rapid expansion of internet-connected devices – expected to reach 20 billion by 2020 – leaves businesses and governments vulnerable to attack. The threat is real.

The Global Cyber Alliance (GCA) is a nonprofit organisation whose mission is to eradicate systemic cyber risk through collective action. Most cybersecurity nonprofits are focused on raising awareness or making policy, but often the results are difficult to see or simply result in a lot of shelf-ware (i.e. more reports). GCA is action-oriented with a mantra of “Do Something. Measure It.” which implicitly is a way of saying “we don’t just talk about cyber.” GCA builds solutions that address serious problems. As a nonprofit, all of GCA’s solutions – actual cybercrime-fighting, systemic risk-reducing solutions – are available for free.

For the past two years GCA has focused on the risk of phishing. We don’t just talk about making the internet safer – we are making the internet safer. **We do this by:**

UNITING GLOBAL COMMUNITIES

We must stand as a global community, across sectors and geography, if we are to effectively address cyber risks.

IMPLEMENTING CONCRETE SOLUTIONS

We build concrete solutions that reduce and eradicate cyber risk, and we make those solutions freely available for any organisation or individual to use.

MEASURING THE EFFECT

We are firm believers in measuring effectiveness, because we must measure to know we are doing the right things, and metrics drive action. We need to know what works and what does not.

The rate at which the threats are growing, combined with the rapid expansion of internet-connected devices – expected to reach 20 billion by 2020 – leaves businesses and governments vulnerable to attack. The threat is real.

What We've Done

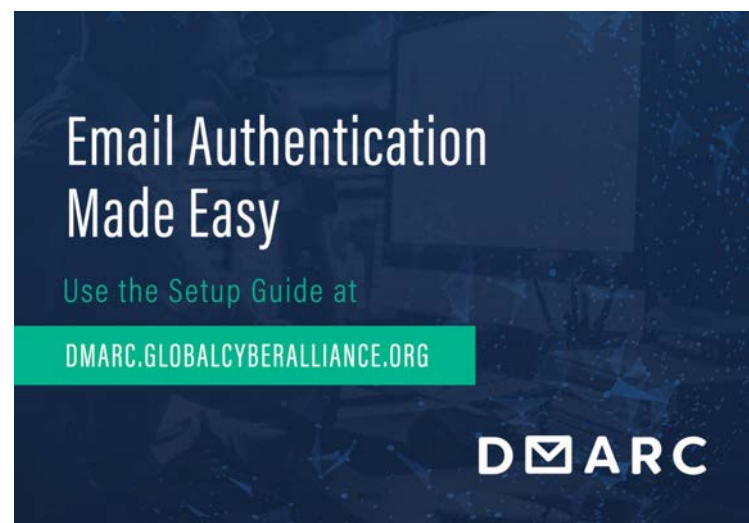
GCA has built a global partnership consisting of more than 200 organisations, spanning 15 sectors and 25 countries. Our partners champion our mission, provide strategic and technical advice, and help us evangelise our solutions.

More than 90% of cyber attacks start with an email. It seemed only logical that this would be the place to start. GCA has developed two solutions to help combat phishing.

DMARC

Domain-based Message Authentication Reporting and Conformance – is a standard made available to the internet in 2010. DMARC allows an organisation to confirm, or authenticate, emails are from who they say they are. DMARC prevents the worst type of phishing: direct domain spoofing. If DMARC is properly implemented, it means only those who are authorized can send email using your organisation's domain. It creates more trust and confidence in your brand, provides protection against phishing, and ensures better delivery of your email messages.

GCA created a Setup Guide that enables world-wide adoption of DMARC. GCA's tool is available in eighteen (17) languages and with more to come. GCA has also embarked on a campaign to drive DMARC deployment by the private sector and government. The U.K. government has been a leader in government adoption, being the first to declare that all U.K. government domains have DMARC in place. In October of 2017, the U.S. government followed suit and has mandated DMARC implementation across all federal civilian agencies. The global financial sector has begun adopting DMARC, and the U.S. healthcare system has been advocating for the adoption of DMARC as well.



Learn more about DMARC at dmarc.globalcyberalliance.org.

QUAD9

Quad9 is a free security solution that uses DNS to protect systems against the most common cyber threats. GCA led the development of Quad9 in collaboration with Packet Clearing House (PCH) and IBM, along with contributions from multiple threat intelligence providers around the world. Since its public launch in November 2017, the service has spread globally to more than 150 countries and blocks access to millions of malicious websites every day. The service is used by individuals, businesses and governments.

How does Quad9 work? Quad9 leverages the power of the DNS to block malicious websites. DNS is like the “phone book” of the internet; it translates addresses like www.anydomain.com to an IP address which often looks like 192.168.0.1. All browsers and anything which uses a web name always uses DNS. All we have done is take some of the existing DNS infrastructure within the internet and have “inoculated” it against websites which contain viruses, malware or are known cybercrime sites.

This is not censorship or content filtering as the user is free to browse content of their choosing or inclination. It is security protection, only blocking access to those sites that have been identified as malicious (such as phishing, poisoned domains, malicious URLs).



Learn more about Quad9 at [Quad9.net](https://quad9.net).

The EU's new General Data Protection Regulation (GDPR)

Andrew Davidson, Head of Marketing, Cyber Security EMEA at Fujitsu shares his seasoned opinion on the EU's new General Data Protection Regulation (GDPR) and reveals that the devil is in the data

A recent joint article chose a revealing headline: 'GDPR: the new data-protection law giving watchdogs a mega-bite.' Much of the coverage of the EU's new General Data Protection Regulation (GDPR) has been focused on the possibility of huge fines being levied on companies that fail to comply with the provisions of GDPR. But at Fujitsu, we prefer to accentuate the positive.

The new regulation is an opportunity. EU statutory regulators agree. They have indicated that companies which distinguish their products and services by data privacy standards will win more business.

This is not only an obligation but an opportunity. With compliance comes competitive advantage, as organisations can better utilise the data at their disposal, gain critical insights and build trusted relationships.

By approaching GDPR from the perspective of people, process and technology as well as enabling digital transformation, you can make the most of the opportunity.

GDPR is not about technology

GDPR is about protecting the personal data of individuals. Technology will help you to do that, but the emphasis needs to be on achieving a holistic view of all the data that you hold and process. To do that you need good policies and

governance. Your processes, systems and technologies then need to be aligned with those policies.

In that way, everything you do can be linked back to the basic principles outlined in GDPR and you will be able to not only comply with the regulation, but achieve significant benefits for your business, your people and your stakeholders.

That's what we mean by the 'devil is in the data' – look closely at the demands of GDPR, understand what you need to do at all levels of your organisation. That's important because every enterprise is complex and there's always a risk of data getting lost or duplicated across functions and within them.

Achieving better visibility can deliver a lot of benefits to the way you operate and the information you can leverage.

Focus on people

The principles behind GDPR are founded in the EU Charter of Fundamental Human Rights. Regulation is a positive step forward for the rights of citizens to have more control of their personal data and to engage with organisations which hold and process it in positive ways.

We believe that this human-centric view of GDPR should be the foundation for how organisations comply with GDPR. It's not just another regulatory burden,

but a means by which better-managed quality information can directly contribute to business improvements and efficiencies with the needs and rights of peoples placed firmly at the heart of the entire exercise.

It is often hard for businesses to create a true sense of ownership when it comes to dealing with privacy issues around personal data. It's been seen as an issue for lawyers or compliance specialists. It's not considered a core part of the business. That also used to be the case for cybersecurity, but the recurrence of high-profile breaches which have affected the reputations of global organisations has transformed that mindset. It is now well understood that investment in cybersecurity not only delivers higher levels of protection, but also engenders trust. This is what we are seeing with GDPR which aims to give individuals more ownership and control over what's happening to their personal data, even if most people won't notice the difference in their daily lives.

Your focus needs to be on the interests of data subjects – people – employees, customers and all stakeholders. Everyone you come into contact with. Their interests are the principal focus, not just technology.

Data is at the core of all businesses

You need to build a culture of exem-

plary data governance. Know what data you have, where it is, what it's for and who has access to it. Organisations need to own the responsibility for protecting the privacy of their customers and employees by designing compliant business processes, based on appropriate technology, to collect and processes personal data.

Effective data governance and management need to be considered holistically, rather than in silos. In an era of cheap storage, many organisations have just stored data without really understanding whether that data is still required. This goes against the GDPR concept of data minimisation – which is to only hold the minimum amount of data required and only for legitimate purposes.

Understand your data, make it visible

In a world replete with threats, a lack of visibility and understanding represents the biggest danger for organisations, not just in terms of GDPR, but across but for organisational effectiveness too.

Hackers know that personal data can be profitable, so they will attempt to steal it. And, it's not just cyber that counts: data can be lost in many other ways. Poor practices can see data lost through using unsecured Wi-Fi in public places or printing out documents and then not shredding them. Good lifecycle management of data in all its forms is vital.

As digitalisation projects gather pace and the Internet of Things (IoT) devices like wearable or remote sensors gather increasing volumes of data (from video to numbers to sound and biometrics), you must get ahead of the data curve.

It's all part of your digital transformation

At Fujitsu, we believe that your

approach to GDPR should be based not just on compliance, but also on contributing to your digital transformation. Data, as we've stressed, is at the heart of any modern enterprise. You need to embark on a journey that ensures you know where and how to invest in locating, managing and protecting and utilising your data to its maximum potential. Complying with GDPR can kick-start this.

And it's not just about personal data. We're arguing for a holistic approach to ALL data. Make it the core of your digital future. Achieving high-quality information and data management can be a differentiator in a dynamic marketplace. Seeing it in this way will help you make the investment case for a robust and creative approach to your data management and governance.

People, policy and processes and technology that deliver 'privacy by nature.'

GDPR calls for organisations to achieve its principles 'by design' which means that when they are developing, designing, selecting and using applications, services and products which are based on the processing of personal data or do so to fulfil their task, then the protection of that data must be designed into them from the start. Our approach extends that principle to everything you do to achieve what we call 'privacy by nature'.

People, policy and process are key to the former. Technical controls consist of applications, infrastructure and security. It sounds obvious, but the key is to ensure that it's all done logically and in the right way. You need to understand the needs and expectations of all stakeholders as well as understand the rights and freedoms of data subjects (as defined by GDPR).

You need to understand all the cate-

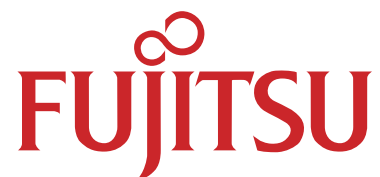
gories of data you hold – and all the sensitivities associated with them. That will enable you to ensure you have categorised the data correctly and then understand what needs to be done to protect its integrity. This helps you define policies and processes. Once they're locked down, you can understand the technology you need to deploy to locate, manage and protect the data. So, for instance, you have to ensure that your systems make it possible to find personal data, extract it and, if necessary, amend or delete it. Ideally, that needs to happen at the application level and filter through to the underpinning infrastructure.

The end game is to ensure 'privacy by nature' – it's fundamental to what you do and who you are. That's why people are the priority. To achieve that balance of people, policies and processes and then achieve the right level of sophistication at the application, infrastructure and security levels takes work. For many, it's not something they want to do alone. Which is where a co-creation partner comes in as well as an ecosystem.

Talk to Fujitsu about how you can make the most of the GDPR opportunity.

www.fujitsu.com/gdpr

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Facilitating better decision-making through technology

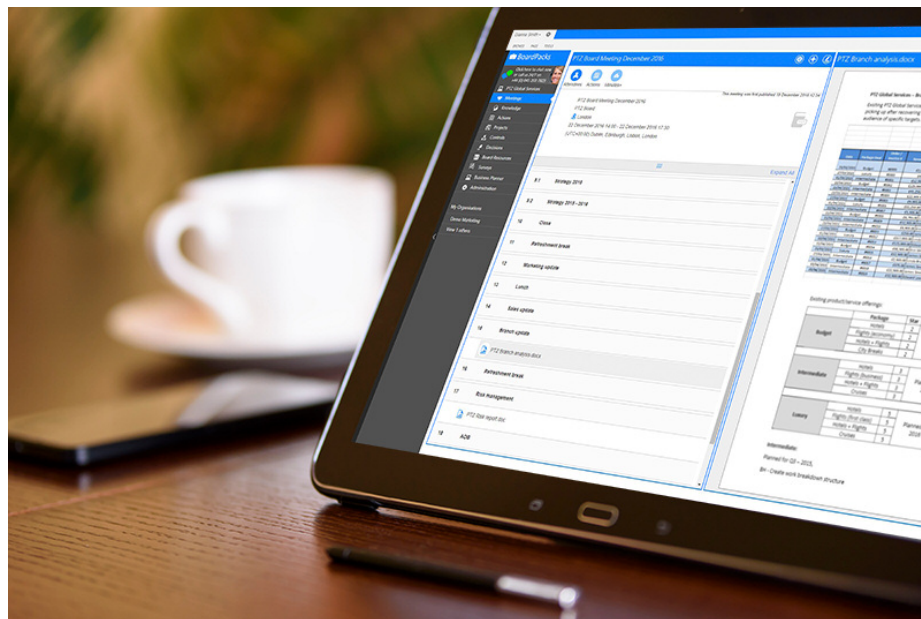
Camilla Braithwaite, Head of Marketing explains how eShare helps organisations embrace technology to allow them to run more effectively

Technology is something we take for granted in our daily lives. We can now complete complex tasks that would have been impossible to even imagine 15-20 years ago at the touch of a button. However, there are still some areas of our working lives that stubbornly remain in the analogue world.

It's because of this very problem that eShare as a company was created by CEO, Alister Esam. When working as an actuary back in 2004, Alister often found himself along with the company secretary witnessing an ineffective board in action. Poor decisions taken by the board at these ineffective meetings helped to contribute to the pensions crisis, which saw pension pots essentially wiped out overnight and led to pensioners campaigning naked outside of parliament, to ensure that actions were taken against the perpetrators.

“eShare’s suite of solutions focus on streamlining manual processes, such as the organisation of a board meeting and ensuring that the correct documentation is readily at hand when and where the directors need it.”

Many companies decided that extra training for board members was the way forward and the right answer to solving the cycle of bad governance many had found themselves in, Alister took a very different approach and saw the benefit that technology could



bring in streamlining processes and creating a system where transparency and accountability was king. What this all boils down to is better governance at the very top of our organisations.

When organisations are being run by engaged board members, they are then better placed to achieve their goals, allowing them to have a greater contribution to their wider community and society in general. Nowhere is the benefit of more effective boards felt more than in the public sector.

The public sector is a broad term that covers a lot of bases, but the principle still applies. Whether you're working in healthcare, housing, local government or any other of the many sectors that this covers, ensuring good governance is key. Governance scandals still break in headline news with

alarming frequency highlighting that more must be done by these organisations to embrace their duties in the governance process and understanding the benefits that technology can bring to those responsible for governance within an organisation, a duty which often falls on the shoulders of the company secretary.

A position which is increasing in its importance in any organisation, the company secretary, traditionally was solely an administrative role, tasked with organising a board meeting and the documents which supported them, both pre- and post-meeting. Whilst this task remains, the amount of other administrative and compliance related tasks has grown rapidly post 2008 – and the financial crash, forced greater regulatory complexities on organisations of all shapes and sizes to ensure



they are being run correctly. With each governance scandal attracting more and more headlines from the media, as well as the greater awareness from the general public surrounding the correct governing of an organisation, there has never been more pressure on those responsible.

eShare's suite of solutions focus on streamlining manual processes, such as the organisation of a board meeting and ensuring that the correct documentation is readily at hand when and where the directors need it. This is the core function of a board portal, but unlike many others on the market, our portal, BoardPacks, is also concerned with improving your organisation's governance.

To monitor board engagement, each document can be tracked to see who has opened it and how long for, as well as being able to record quickly and easily who attended which meetings. Full transparency guaranteed at all stages of the meeting.

The good news for the public sector today is the increased willingness to adopt the technology. The NHS has recently announced a partnership with Microsoft to allow a smooth adoption of Office 365 and the full range of apps and programmes that this brings, alongside similar schemes announced in education and other public sectors. The wider use of this technological framework allows for easier implementation of other supporting technologies. Gone are the days of a protracted and drawn out process to install and use applications, which had to be agreed and tested by various IT departments.

The partnership with Office 365 allows for technologies, such as eShare's MeetingSquared solution that follows much the same principle as BoardPacks. If meetings are the forum for key decisions to be made across your organisation, then why can't the process of organising and attending a meeting be easier and the documentation of key decisions be easier to record within the Office 365 environment?

eShare's solutions work on Windows, iOS and Android devices, meaning the information is accessible to all on their preferred operating system and device. Our user interface has been designed and tested with our extensive range of clients to ensure that it is easy for all to use, from younger secretarial assistants to mature housing association board members.

"When organisations are being run by engaged board members, they are then better placed to achieve their goals, allowing them to have a greater contribution to their wider community and society in general. Nowhere is the benefit of more effective boards felt more than in the public sector."

eShare have already helped many public sector organisations, so if you would like to know more about how we can assist your organisation, please contact info@eshare.net and we would be delighted to arrange a free demonstration of our solutions.



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The five key business benefits of GDPR

Will GDPR have a positive impact on your business? Sneha Paul, Product Consultant, ManageEngine says that the impending regulations will have five key benefits

The impending General Data Protection Regulation (GDPR) is seen as a force of major disruption by so many businesses. The regulations which come into force on 25th May aim to drastically increase the transparency in the data processing methods of any worldwide business that handles the data of EU citizens. As 'data subjects', EU citizens will be handed greater control of their own data, deciding who gets to use it and how those businesses can use it.

The "right to erasure" will allow data subjects to request that their own personal data is permanently deleted by organisations that they do not wish to be in possession of it. Businesses that fail to comply with the requests to be removed will face immense financial consequences, as will businesses that experience leaks and data breaches. Businesses that do fall foul of GDPR will be fined €20 million or 4% of their annual turnover – whichever is the larger sum.

GDPR won't just affect companies based in the EU, despite the fact it concerns the data of EU citizens. Any business handling the data of EU citizens – whether customers, employees or other stakeholders – must comply, no matter where the business is located. However, it's not all doom and gloom. The GDPR comes with plenty of advantages for complying businesses:

1) Improved consumer confidence

GDPR compliance will prove to customers that your organisation is a good custodian of data. This new legislation mandates that each organisation have a data protection officer (DPO), along with regular audits of data processing activities. Furthermore, your organisation will have to comply with a set of data protection principles under the GDPR, ensuring that the necessary framework is in place to keep data subjects' personally identifiable information secure.

During the past year, attacks against companies like [Wonga](#) and [Equifax](#) suggest that the consequences of a data breach can be devastating to your brand equity, with customer defection shooting through the roof and costs escalating for affected companies. The GDPR's proposed security practices will bolster your brand's reputation, showing customers that you have a robust data governance system in place.

2) Better data security

Cyber security breaches loom as a big threat to enterprises in the UK, with 68% of large firms in the UK having encountered a cyber-attack, according to the [Cyber Security Breaches Survey 2017](#). With the scale and sophistication of these attacks growing each day, having a GDPR-compliant framework in place will extend your cyber security practices.

The GDPR mandates using [privileged and identity access management](#) to give only a few professionals access to critical data in your organisation, thereby ensuring that data does not fall into the wrong hands. Additionally, under the GDPR, your organisation will have to disclose any breach within 72 hours of its occurrence. GDPR compliance lays the groundwork for improved data security.

3) Reduced maintenance costs

Complying with the GDPR can help your organisation cut costs by prompting you to retire any data inventory software and legacy applications that are no longer relevant to your business. By following the GDPR's mandate to keep your data inventory up-to-date, you can significantly reduce the cost of storing data by consolidating information that is present in silos or stored in inconsistent formats. Your organisation will also be freed of data maintenance costs, which otherwise would have been incurred in the form of



man-hours and infrastructure maintenance.

Another cost benefit of the GDPR is that your organisation will be able to more effectively engage with customers. The communication will be more personalised because of the granularity of the information collected, thus saving you the sunk cost of pursuing uninterested consumers.

4) Better alignment with evolving technology

As an extension of GDPR compliance, your organisation will have to move towards improving its network, endpoint and application security. Migrating towards the latest technologies – virtualisation, cloud computing, BYOD and The Internet of Things (IoT) – can serve two purposes: one, giving you a way to more effectively manage the growing demand for data and two, allowing you to offer end users augmented products, services and processes.

With third-party management tools, your organisation can constantly monitor its new environment for any data breach. These tools monitor log data and keep a tab on the data transferred outside your environment. They also check the integrity of files and folders in your network, endpoint devices and applications, as well as on the cloud. Most third-party tools will send out an alert notification whenever an anomaly is detected, thereby giving you time to minimise or avert any compromise.

5) Greater decision-making

Under the GDPR, organisations can no longer make automated decisions based on an individual's personal data. After all, automated decisions, such as determining whether or not to provide insurance or a loan to a customer, can be prone to error. The GDPR mandates the right to obtain human intervention, thereby decreasing room for arbitrary decisions.

Thanks to the GDPR, your organisation's data will become more consolidated, ensuring that your data is easier to use, and you have a greater understanding of its underlying value. This insight will let your organisation learn more deeply about its customers and identify areas where customer needs are unmet. By using customer information effectively, your organisation will be able to make better decisions and consequently get a better return on its investments.

Embracing the GDPR

Organisations need to understand that the GDPR is not just a regulatory obligation, but also a means for achieving business and technology alignment. With data becoming the new oil in today's digital economy, companies need to consider a comprehensive approach while aligning their organisation's information and data management policies with regulatory frameworks.

Sneha Paul is a product consultant at ManageEngine, a division of Zoho Corporation, where she actively follows the IT management industry and helps organisations address the challenges they face in managing their IT. For more information on ManageEngine, please visit www.manageengine.co.uk; or follow the company blog at <https://blogs.manageengine.com>. ■

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Product Consultant

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Technology: Why businesses today need to be ready for anything

Daren Howell from Sungard Availability Services explains why businesses today need to be ready for anything when it comes to using reliable technology

It's easy to take for granted or forget the extent to which our lives now rely upon technology that is always on. Every now and again, however, something happens to remind us of this reliance and it's often an uncomfortable situation for everyone involved. [Sungard Availability Services](#) predicts that as IT environments become increasingly complex, unfortunately, these types of incidents are only going to increase.

Over the past few years, there has been a steady rise in demand from businesses for recovery services, reversing what was a long-established downward trend. Businesses are facing an evolving threat landscape, with an increase in malicious cyberattacks, alongside changing working habits and the emergence of more complex technologies such as artificial intelligence (AI) and the Internet of Things (IoT).

[Sungard AS](#), a leading provider of information availability through [managed IT](#), [cloud](#) and [recovery services](#) and certified with [Cyber Essentials Plus](#) for its UK government Cloud Services offering, produces an annual [Availability Trends](#) report. This reveals that there are four key areas where businesses are struggling to remain available:

Taking care of bricks and mortar

When it comes to technology investment, businesses have been, quite rightly, very focused on protecting

themselves against the cyber threat and the recent and globally widespread WannaCry attack is a good example of why these concerns are well founded. However, businesses also need to ensure that they are maintaining the physical fabric of their business and IT environments too.

This year's analysis showed that eight out of ten invocations are due to workplace incidents and 2016 saw the highest level of environmental issues since the annual analysis began over two decades ago. As well as ensuring a robust and secure virtual infrastructure, businesses also need to pay closer attention to the environment in which they house their employees and hardware.

Powering the people

It may surprise some that something as simple as maintaining power to the workplace is a real issue for businesses. Despite power outages consistently making the top three reasons for businesses to invoke their recovery plans, these instances are on the rise for the third successive year, now accounting for one in four failures.

Staying in touch

Issues arising from communications-related failure have been on the up for several years and are the current joint leading cause of business invocations (power and hardware being its bedfellows). This increase has gone hand-in-hand with the growing trend

for more flexible working practices to attract today's employees in tandem with the mobility modern devices afford.

"We see a significant need in business continuity to evolve from plan building to plan execution. And we believe this app is a major step in getting there."

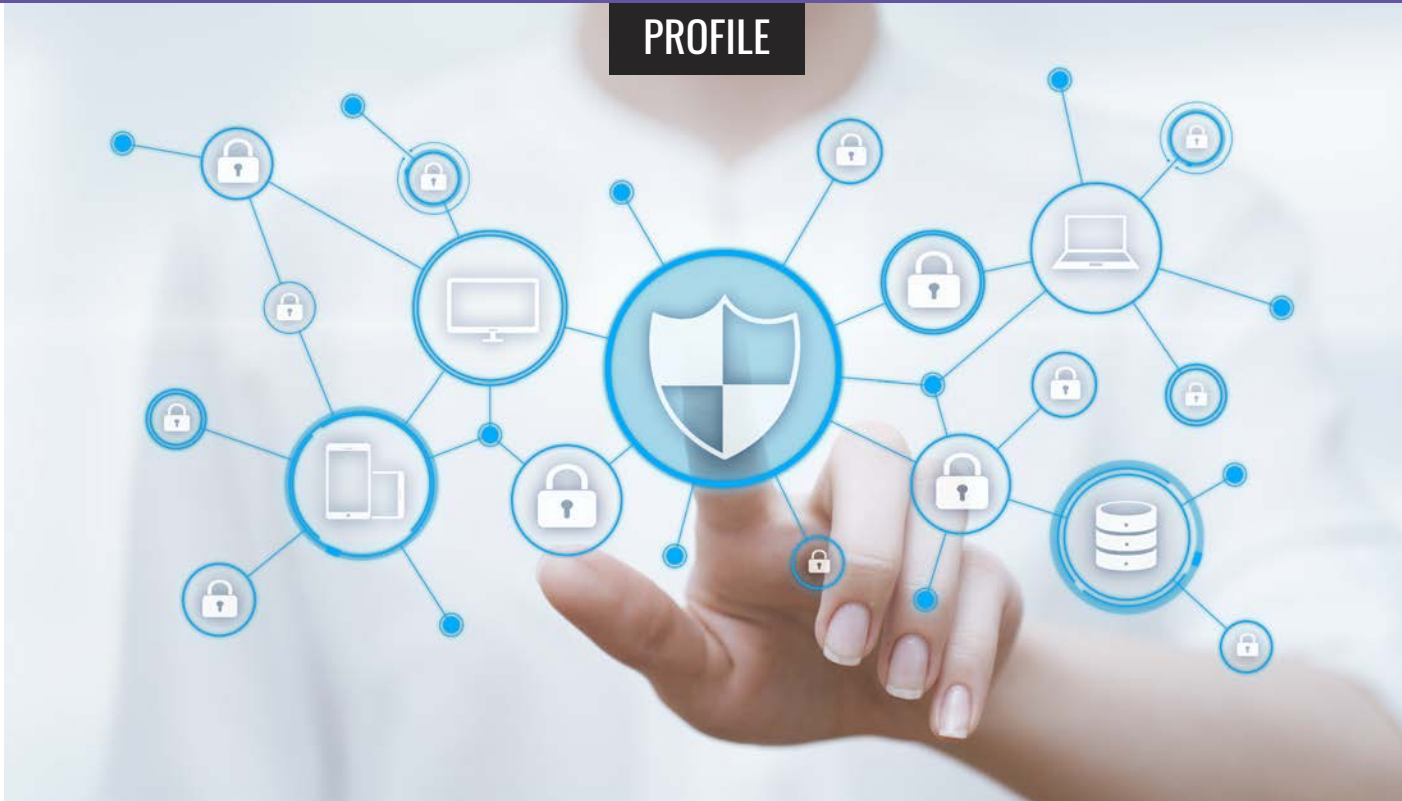
This requires robust, resilient, voice and data communication technology to be available. If employees are unable to communicate with each other, not only do productivity or efficiency plummet, but there is also a significant impact on staff morale, their ability to provide support to customers and ultimately do their job. In light of this, is it surprising that only 11% of businesses' mission-critical applications are suitable for use on mobile devices.

Trustworthy technology

Being able to trust the hardware on which a business depends on is absolutely vital and although the number of invocations made as a result of technology are maintaining a downward trend, issues relating to hardware failures are increasing substantially – by 140% in 2016.

Businesses must be prepared to respond

When an incident like this occurs, as it inevitably will, it is crucial that organisations are able to return to business as usual quickly. Today's complex IT



environments make this a far from straightforward task.

Recognising this, Sungard AS introduced its Act with Assurance mobile app, which ensures businesses are ready for any potential business interruption. The app coordinates with its existing Assurance Software platform to provide a more interactive, efficient way to manage business continuity. It delivers individualised playbooks to recovery team members for each test exercise or actual event, direct to their mobile devices.

“The most important part of managing an incident is communication. It’s also the biggest challenge recovery teams face,” says Ted Marquardt, Senior Product Manager at Sungard AS. “Unfortunately, when disaster strikes, it is not uncommon for incident responders to find themselves frustrated by plans in static, outdated PDFs or binders, or to be interrupted by conference calls with requests for updates. These barriers to recovery lead to gaps in communication during critical times. The Act with Assurance app gives recovery teams the ability to interact live through a new communication channel, which is

absolutely essential to effective incident recovery.”

Act with Assurance real-time messaging capabilities are critical when time is of the essence. Incident coordinators can stage task assignments and monitor up-to-the-minute task progress, streamlining communications during an event. Responders see their customised task lists at a glance, allowing them to stay focused and problem-solve and they can provide updates with minimal interruptions by simply tapping their smartphone screen. Updates then feed back to the Command Centre in Assurance, bringing teams together at just the right time by facilitating better communication while the recovery is underway.

“Apps for other business continuity software are merely portals to the existing sites with no additional functionality. Act with Assurance is a native app developed as a powerful extension of Assurance’s incident management solution, building on the business continuity data our customers are gathering with Assurance,” Marquardt continued. “Other business continuity software companies are focused on

planning. We see a significant need in business continuity to evolve from plan building to plan execution. And we believe this app is a major step in getting there.”

With the ever-increasing threats businesses face today, they must be ready for anything to avoid losing customer trust, harming revenue growth or in the worst cases, putting the future of the company in jeopardy. Act with Assurance guides businesses through an effective recovery step-by-step.



Daren Howell

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All things Agile

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Learning from past experience and sharing knowledge with others are central to business agility. The Consortium publishes Agile success stories from a wide range of industries, so that you can learn from others that have shared the same challenges – both in your own sector and beyond.



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Researching new areas, developing new thinking and best practice guidance around business agility. Our collection of white papers presents the latest research and analysis from our own experts and from other thought leaders. We collaborate with leaders in Agile practices worldwide to bring you a comprehensive knowledge resource.



Templates and Tools

Download templates and tools that may make your route to business agility just a little easier. Why reinvent the wheel? Check what's there, and if there's something you need but cannot find, then please let us know.



Events and Webinars

Jenny Bailey is hosting regular webinars to explore new thinking around critical areas of agility. Join her and her expert guests to be a part of this experience and have your questions answered. Most webinars are open to non-members and free to attend. Watch out for member training days, offering experiential workshops to support professional development.



Publications

Consortium handbooks, pocketbooks and best practice guidance are renowned worldwide. We offer open access to digital versions of all Consortium publications, for you to use as quick reference. Publications include Agile Project Management (AgilePM®), Agile Portfolio Management (AgilePm™), Agile Business Analysis (AgileBA®) and many more.

Paving the Way for Generation Agile - Agile Business Conference 2018



"Are we preparing our young people to be successful and effective in an uncertain world?"

The world is changing ever faster – that is now indisputable. It's almost universally accepted that we need to work differently to be adaptive, responsive, and more Agile. What happens, then, when we shift our perspective and ask,

"Are we preparing our young people to be successful and effective in an uncertain world?"

Are we taking a responsible view and creating Generation Agile? This challenge will be the focus of the two-day Agile Business Conference on 26 & 27 September 2018. Experts will explore what is being done, and what should be done, through the lenses of people, strategy and projects. All three are needed to create new and holistic ways of working; equipping the next generation for the business environment of the future.

The Agile Business Conference is the longest running Agile conference in the world and is organised by the Agile Business Consortium, the not-for-profit organisation that is leading, promoting and enabling business agility worldwide.

Delivery

"The future isn't a place. It's a set of tools"

David Weinberger, Author

In today's world, strategic success relies on effective delivery. Businesses need to innovate and respond to a constantly shifting environment, yet still ensure appropriate control. Project, programme and portfolio management are critical skills – the essential route to making strategy reality. Agile methods such as Scrum, Lean, XP, DevOps, Kanban and AgilePM® are fast becoming the norm, and are used across the full range of business functions.

What are the latest developments in this field, and how are Agile practices changing?

These are critical issues that individuals and organisations need to engage with to forge an effective way forward.

We need to pave the way for Generation Agile.

People

"Leadership is not about the next election, it's about the next generation."

Simon Sinek, Visionary Thinker

Are traditional routes to learning fit for purpose in a world where "the things we need to know" are changing day to day, and more people are moving into careers that simply did not exist five years ago. Millennials are now the largest age group in the workplace. They expect flexibility in how they work, and the freedom to act within a context of transparency and authenticity. How important then is knowledge, compared to the ability to collaborate, learn from others, and flex to changing circumstance?

Strategy

"It's time to optimize our economy for the human beings it's supposed to be serving."

Doug Rushkoff, Author

The traditional five-year plan is now dead in the water. Traditionally, chief executives have been expected to look ahead and predict what the future will bring. Now Artificial Intelligence is disrupting whole industries, Gallup is showing remote working up from 39% to 43% in just four years, and streamed data and real-time analytics are prompting ever faster decision making. How can organisations improve agility and approach development strategies in a more Agile way?



To be a part of Creating Generation Agile at the 2018 Agile Business Conference on 26 & 27 September in London visit agileconference.org

Early Bird Tickets expire 30 June 2018

Organised by



The longest running annual Agile Conference in the world

The importance of having established GDPR-compliant policies

Andrew Cowling, Channel Marketing Specialist at Fujitsu Scanners imparts his expertise on why it is important to consider digital processes to help towards GDPR-compliance and the wider digital transformation benefits

The May deadline for GDPR compliance is rapidly looming into full view, by this time organisations must have established GDPR-compliant policies to ensure that anyone holding personally identifiable data can prove the consent, the security and the management of that data. There are a number of questions that data holders need to ask themselves:

1. Right to access – can you find all the data you hold on an individual, how quickly can you respond to SARs?
2. Retention periods – do you know how long you can lawfully hold the data for?
3. Data erasure – are you confident that the right of an individual to be forgotten can be met and that every single trace can be removed?
4. Privacy by design – are you building in security steps from the outset?
5. Security – how many copies of your documents exist?
6. Consent – do you have consent to hold the data and how will you use it?
7. Audit trails – GDPR is not just about being compliant but proving it in a court of law – can you confidently prove your processes are lawful?

When it comes to achieving GDPR

compliance the starting point recommended is to conduct an assessment of the relevant data held today and where it resides – opening with the digitisation of paper-based documents through scanning and merging with any digitally born material.

More than just compliance

While GDPR is a strong reason, there are a number of reasons for organisations to additionally embrace moving from paper to digital processes.

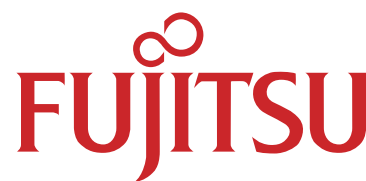
Investment in digital transformation now can deliver savings and efficiencies across the whole business, as well as helping to prepare for future regulatory compliance, legislation can be a powerful tool to drive a cultural change, so GDPR should also be seen in that light.

These benefits include:

- Better organised data, all stored in one place;
- Increased storage capabilities with Cloud-based servers;
- Quicker to both find and retrieve files;
- Ability to manage data more effectively;
- Easier to share information/files between colleagues and across office locations;
- Increased efficiencies/time savings for administrative staff;
- Increased office space with less physical filing and;
- Greater security of data.

Deliver business efficiencies while helping to achieve compliance with GDPR. The potential risks associated with GDPR – most notably the fines and reputation – mean organisations simply have to be prepared.

Fujitsu is working with a number of partners on specific solutions for the public sector looking in depth at areas such as SARs, retention periods and data handling and now have a solution that offers a methodical and structured approach to GDPR with impressive deployment and proven track record success in addressing stringent German privacy laws over the last decade. If you'd like to know more then please contact us today.



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The security dynamic around public spaces in the UK

Specialist defence and security writer, Tom Jones shares his views on the security dynamic around public spaces in the UK

The security dynamic around large public events in the UK is currently undergoing some real, drastic change. With a recent spate of attacks in public places, mostly involving vehicles, the UK public are having to get used to seeing highly visible measures like road barriers and armed security forces at events.

In recent times, particularly as ISIS has destabilised and becomes less attractive for terrorists to go and join, domestic terrorists have decided to stage attacks in their home country, rather than attempt to travel out to terrorist training centres or to join groups – which may alert authorities. They've also turned to more commonplace objects than guns or I.E.Ds to make an impact. They've turned to vehicles, as exhibited in attacks such as the 2016 Berlin truck attack and London, where Khalid Masood hit more than 50 pedestrians with a single vehicle.

Commercial vehicles do have a history of being used by terror groups and sub-state actors, the most obvious example being the ubiquitous Toyota Hilux, which is often mounted with a machine gun and known as a 'technical'. In this form, it has served – and continues to serve – as a modern type of cavalry in countless low-intensity conflicts across the world.

However, domestic terrorists have turned to vehicles for rather prosaic reasons. First, is that they're easy to get hold of. Obtaining firearms – even illegal ones – is an onerous and expensive process in the UK, requiring licences or well-established, serious criminal connections. Hiring a van takes a driving licence.

Second, their acquisition arouses little suspicion. Someone buying large quantities of material known to be used in bomb-making within a small area is obvious. Hiring a white transit isn't such an obvious alarm

bell, especially if suspicious activity isn't reported. Finally, terrorists want something deadly and effective. Large, heavy vehicles such as vans or lorries are both – they're manoeuvrable, can travel at quite high speeds and are heavy, so they have a lot of momentum – which also means they're difficult to stop. In even the most untrained hands, they present a deadly tool.

Therefore, we're seeing so much security activity at public events now. Security forces are aware that now, any large group of people presents a serious target, so they're taking serious steps to negate any potential threat.

The first major development is that the kind of anti-vehicle barriers we've seen outside the House of Commons are now becoming commonplace at major UK sites, having recently been installed in places like Windsor Castle and Buckingham Palace. Concrete anti-vehicle barriers are also being deployed in increasing frequency to protect event spaces.

The first reason is obviously that they present a stopping force to any vehicle; they also allow police or security forces significant vehicle access prevention powers. Keeping traffic away from a site is the most obvious and most effective tactic to prevent vehicle attacks. If large areas around a site are pedestrianised, then any attempt to stage an attack is made more obvious and security forces are also given more time to react.

The second development, which is equally visible, is the increasing deployment of armed police. British 'bobbies' used to be infamous as the unarmed police force, but the fact is that the evolving security threat means this level of armament is nowhere near sufficient. Armed police officers are far more able to take control



Anti terrorism safety barriers on Westminster Bridge, London, June 2017

of a situation; if a vehicle is judged to be a threat, a carefully aimed round can disable the driver, preventing them from staging any further attacks once the vehicle is stopped.

British Police use a variety of firearms, the most common of which is the Heckler and Koch MP5SF. This is a highly accurate, reliable weapon that is ergonomically designed for rapid and sudden use; all British Police MP5s used are single fire or semi-automatic only. Hollow-point rounds are also used to prevent over-penetration, that is rounds passing through a target or wall, which may cause collateral damage. British police also use a range of firearms using the larger 5.56×45mm NATO cartridge, which have significant stopping power and can easily break the protective glass of a windscreen in front of a target.

Finally, of course, what you can't see is the doctrinal development that security forces will have undergone. Measures have become clearer as security operators have sadly become more familiar with the problem and all security measures are deployed with totally

joined-up thinking to negate threats and armed security police also undergo almost ceaseless firearms training. It is important to remember that armed police and road barriers are not just physical security measures – they are also deterrents. The highly visible presence of anti-terrorist measures may occasionally raise eyebrows from passers-by, but they also serve to highlight preparedness to potential terrorists. ■

Tom Jones graduated from Hull University in 2016, where he studied History and Politics, specialising in military strategy. He has written defence articles for a range of media outlets and is currently writing a book on British Counter-insurgency tactics during the Malayan Emergency. He also writes occasional field sports, agricultural and motorsport articles and lives in Yorkshire.

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A new security standard to protect people and places

Jaz Vilku, Marshalls' Managing Director of Landscape Protection, argues that the new PAS 170 standard will offer organisations an assured product to secure against criminal threats and accidental impacts for the very first time

Government organisations are increasing their emphasis on protecting highly populated urban areas and infrastructure from different types of vehicle attack, from terror to ram raids, with physical perimeter security. Up to now, much focus has been placed on security products manufactured to the PAS 68 and IWA 14.1 standards – the latest specification to assist in terror prevention. The new PAS 170 standard will offer organisations an assured product to secure against criminal threats and accidental impacts for the very first time.



Protecting people and infrastructure is, unsurprisingly, now a core consideration for planners and security advisors in planning new and existing buildings, public spaces or events, whether that's to protect against a vehicle-borne terror attack, an accidental collision or a criminal ram raid targeting commercial property.

Both major city councils and district and borough authorities have increased their focus on security measures that can mitigate against these incidents and Marshalls has seen a growing number commission and install protective street furniture manufactured to the British Standard Institution's (BSI) PAS 68 and IWA 14.1.

Incorporating this type of security measure is an essential part of pro-

tecting people, places and infrastructure. But, it is equally important that the type of product installed is proportionate to the threat. In many situations, such as in car parks or outside an ATM, local authorities may only need security products that mitigate against low-speed passenger vehicles and not those manufactured to the highest specifications.

Delivering a more cost-effective protective solution

Up until now, 'anti-ram' has covered these lower-rated products. But a tested and proven standard that provides an assured security product for this level of threat didn't exist. To meet this need, the government has introduced PAS 170, a new series of requirements that will transform how local authorities can protect against

the vehicle threat from both criminal and accidental impacts.

As opposed to PAS 68 and IWA 14.1, where the testing weights typically range from 1.5 tonnes to 7.5 tonnes for speeds of either 30, 40 or 50 mph, PAS 170 delivers a testing standard for vehicles of up to 2.5 tonnes travelling at between 10 and 20 mph.

This difference means that street furniture manufacturers can conduct a greater number of product tests – using a wider range of vehicles and speeds, which can provide an organisation more choice in picking the right type of security product for a particular space.

Roger Knight, Marshalls' Head of New Product Development and Engineering



for Landscape Protection, said: "The knock-on effect of introducing PAS 170 is local authorities can now access more cost-effective, tested products for sites such as shop fronts, ATMs, car parks and high streets, where there is possibly only a need to specify security that can mitigate against incidents involving low-speed passenger vehicles. In these situations, there could be no requirement to consider a product that can stop a 7.5-tonne articulated lorry travelling at 50 mph."

Protecting against the impact of ram-raiding

This new standard will have a significant impact when it comes to negating ram-raids against commercial property. The rise in vehicular crimes has seen a sharp increase in demand for anti-ram solutions. But until now, there was no testing standard available to assure buyers of what speed and weight this type of product could withstand and how they would perform.

PAS 170 will provide organisations with this assurance of proven performance for the first time and will also enable them to reduce their insurance premiums, given the security measures

that are accredited by a government standard.

While it offers greater flexibility in specifying security measures, this new requirement is not intended to replace any element of the full-scale vehicle impact test methods, which were created and designed to mitigate against a vehicle-borne terrorist threat using unmodified commercial vehicles. These standards – the latest Publicly Available Specification for security barriers used in hostile vehicle mitigation – are set by The Home Office and Office for Security and Counter-Terrorism, together with key agencies The Centre for the Protection of National Infrastructure (CPNI) and The National Counter Terrorism Security Office (NaCTSO). They were developed to help government organisations assure levels of protection against intentional or accidental vehicle impacts and ensure defences were customised to the risk profile of a specific site, such as a town square or high street.

Bespoke security products designed to PAS 170 requirements
Marshalls has a range of Rhino Anti-Ram bollards which are tested to

PAS 170 and can be tailored to factor in landscape restrictions, such as a limited excavation depth or the requirement for lift assist to enable occasional vehicle access, depending on the site in question.

Retailers on the high street, specifiers and business owners more generally are concerned that large, intimidating barriers may create an environment of fear among the public, so aesthetics must also be a key consideration. Marshalls' bollard cores have been developed and tested so that they can be specified at this standard with decorative sleeves in various materials, to complement any surrounding area.

It's vital that those responsible for shaping public spaces recognise that there is no one size fits all response to the risks posed by intentional or accidental vehicle incidents. The threat level should govern the type of security that's specified and as such, the new PAS 170 standard will provide specifiers and security professionals with more flexible, cost-effective options to secure their public spaces.



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EU-Africa relations: The challenges for a renewed partnership

Dr Alex Vines OBE and Tighisti Amare from The Royal Institute of International Affairs, Chatham House discuss their views on EU-Africa relations and the challenges ahead for a renewed partnership

The EU is still Africa's principal partner for trade, development and humanitarian assistance. Although Africa's share of European trade and investment is globally in comparative decline, the continent's strategic importance for Europe is on the increase, particularly because of concerns over counter-terrorism and migration.

The Joint Africa-EU Strategy (JAES) has been the spine for Africa-European relations since it was adopted at the Lisbon summit in December 2007. The ambition was to have a long-term strategic framework under which bilateral relations would progress.

There have been some efforts to evaluate the progress of the JAES, Action Plans for 2008-10 and 2011-13 and more recently the Roadmap 2014-17 adopted at the 4th Africa-EU summit held in Brussels, April 2014. Changing Africa though has meant that although the key objectives of the original strategy remain valid, recent developments mean that the JAES needs updating, particularly after the AU's adoption of its Agenda 2063 and also because of other EU initiatives, such as its Global strategy, several regional strategic frameworks (the Horn and Sahel and Gulf of Guinea maritime security) and its strategic partnerships (with South Africa and the AU).

In reality, policy about the evolving Africa-EU relations is concentrated around summits. These summits are the apex of political dialogue between Europe and Africa and there have been five of them to date: Cairo (2000); Lisbon (2007); Tripoli (2010); Brussels (2014); and recently in Abidjan (2017).

There has also been a summit in Valletta on migration and asylum in November 2015. But between summits

dialogue is limited and the securitisation of the migration agenda and divergences over human rights and international criminal justice have reinforced the African perception of a one-way dialogue and have overshadowed progress in other areas such as climate change and environment and agriculture, food security as well as the environment.

There has been a better EU record with the operationalisation of the Africa Peace and Security Architecture (APSA) supporting the African Standby-by Force (ASF) and other ad hoc military commitments, such as the AU mission – Amisom in Somalia and more recently the G-5 Sahel. The main implementing tool for the Africa-EU peace and security partnerships is the African Peace Facility, with more than €2.1 billion allocated to it since its creation. There remains an over-reliance by Africans on European funding and an urgent need for increased capacity building.

There are areas where both continents are in broad agreement, such as tackling climate change or fighting terrorism in the Sahel and the Horn. However, migration, – a key driver for the EU's new call for strategic partnership with Africa – is high on the list of difficult conversations. Currently, 70 to 80% of African migration is taking place within the continent, but outward migration is growing fast. This has become a primary concern for European countries still battling high unemployment rates among young people, inequality and populist parties that are attracting voters on anti-immigration sentiment.

The EU is not prepared to accept all informal economic migrants. But for African governments, agreeing to cooperate in migrants' return home has become a matter of huge sensitivity.



Africa's population is also projected to double by 2050 and is young – 60% of the African population is currently below 25 years of age – and frequently unemployed. Despite enjoying fast economic growth in the past decade, African economies have failed to create the volume of jobs needed to offer these young people an economic future. Unless this is remedied, there is fear among EU governments that, as Africa's closest neighbour, Europe will continue to be a destination of choice for most African outward migration.

Both the AU and EU acknowledge that more needs to be done to provide a real future for Africa's young people. The European Development Fund has been an essential source of funding, but development aid alone will not be sufficient. Private sector investment to complement official aid will be vital to creating the necessary quantity of jobs and will require the emergence of a stronger and more dynamic African private sector.

The reality is that much of the Africa-EU relationship is still about EU donated money although Brussels policy-makers and some European leaders recognise the need to move the EU's relationship with Africa away from the 'traditional' donor-recipient dynamic, towards a genuinely fresh and respectful relationship. Changing this out-dated mentality is tough especially as the EU continues to set the agenda and often fails to consult its African partners regularly. EU politicians are also under increasing domestic pressure to be seen to be acting against uncontrolled migration.

The future direction of the Africa-EU partnership will largely be shaped by the agreement that will replace the Cotonou Accord, which expires in 2020. In the negotiations, African leaders will need to be more strategic in shaping the agenda of any nascent part-

nership to reflect the continent's own development goals and ambition for structural transformation, as set out in the AU's Agenda 2063. And the talks will have to learn from the troubled recent history of negotiation over Economic Partnership Agreements (EPAs) between the EU and groups of developing countries, as well as lingering African suspicions over European good faith.

This places reinvigorated trade and investment at the heart of Africa-EU relations. It is only through supporting private sector growth and scaling-up of African businesses that the volume and quality of jobs needed to address Africa's unemployment challenge can be addressed. Not only would success on this front minimise the outflow of economic migrants to Europe, but it would also help draw the poison of decades of one-sided donor-recipient relations and move the relationship towards a genuine partnership. ■

Alex Vines is Head, Africa Programme, Chatham House; Tighisti Amare, is Africa Programme Manager, Chatham House and was in Abidjan for preparatory meetings for the Africa-EU summit in November 2017.

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Including refugees in national systems: Examples from Ethiopia

UNHCR, the UN Refugee Agency details the facilitation of refugees in national systems – with interesting examples from Ethiopia

Ethiopia has a long history of welcoming refugees onto its territory. Today, it provides protection to more than 910,000 refugees and asylum seekers from 24 countries, making it the second largest hosting country in Africa and the sixth hosting country worldwide.⁽¹⁾ Refugees from South Sudan, Eritrea, Yemen and Somalia represent the vast majority of those hosted in the country.

Building on Ethiopia's nine 'Pledges' made at the Leaders' Summit of 2016,⁽²⁾ Ethiopia is a leader in the implementation of the Comprehensive Refugee Response Framework (CRRF).⁽³⁾ The Framework is a new blueprint for refugee protection, assistance and solutions, characterised by more robust responsibility-sharing and a broader engagement of actors, together with the greater inclusion of refugees in national systems in the countries that host them.

On the ground, support to deliver basic services to refugees in key sectors, such as education, health, child protection and water and sanitation, are provided by the Ethiopian Government through the Administration for Refugee and Returnee Affairs (ARRA), UNHCR and other UN and NGO partners.⁽⁴⁾ Increasingly, through greater engagement with the World Bank, private foundations such as IKEA and other non-traditional humanitarian partners, refugees have begun to participate more in the Ethiopian economy. Key to this are the commitments by the Ethiopian Government to grant refugees the right to work, freedom of movement outside refugee camps and a recently adopted measure to extend individual documentation and registration of vital events such as births, death and marriages.

The value added of the CRRF approach is clear. By facilitating the inclusion of refugees in national systems, the government ensures a more holistic, cost-efficient

and coordinated response that can benefit both host and refugee populations. In return, the government receives greater support from development actors such as the World Bank through a favourable financial facility that aims to strengthen the capacity of governments and communities to absorb the effects of large-scale movements of refugees. Such an approach is all the more significant given that Ethiopia is the second-most populous country in sub-Saharan Africa and has an estimated 30% of the population still living under the poverty line.⁽⁵⁾

Water and sanitation are at the very core of sustainable development in Ethiopia. Over the last three decades, significant investments have been made to improve access to drinking water, especially in rural areas, resulting in over 52 million people being able to access an improved drinking water source as compared to only 6 million in 1990.⁽⁶⁾ An estimated 57% of the population now have access to safe drinking water (compared to 14% in 1990) and 28% have access to basic sanitation (up from a 3% baseline in 1990).⁽⁷⁾ These investments have effectively improved health outcomes for the population.

The Ethiopian Government has put in place various policies, strategies, sectoral development plans and institutional arrangements to ensure access to clean water and sanitation. The responsibility for the development and provision of these services is shared among the federal ministries (water, health, education and finance) and their respective regional and local offices.

In most cases, water supply systems in refugee camps are managed by non-governmental organisations or ARRA with financial support from UNHCR, UNICEF and other donors. As refugees were settled in sparsely

populated areas without reliable access to water, water systems were established, serving refugees and nearby host communities alike. While the building up of the water systems was needed to address the urgent needs of the refugee and host community, they remain however parallel to the national systems which are operated by partners at high costs.

In the west of Ethiopia, the 2014 influx of South Sudanese refugees were used to pilot a new utility model through the expansion of the water supply scheme for Itang town in the Gambella region. Utilities are part of the Ethiopian governments' ONE WASH strategy and are implemented in towns and cities, they have however not yet been implemented in refugee-hosting areas.

An economic analysis showed that the costs of emergency water trucking needed to supply water for the new refugees were equivalent to the capital expenditure required to build the entire water network in the camp and connect it to the existing Itang town system, after which only the running costs and pumping would need to be covered. With the empirical evidence clearly supporting the new vision, UNICEF, the Regional Water Bureau in Gambella, UNHCR and ARRA invested in a system that now spans the newly established refugee camps of Kule, Tierkidi and Nguenyiel, as well as two nearby towns of the hosting community.

The Itang Integrated Water Project is a first in the country to connect refugee camps with local communities under the new utility approach. A board is established to oversee the function of the water utility, comprising of members of the water bureau, ARRA, host community and refugees. When finished, a total of 250,000 people will benefit from the new water system (75% as refugees).

The creation of the water system has effectively reduced the price of water for the host community to an average of 11 Ethiopian Birr (about \$0.41) per cubic meter in Itang and Thurfam towns.⁽⁸⁾ In the initial phase, UNHCR will cover the water costs for refugees, the overall costs of water provision will be reduced due to economies of scale and the avoidance of parallel systems.

Gradually, as refugees gain the right to work and become more self-reliant through small loans and livelihood opportunities, the utility will start to sell water to refugees as well. To ensure the sustainability of these efforts in the medium-term, refugees will need to be anchored in Ethiopia's development plans and the national budget.

This project has proven to be a strong example of extending services to refugees simultaneously easing the burden on the hosting communities and providing for a win-win situation. This goal, embedded in the CRRF, helps to foster social cohesion between refugees and host communities while ensuring sustainable practices that can be scaled and modelled elsewhere. ■

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EU-Africa Relations: A perspective from the European Council

Writer, MF Warrender from Open Access Government sheds light on EU-Africa Relations from the perspective of the European Council

The European Council is the institution that defines the European Union's overall political priorities and direction. Established as an informal summit in 1975, the European Council was formalised as an institution in 2009, with the members being the heads of state or government of the 28 EU member states, the European Council President and the President of the European Commission. The current President is Donald Tusk. The Council is not one of the EU's legislating institutions and therefore does not negotiate or adopt EU laws. However, what it does do is set the EU's policy agenda, traditionally by adopting 'conclusions' during European Council meetings, which identify issues of concern and actions to take.

The most popular way that the European Council takes its decisions is by consensus, yet there are sometimes decisions made via unanimity or qualified majority in certain specific cases outlined in the EU treaties. If a vote is taken, neither the European Council President nor the Commission President may take part.

The European Council works on a wide range of policies and issues affecting the interests of the EU and its citizens. One of these issues is EU-Africa relations. Europe and Africa have close historical, cultural and geographical ties and the European Council pushes to cooperate with Africa in several different areas such as migration, trade, development and counter-terrorism. The EU supports counter-terrorism initiatives and activities on the African continent. It has recently stepped up its support for security in this region and committed in June 2017 to provide €50 million to support the newly established G5 Sahel Joint Force to improve security in the region. Security is a principal sector in which cooperation is vital.



Furthermore, as part of the Common Security and Defence Policy (CSDP), the EU has launched several military and civilian missions and operations in Africa. EU missions are currently deployed in The Central African Republic, Libya, Mali, Niger and Somalia. Security has always been a primary concern.

The way in which African countries and the EU cooperate is through multiple coinciding frameworks and regional strategies, which facilitate relations between the EU and Africa. One of which; the Cotonou agreement, was adopted in 2000 and is the overarching framework for EU relations with African, Caribbean and Pacific (ACP) countries. The EU has negotiated a series of economic partnership agreements with these countries as a part of the agreement. It is the most comprehensive partnership agreement between developing countries and the EU, covering the EU's relations with 79 countries, including 48 countries in Sub-Saharan Africa. It strives to reduce (and eventually completely eradicate) poverty, while working on the

gradual integration of ACP countries into the world economy. This is excellent for both development and economic and political trade – two areas that have been previously mentioned as principal sectors for cooperation.

Another political framework used to push for partnership is the Joint Africa-EU Strategy (JAES), adopted in 2007, which acts as the formal channel for EU relations with African countries. It defines the long-term policy priorities between the two continents, based on a shared vision and common principles. Its four main objectives are:

1. Improving the Africa-EU political partnership;
2. Promoting: Peace, security, democratic governance and human rights; Basic freedoms, gender equality; Sustainable economic development, including industrialisation and; Regional and continental integration
3. Effective multilateralism and;
4. A people-centred partnership.

This partnership has truly led to concrete action in many areas, through the reinforced intercontinental dialogue from the strategy's implementation. This success has propelled plans of action regarding specific areas in Africa, targeting localised problems and tackling them head-on.

“The European Council is the institution that defines the European Union’s overall political priorities and direction. Established as an informal summit in 1975, the European Council was formalised as an institution in 2009, with the members being the heads of state or government of the 28 EU member states, the European Council President and the President of the European Commission.”

Three examples of this include the regional strategies such as The Horn of Africa, Gulf of Guinea and Sahel. The first of these, the Horn of Africa, refers to a region in East Africa which has faced repetitive droughts over the past years, causing a severe humanitarian crisis. This prompted the EU in 2011 to adopt the strategic framework for the Horn of Africa ⁽¹⁾, which outlines the steps to be taken by the EU to aid the people of this

region. This implementation highlights how the Council is willing to act in specific areas to create effective results.

Similarly, the Gulf of Guinea is a region facing growing instability due to a lack of control over coastal waters and the coast itself. Because of this, criminal activity is on the rise, such as piracy and armed robbery at sea, oil theft and trafficking of drugs, human beings, arms, diamonds, counterfeit medicines, illegal waste. The strategy on the Gulf of Guinea ⁽²⁾ was adopted by the council in 2014, outlining the means for the EU to help the region tackle the challenges it continues to face. Finally, an EU strategy for security and development in the Sahel ⁽³⁾ was presented in 2011 by the High Representative and the Commission, upon the Council's request. It focuses on four strands of action:

1. Development;
2. Good governance and internal conflict resolution;
3. Political and diplomatic security and rule of law and;
4. Countering violent extremism.

Overall, the European Council prides itself on the policies put forward to strengthen the partnership with Africa, hoping to improve education, boost investment and create jobs, by targeting all the sectors mentioned above. The EU has prioritised strengthening the partnership further with the region and invests in “People, Prosperity and Peace”. ⁽⁴⁾ ■

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Making all the difference: Construction and concessions in Europe

Eiffage is a major European player in construction and concessions, as this insightful article by the company explains

Eiffage deploys its expertise through eight business lines – construction, real estate, urban development, road, civil engineering, metallic construction, energy and concessions – structured as four separate branches.

Eiffage innovates in the work we do, to build a sustainable future. This is reflected in initiatives such as Phosphore, our prospective research programme on sustainable cities and Astainable and our digital urban design tool. Through the Eiffage Foundation, the company is committed to supporting non-profit organisations that serve the local community.

This culture of constant innovation, commitment and expertise among the Eiffage's 65,000 employees is reflected in the quality of the 100,000 projects carried out every year, all over the world.

Infrastructures Branch

Our Infrastructures Branch specialises in all the necessary skills for designing and building infrastructures on land and sea. Our teams are also experts when it comes to calculating and building envelopes and steel structures. We find multi-technical solutions for all industrial sectors.

Three professional sectors

Our three professional sectors – road,



civil engineering and metallic construction – are active throughout France. The Infrastructures Branch also covers Europe, as well as America, Asia and Africa, thanks to some solidly-established positions, notably in Senegal (since 1926).

Road

Eiffage Route teams contribute to the upgrading of the entire French road network, from local roads to motorways, handling both new construction works and rebuilding. We are involved in building a port, an airport and industrial roads, plus we are also experts in urban planning.

Civil engineering

Engineering structures and facilities, underground works, river and mar-

itime works, earthworks, demolition, decontamination, foundations and repairs are all in a day's work for the company's seasoned civil engineers.

Their projects range from the highest viaducts to the most sophisticated tunnels, including waste and wastewater treatment plants, transport installations and power facilities, rail tracks and even wharves.

Metallic construction

Eiffage Métal teams can count on expert knowledge from their staff when it comes to turnkey metal constructions. Our teams design and make envelopes, as well as structures for buildings and civil engineering structures. They also provide multi-technical solutions for a full range of

industrial sectors, including the nuclear, oil services and wind energy sectors in particular.

International projects

International projects represent one of the most significant growth areas for Eiffage's Infrastructures Branch.

The branch has two *modus operandi*. In the export mode, it builds projects for its customers. In Africa, for example, its teams have completed the reorganisation of part of the port of Tema in Ghana, for a subsidiary of Bolloré Logistics. In Madagascar, following on from the Kamoro bridge, a second engineering structure is to be built on the island: the Mananjeba bridge, further to the north of the country. In Angola, the project to install 104 steel footbridges is continuing in the capital, Luanda.

In Djibouti, Eiffage Génie Civil has won the contract to implement the PEPER project (production of drinking water by renewable energy). Eiffage will work on the project in consortium with Tedagua, a Spanish water treatment specialist, subsidiary of Cobra (ACS group). It will include a desalination plant and a 5,000 m³ storage tank, as well as an 8.5 km-long pipeline of 700mm in diameter, which will be built to connect the plant to the city's public water system.

The company has been also entrusted with the second work package of the Keur Momar Sarr 3 (KMS 3) drinking water treatment and distribution project in Dakar, Senegal. The contract covers the supply and laying of 38 kilometres of 1,500 mm diameter ductile iron pipes, which are to be connected to the future water treatment plant.

The company has numerous sub-

siaries across Europe – in Germany (Heinrich Walter Bau in civil engineering, Faber in roads, Eiffage Rail and Wittfeld in rail and SEH in metallic construction), in Spain (Eiffage Infraestructuras, a road construction specialist and leading producer of aggregate and coated aggregate and Eiffage Métal Iberica, which is particularly active in the onshore wind turbine tower market), in Belgium (via the Smulders group, a major European offshore wind power player) – and in the Americas (ICCI and Puentes y Torones).

In Colombia, Puentes y Torones won a contract to build the Honda bridge, a 407-mile-long cable-stayed structure that will facilitate travel between the centre and north of the country and work continued at the site of the Bucaramanga bridge in the north of the Eastern Ranges of the Andes. In Canada, ICCI won several orders to build or renovate engineering structures in Ontario and Alberta, as well as leading the works at the Noden Causeway bridge and the Seaway ship lock on the Saint-Laurent river.

A responsible player

Eiffage's Infrastructures Branch grew from a series of mergers and buy-outs linking historic companies, all experts in roadworks, civil engineering and metal. Today, we are proud of our achievements in France and abroad, which include thousands of kilometres of roads and motorways, dozens of railway lines from metropolitan networks to high-speed links, envelopes and structures for buildings and civil engineering works, large-scale environmental utilities (water and waste treatment plants, power stations, dams), as well as sports and urban infrastructures, such as stadiums and car-parks. Through a wide variety of

projects, we have contributed to improving the living environment of millions of people.

Making all the difference in our actions

Our employees and partners are our key asset, which is why we are so attentive to their needs. We are committed to a fairer corporate model with greater solidarity and today, belong to one of the major employee-owned groups, which has always been considered a forerunner. At the same time, we continue developing new safety programmes, which are proving successful, since over two-thirds of our sites have already reached the zero-accident target – some of them for several years running.

In the field of training, the Eiffage schools set up all over France since 2006 have now trained several hundred-young people, who initially stood little chance of finding employment, but are now in the company workforce. We have also increased our offer of diploma-based training in know-how transmission by our 1,200 tutors, hard at work in the field preparing to hand over to the next generation.



Eiffage
Infrastructures Branch
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Technological expertise in the electronics sector

Bomare Company, the first Algerian exporter of electronic products to the European market, lifts the lid on their work concerning technology in the electronics sector

Created in 2001, Bomare Company is the first Algerian exporter of electronic products to the European market. Bomare Company has acquired during its 17 years of activity an undoubted technological expertise and a know-how, which allows it to distinguish itself from others in the electronics sector, on both the national and international scale.

Bomare Company offers a wide range of quality products and services for its customers including TV, smartphones, tablet, DIDs and satellite receivers. The Algerian company also specialises in industrial subcontracting: including the automatic insertion of all types of mainboards for all types of industries such as renewable energies, aeronautic, aerospace, railway and the automotive industry, for example.

Bomare Company has four production units that span 15,000 m², including two clean rooms that comply with the international standards.

Currently, Bomare Company employs more than 600 Algerian employees, 40% of them are technicians and engineers, 42% are women with an average age of 30 years.

Bomare Company has numerous partnerships with world leaders such as LG Electronics, KTC and HISENSE. It has also partnerships with Algerian universities, Development Center of

Technical details

Company name:
Sarl Bomare Company
(100% Algerian right).

Share Capital:
620.331.000,00 DZD.

Head Office:
26, Mohamed Ouidir Amellal Street,
16 406, El Biar, Algiers.

Creation date:
2001.

Sector of activity:
Consumer electronics industry &
industrial electronics.

Trademark:
Stream System.

LG's TV and smartphone
manufacturing.

Advanced Technologies (DCAT) and with several professional training centres.

We are the first company in Africa and the Middle-East, which has a TV panel maintenance center to repair all types of screens (Plasma, LCD, LED, DLED, OLED), thanks to its developed equipment and the continuous training of its employees.

In addition, Bomare Company has obtained several standards, labels and certifications such as:

- RoHS (2002/95/CE) (restriction of hazardous substances).
- Label BASSMA DJAZAIRIA TV and IT products.
- ISO 14001: 2008 version.
- EUR1: For export.
- Export Trophy 2015.

As a true corporate citizen, Bomare Company cares about the respect of the environment and the health of its customers, consequently, its products meet RoHS standards that restrict the use of dangerous substances. In 2016, Bomare Company benefited from the "Bassma Djazairia" label and won the WTCA's (World Trade Center Algiers) Export Award 2015.

Still, in 2016, it signed an exclusive agreement with the Spanish partner for the distribution of "Stream System" products worth \$50 million for a period of five years to Spain and Portugal. Through this agreement, 250,000 devices will be sent in the long term, including 80% of TV and 20% of smartphones.

Bomare Company continues to develop itself and aims for an extension through the international market by



ensuring sustainable and long-lasting exports to climb quickly to the top worldwide. Thus, reflecting the vision of its founder Mr Ali Boumediene, mainly oriented towards technological development and exportations. All this can be realised only in a climate of TRUST, which reflects the corporate culture of BOMARE COMPANY, that seeks to establish a mutual trust between its employees and partners, this corporate culture includes five core values: transparency, respect, unity, solidarity and triumph.

Bomare company manufactures the entire range of LG TVs and smart-phones marketed in the Algerian market, part of this production will soon be destined for export.

The key competencies of Bomare Company are:

- Research and co-development;
- Production of all types of electronic cards;
- TV panel maintenance centre to repair all types of screens;
- Customer services;
- Products assembly;
- Qualified human resources;
- Export of electronic products to Europe and;
- Qualification by Alstom: we are an approved supplier of Cital (Alstom) an electronic card has already been manufactured in this context. The partnership contract was signed early in 2018.

By 2021

- 54% integration rate for our smart-phones range;
- 70% integration rate for our TV range;
- Production of 1.5 million TV's per year;
- Production of 3 million of smart-phones per year;
- Exportation of 60% of products to Europe and other continents;
- ISO 14001: 2008 version and we are working to get the 2015 version (environmental management); (undertaken approach);
- ISO 45001: 2018 version (management of health and safety at work); (undertaken approach).

Our clients are:

We are present on the Spanish and Portuguese market and we will launch our products in French and Italian market.



Bomare Company Consumer Electronics Industry & Industrial Electronics

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www.bomarecompany.com
<https://twitter.com/StreamALG>
www.facebook.com/streamsystem/



CABINET OFFICE

Spend recovery services: Get what you pay for – and only pay for what you get

The Crown Commercial Service (CCS), an executive agency sponsored by the UK's Cabinet Office, reveals their work around spend recovery services

Every year, government bodies including central government departments, local authorities, universities, schools, NHS Trusts and arm's length bodies are incorrectly charged for the goods and services they procure.

In the private sector, spend recovery services are a commonly-accessed route to recovering these costs – ensuring that organisations only pay for the goods and services they actually receive. The public sector has been slower to respond.

Crown Commercial Service (CCS) – the UK's largest public procurement body, responsible for shaping and delivering government procurement policy – estimates that £220 million in overcharges and incorrect pay-

ments could be recovered over the next four years. To facilitate the identification and recovery of these valuable funds, CCS has created the Spend Analysis & Recovery Services framework.

How it will work

There are 19 suppliers appointed to the Spend Analysis and Recovery Services (SARS) framework, including companies with specialist expertise in key areas like utilities, telecoms and VAT.

These suppliers will work in partnership with CCS and public-sector organisations on a contingent “no-win-no-fee” basis to analyse financial transactions and commercial agreements; identifying overpayments, errors, or financial benefits which have not been previously realised.

Behavioural Insights (RM6004) framework

In addition to Spend Analysis and Recovery Services 2 (RM3820), it is worth mentioning the innovative Behavioural Insights (RM6004) framework, which enables one to tap into the very best behavioural insights expertise. In summary, it is a single lot, multi-supplier agreement.

Going into more detail, a supplier appointed through this framework can inform policy and service design by using behaviour change, with an emphasis on finding innovative ways of encouraging, enabling and supporting people to make better choices for themselves.

John Manzoni, permanent secretary for the cabinet office and chief executive of the Civil Service comments: "Behavioural insights have been a part of policy making at the heart of government for a significant amount of time now. This new framework will enable all public-sector organisations to access this expertise, helping them to design efficient, effective public services that meet the real needs of citizens." ⁽¹⁾

In essence, the solution will encompass the end-to-end process of delivering a variety of applied behavioural insights services which can be summarised as follows:

- Policy analysis, development and advice;
- Service insight, service design, service delivery and

organisational reform;

- Design and implementation of trials;
- Evaluation and reporting of trials;
- Capability building, including the design and delivery of learning activities and;
- Thought leadership, including strategic work to review and identify untapped opportunities to apply behavioural insights.

Finally, the benefits of the Behavioural Insights (RM6004) framework are summarised below:

- A new and innovative approach to accessing behavioural insights expertise;
- Buying services can be complex and costly, this agreement can reduce the time and costs associated with the procurement by offering a facility that has already been competitively tendered and;
- Crown Commercial Service (CCS) have introduced a number of suppliers that are new to working with government and will contribute to driving innovation.

(1) <https://www.research-live.com/article/news/government-redesigns-behavioural-insights-framework/id/5033962>

Suppliers on the agreement can also support public bodies with reviews of contract compliance, looking at specific areas of their procurement activity. Contracts are analysed to make sure an organisation is only paying what it should be. If an organisation is not fully benefiting from existing deals and services, the suppliers will identify it, so it can be rectified.

These reviews can analyse and recover errors or overcharges up to six years after the error or overpayment has occurred.

There are no upfront costs, and the process requires minimal internal resources from customers – suppliers do all the heavy lifting. Customers can also gain access to CCS's commercial expertise, and support to access the breadth of CCS's wide range of commercial solutions for financial services.

Matthew Sparkes, Deputy Director for Financial Services at CCS said: "The use of spend recovery services is commonplace in the private sector, not just to identify and recover valuable funds, but also to understand where to make process improvements that ensure errors won't happen again.

"Spend analysis is a meticulous process which many big companies in the private sector – never mind the public sector – would struggle to carry out on their own. The government simply cannot afford to allow pockets of unnecessary spend to go unnoticed.

"By combining our own CCS category expertise with our suppliers' commercial expertise, we can ensure that the public sector pays only for the goods and services it actually receives."

Continued on page 285 →

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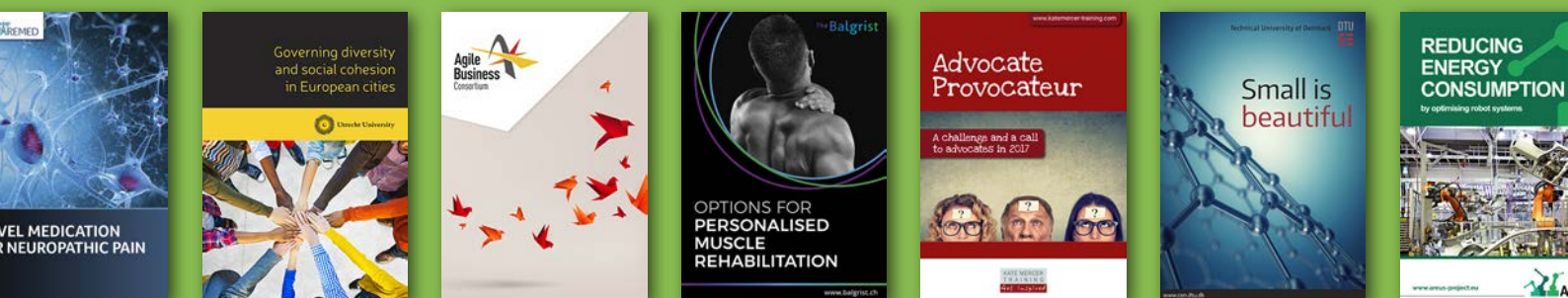
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← Continued from page 283

How to use the agreement

There are three ways to begin the process of appointing a supplier through Spend Analysis and Recovery Services (SARS).

Further competition: Any organisation with significant spend can drive down suppliers' percentage fee by holding a further competition – this is when an organisation asks suppliers to bid against each other for business. This can provide real value for your organisation.

Direct award: If an organisation has found a supplier that offers the services they need and is happy with the percentage fee they are offering, then direct award offers a fast, simple solution.

Aggregation: If a department is part of a wider organisation, it can be financially beneficial to organise an aggregation. This is when you combine your requirements, allowing you all to get the best deal from bulk ordering.

Lotting structure

The agreement is broken down into 7 lots covering the largest areas of government procurement spend:

Lot 1: Statement Transaction Review

Lot 2: End-to-End Review

Lot 3: Contract Compliance – Utilities

Lot 4: Contract Compliance – Telecoms / Mobiles

Lot 5: Contract Compliance – Contingent Labour/ Agency Staff

Lot 6: Contract Compliance – VAT

Lot 7: Contract Compliance – Property/Rental Review

Find out more

For more information, visit <https://ccsheretohelp.uk/>

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Crown Commercial Service (CCS)
Tel: +44 (0)345 410 2222
info@crowncommercial.gov.uk
<http://ccsheretohelp.uk/sars>
www.twitter.com/gov_procurement

Spend Analysis and Recovery Services II (SARS II) – Framework Agreement RM3820

Could this framework facilitate significant financial benefits to you....

The SARS framework was designed to help Customers procure Spend Analysis and Recovery Services from a range of suppliers who provide retrospective 'audit' and analysis of core spend and supplier transactions (invoices and payments), to identify and recover any supplier overpayments, overcharges or missed opportunities (discounts, rebates etc.) from a customer's suppliers on a 'gainshare' basis.

This means that the customer only pays a percentage fee of any amounts actually recovered, not simply identified i.e. An effective NO financial cost to the Organisation.

Unlike many sequels SARS II represents in our view a significant improvement on the first.

SARS II now allows Public Sector organisations to procure a more specific range of services by splitting the Framework into a number of lots. This enables more focus on the provision of different 'specialist' services whilst still providing the flexibility to request all required services from a single Supplier.

Advantage of SARS II to the Public Sector

The specific advantage of SARS II to any Public Sector organisation is the significant time, resource and financial savings because virtually all the procurement issues i.e. Supplier suitability, experience and financial stability have been addressed already in the Supplier selection process. In addition, because the Framework was carried out under OJEU, all of these issues have been addressed as well.

Therefore, the only remaining challenge is who do I choose?

twice2much of course 😊

In all seriousness, the challenge of who you choose is not really solved by the Framework (and can't be given that the framework is available to ALL Public Sector bodies, regardless of size, spend, system in use or complexity of the organisation).

There are two procurement options available under the framework:

1. Direct award
2. Further competition

We would be happy to explain these options in more detail with you.

Historical Private and Public Sector approaches to procurement of Spend Analysis and Recovery Services.

Private Sector

The Private Sector has more often than not required physical presentations (meetings in person) from the 'finalists' (following a previous filtering or elimination process).

Focus is on:

- Who they believe will generate the greatest returns from the review (often NOT those charging the lowest fee)
- The approach to be used by the Supplier
- Which Supplier they believe provides the best fit within their organisation

In this way, they are choosing who they feel they can best work with and who they believe will generate them the most returns from the review. This is a subjective judgement call as likely recoveries are notoriously difficult to predict.

Public Sector

Public Sector organisations in most cases selected a Supplier to provide Spend recovery services based solely on the evaluation of tender responses with no presentations taking place.

This can lead to the organisation not realising the full potential benefits of a Spend Analysis and recovery review.

Reviews are a 'partnership'



What needs to be understood with the procurement of these services is that whilst you are procuring technological and specialist expertise, these reviews are truly about working in 'partnership' to identify and recover previously unidentified opportunities for financial recoveries and savings.

Maximising these recoveries is therefore also about relationships, understanding and flexibility, things that can rarely be addressed in tenders.

Spend Analysis and Recovery Services II - Procurement made easier...

Please do not hesitate to contact us to discuss any questions you may have. We would be delighted to help.

Crown
Commercial
Service
Supplier

No cost reviews introduced – share of 'real' recoveries only...
... internal resources reduced – reviews performed off-system, off-site and out of sight

Crown
Commercial
Service
Supplier

Twice2much specialises in Accounts Payable Recovery Auditing, reviewing Client's historical spend and identifying opportunities for recovery of overpayments or unclaimed financial benefits.

We work with Finance and Internal Audit departments of major private and public sector organisations to provide a comprehensive review of their accounts payable systems and enable them to benefit from the significant 'unbudgeted' financial windfall that we consistently deliver.

Our reviews are predominantly carried out on a share of recoveries only basis, achieving an effective no-cost review to the organisation.

We have designed our service to minimise the need for Client resources. Our reviews are therefore carried out predominantly off-site, off-system and out of sight for your benefit.

Our specialised teams of audit professionals work unobtrusively with your Finance Department to identify all potential sources of overpayments and recover them on your behalf.

Core Accounts Payable Recovery Audit services:

Duplicate

- Targeted at identifying overpayments to suppliers previously 'invisible' to clients
- Algorithms created to identify payment anomalies
- Covers end to end process
 - Identification
 - Validation
 - Collection
 - Correction entries
 - Reporting
- Collect on behalf of Client
- No recovery – no fee
- To date in excess of £100m recovered for Clients

VAT

- Detailed analysis to identify unclaimed VAT at transaction line level
- Provision of all documentation and support to substantiate claims
- Expert reviews enable VAT to be reclaimed for services previously thought to be 'unclaimable'
- To date in excess of £10m recovered for Clients

Statement

- Provides clients with statement collection and review on a share of recoveries only basis
- Identifies two main 'invisible' recovery opportunities
 - Statement credits previously not received from supplier
 - Credits previously processed but not claimed

Spend Recovery Auditing is not limited to the core reviews above but cover a range of services, all of which can be provided with minimal impact on your internal resources.

Other reviews commonly include:

- Contract compliance reviews
- Rebate and contract claimback reviews
- Prompt payment discount reviews
- Property reviews
- Import duty reviews
- Utilities and telecoms reviews
- Spend analysis

Opportunities for recoveries

- Payments to incorrect suppliers or duplicate payments to the same supplier
- Invoices processed gross of VAT when VAT is unclear or not identified at the time of input
- Incorrect prices charged by suppliers when compared with contractual terms agreed
- Prompt payment discounts that have not been taken
- Recovery of over-charging of rates, rents, insurance and service charges
- Recovery of over-charging of telecoms and utilities services

Recent Successes

Client A

Duplicate Reviews - £2 million in 12 months
Statement Review - £400,000 in 6 months
VAT Reviews - £550,000 in 2 months

Client B

Property Reviews - £2.4 million in 7 months

Client C

Contract Compliance Reviews - £2.8 million in 4 months

Why outsource?

We can provide the time, resource and expertise that many in-house teams cannot afford:

- Specialist teams of audit experts
- Tailor-made software solution that had been designed specifically for the task
- Dedicated recovery function

In this way, our Client's can free their resources up to focus on the delivery of their core activities and services.

We have acted for major organisations across many industry sectors that employ increasingly complex accounting processes. We're expert in discovering the errors that can be easily missed.

We maximise recoveries by using sophisticated algorithms that not only identify the obvious recovery opportunities but also the more obscure.

Our philosophy is to add value to the Clients we work for and exceed their expectations.

Rockford Associates: A professional firm of recovery audit specialists

Ray Dorney, Director at Rockford Associates Limited explores the work of this leading professional firm of recovery audit specialists

Rockford Associates is a leading professional firm of recovery audit specialists. Since 2001 we have conducted over 650 audits and recovered over £100 million pounds on behalf of private and public-sector clients on a contingent no recovery no fee basis.

We work across the private and public sectors and our clients include commercial organisations operating in all market sectors, as well as county, city and metropolitan borough councils, NHS trusts, housing associations, universities, leading charities and government departments.

We are confident that our experience, values and multi-faceted audit approach will maximise recoveries due to our clients. Rockford operates on a no recovery-no fee basis at no cost or risk to our clients.

Crown Commercial Service – Spend Analysis and Recovery Services II framework. Ref: RM3820

Rockford Associates has been awarded a place on the Crown Commercial Service's (CCS) new 'Spend Analysis and Recovery Services II' framework, Ref: RM3820.

The new framework means that public sector organisations across the UK can access the most effective forensic analysis services, to recover historical

overcharges or over-payments from their supply chain. These recoveries can be achieved quickly and simply through the Framework and suppliers with the minimal internal resource.

The Framework and CCS will provide support, guidance and ease of access to these services for the public sector, in order to ensure our customers optimise the results from the Framework and recover as many inaccurate payments, pricing errors or missed contractual benefits as possible.



Rockford Associates – Client Survey

- 94%** – Rated very professional;
- 91%** – Agreed of value;
- 100%** – Agreed non-disruptive;
- 91%** – Agreed another audit likely and;
- 100%** – Would recommend service to others.

Recovery Audit Services

Our core offering is the analysis of payment records to aid the identification of purchase ledger overpayments and their subsequent recovery from suppliers; additional services include the recovery of the unclaimed or under-claimed VAT and a supplier contract compliance review.

Rockford adopts a multi-faceted audit approach with a view to maximising recoveries for our clients.

Our accounts payable audit consists of a review of historic payment transaction data. We use our proprietary in-house forensic software to uncover overpayments resulting from:

- Goods or services being paid for twice;
- Payments being made to the wrong supplier;
- Payments being made in the wrong currency;
- The by-passing of existing software duplicate checks;
- The same invoice being paid across different accounts payable systems, countries, divisions or ledgers and;
- Credit notes being paid as invoices.

Our Pathfinder software produces

over 18 audit reports, each looking to identify overpayments using different criteria and algorithms. Where applicable, our software will look for overpayments across data from different entities, countries, divisions and systems within our client organisations. This can be of particular value where a client has been subject to organisational change, undertaken mergers, acquisitions, transitioned to electronic payments or shared service centres (SSC's) and where it has changed their financial software.

We will also identify and investigate those suppliers who, from our previous experience with other clients, are most likely to have hidden or removed overpayments.

How We Work

Our auditors are highly experienced and self-sufficient and because our auditors work on-site, they can undertake a wide range of recovery work from identification and verification of potential overpayments and savings through to final recovery with minimal disruption and disturbance to our clients.

Data Collection

In preparation for an audit, we request historic accounts payable data from our clients. Rockford has a detailed knowledge of the underlying data structure of all leading and legacy financial system software. Our data team are therefore able to offer precise knowledge and support, making the data extract exercise for our clients a simple and quick extract-only task.

We will then process our client data through our proprietary software, preparing the reports from which our auditors can prepare for an audit.



Preparation

Before our on-site audit commences, our auditor will analyse our audit reports and identify those potential overpayments that will be investigated during the audit recovery stage. Our auditor will also prepare the supplier circularisation ready for client approval.

Rockford will at this stage also instigate with our client the necessary arrangements for the on-site audit to commence.

Audit Recovery

Once on-site at a client, our auditor commences the recovery audit. Following an initial introduction meeting, our auditor will action the supplier circularisation and start to investigate potential overpayments and VAT recoveries by review of relevant vouchers.

The auditor will undertake all work necessary in contacting suppliers to confirm and agree on any potential recoveries. All agreed recoveries will be fully documented and progressed through to recovery.

Our auditor will hold weekly meetings with our client to report on progress of the audit and recoveries.

Review & Reports

At the end of an audit, we will present our supplier master and transaction analysis reports and our findings and recommendations report.

What our Clients Think

Very impressive auditor, Lots of Knowledge, answer to every question asked, nothing too much trouble, went that bit further.

D.P. Deputy Manager – Education

Very satisfied, have used Rockford over the last ten years and will continue to do so.

L.C. A/C Payable Manager – NHS

Everything very thorough, everything spot on – no disruption.

D.H. Operations & A/C Manager – Airport

Really valuable to our business. Very impressed with the performance of the Auditor.

D.D. Accounts – Housing Trust

For more information please call **+44 (0)1494 578 111** or visit www.rockfordassociates.co.uk.



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Government policy: University Consortium provides behavioural insights

The Behavioural Science Consortium supplies expertise that benefits government policy and services via their Behavioural Insights Framework, as this joint article from Sheffield Hallam University & The University of Manchester reveals

The Behavioural Science Consortium comprises researchers from Sheffield Hallam University and the University of Manchester working at the cutting edge of behavioural science and public policy across a range of topic areas. We bring with us not just extensive expertise in both qualitative and quantitative approaches to research, but also academics who are actively engaged in world-leading innovations in trials and evaluation and in education and training.

The Crown Commercial Service Behavioural Insights Framework

The Crown Commercial Service Behavioural Insights Framework provides an exciting opportunity for the Behavioural Science Consortium to apply what we know about the science of behaviour change to government policy and services. As the only University-led supplier on the framework, our approach will be informed by progressive, evidence-based approaches and rigorous evaluations to ensure that all government policy and services and their evaluations are informed by only the best behavioural science. We will help organisations identify where behavioural science can be applied to best effect and upskill the workforce to enable them to utilise and apply evidence-based approaches to their work.

Why are expertise and evaluation important?

To change a behaviour one must: want

to do it (be motivated), have the skills and knowledge to be able to do it (be capable) and have the resources and social support to do it (have the opportunity) (Michie et al., 2011). This model has provided insights into behaviours, such as self-management of long-term conditions, transport choice, recycling behaviour, relationship and sex education, healthy ageing and the prevention of female genital mutilation and our approach is sufficiently flexible to allow us to understand the behavioural challenges of the future in a systematic science-driven fashion. The Behavioural Science Consortium has a thorough understanding of the evidence so that we can ensure that the approaches we recommend have the best chance of being effective and as such, to avoid making the same old mistakes.

Sometimes behaviour change interventions designed with the best of intentions, but without the appropriate underpinning behavioural insights expertise, can have unintended consequences. For example, in one intervention designed to decrease conception rates, teenagers were provided with a simulated 'baby' that required feeding, burping, rocking and nappy changing, and which recorded the level of care provided (for example, the amount of time it was crying). It was widely deployed across several countries, but a recent trial found that it increased concep-

tion rates (Brinkman et al., 2016). Evaluation is, therefore, essential to ensure that behaviours are changing in the desired direction. We have expertise in a wide range of research methods and as such, we can draw on the best techniques and methodologies to evaluate existing interventions or to plan practical and rigorous evaluations of new interventions.

"Sometimes behaviour change interventions designed with the best of intentions, but without the appropriate underpinning behavioural insights expertise, can have unintended consequences."

What does this approach mean in practice?

Firstly, it means thinking about the ultimate aims of government policies and services in behavioural terms: in that, we need to think about what behaviours need changing. It can be one-off behaviours (for example, throwing chewing gum in a bin), a series of behaviours (such as logging into an online system, completing all sections of the online form, submitting by a deadline), or a few different behaviours (for example, reducing sedentary behaviour, increasing walking and increasing attendance at gym classes). We have effective solutions for each of these types of problems.

Secondly, it means thinking differently about how government policies and



services can achieve their aims. For example, “training” is a commonly-proposed solution, but too often it involves providing people with information, which might increase one aspect of their capability to act – but does little to motivate them or provide them with the opportunities to act.

Moreover, providing people with information falsely assumes that they will make rational decisions based on that information. Behavioural science tells us that people behave in ways that reflect a complex mix of rational and irrational decision-making. Understanding how and why people behave in the ways that they do, based on factors such as habits, social influences and the environment around them are essential to design services and policy that truly meet the needs of the public.

Thirdly, we will ensure that the chosen intervention addresses the factors that are most likely to make a difference and help to decide what needs to change. This can be done quickly, where there is a good prior understanding of the barriers, or we can

undertake research to identify what those barriers are. Our approach considers a wide range of types of intervention, with an understanding that one-size rarely fits all and that different problems require different solutions. With our large team of experts that have the knowledge of the evidence base, we will identify key techniques to change behaviour for the given situation and population, with a focus on choosing techniques for which there is good evidence of effectiveness and that fit within the constraints of a given service or context.

Getting in touch

If you would like to find out more about the Sheffield Hallam University and the University of Manchester Behavioural Science Consortium and the services we can offer your organisation or service, then feel free to visit our [website](#).

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The importance of managing the UK government estate

A spokesperson for the Office of Government Property (OGP) details the importance of managing the government estate and smart working

The OGP (previously named the Government Property Unit (GPU)) supports the UK government and the wider public sector to manage their estate more efficiently and effectively. In doing this, they help to deliver the finest public services and support the Prime Minister's priorities by unlocking surplus land and property for growth and housing.

They also create great places for people to work and use our estate to rebalance the UK economy in line with the government's Industrial Strategy. We interviewed a spokesperson at the Office of Government Property (OGP) to find out more.

Can you explain how the OGP is working hand in hand with the newly launched Government Property Agency?

The OGP is also working hand in hand with the newly launched Government Property Agency to support the government's transformation agenda, as a key part of our Building a Brilliant Civil Service. OGP also works to strengthen the property expertise across government and acts as the leadership body for the 2,000 members of the Government Property Profession.

Can you tell me how the OGP and how government estate has been transformed and reduced since 2010?

In terms of how the government estate has been transformed and reduced, since 2010 we have:

- Disposed of over 250 properties, raising £2 billion in sales and saved £300 million per annum in running costs.
- Reduced the vacant space within our central estate to only 1.5%, far below the private sector average of 7.5%.

- Delivered our 2020 emissions and paper reduction targets three years early; reducing our carbon emissions by 33% and our paper consumption by 50%.
- We have also worked with 90% of English councils to deliver better integrated, customer-focused services, securing £70 million in capital receipts, £20 million savings in running costs, 5,700 jobs and releasing land for 1,300 homes.

Tell me more about the 2018 Government Estate Strategy and the importance of reducing estate and what the buildings or land could be used for?

This strategy, which is due to be published later this year, will set out how we will use the estate as an enabler to deliver better outcomes for the public during this Parliament, driving our activities.

We will use the power of our estate to help energise the housing market, create supportive infrastructure and release surplus land for house building.

We are continuing to make our property more efficient so that we can release land for at least 160,000 homes and help deliver £5 billion of receipts by 2020.

Reducing the estate will both free up more land from housing but also allow the civil service to harness new technologies to deliver leaner, more accessible public services that are more responsive to citizens' needs.

What progress has the OGP made so far concerning the more challenging objective of creating an integrated estate?

OGP jointly delivers the One Public Estate (OPE) programme in partnership with the Local Government Association, which facilitates cross-government



working between local authorities and central government departments to unlock collaborative, property focused projects across the wider public sector.

One of the core objectives of OPE is to deliver integrated customer-focused services across the public sector through the more efficient use of public sector land. This includes co-locating services, such as Jobcentre Plus offices and local GP centres.

Through OPE, we have already exceeded our aim to deliver 45 co-locations (between local and central government) by 2020, with these partnerships expected to deliver further co-locations in the coming years.

How can using shared working spaces and using cloud technology in these spaces save money, improve collaboration and ensure staff have what they need to work smarter?

In the broader digital economy, workers are less tied to physical offices and work increasingly from home whilst meeting together as necessary in suitably placed facilities.

Shared offices and using cloud technology increases collaborations, supports flexible working practices and make it easier to share ideas and resources.

Smart working increases productivity, reduces estate costs, opens up the workplace to a more diverse workforce, and improves wellbeing and engagement.

What role does technology expected to play in smarter working, such as shared Wi-Fi?

Technology is the driving force behind smarter working, by making it possible for more collaborative working styles and a more dispersed workforce.

Shared Wi-Fi, collaborative working programs such as the OneDrive, SharePoint and google drive and video conferencing all make smarter working possible and allow more a more agile and efficient civil service.

Can you tell me also about the Government Hubs Programme and what this sets out to do?

The Hubs programme draws together departments' strategic plans and the overall workforce strategy for the Civil Service. We want to create a modern, flexible estate, comparable with the best in the private sector.

Hubs will be shared spaces, showcasing best practice and delivering modern, fit for purpose accommodation across the whole of the UK.

Is there anything you would like to add?

The Government Property Agency (GPA), which launched on 1st April this year, will improve the efficiency and effectiveness of the government estate and generate benefits of between £1.4 billion and £2.4 billion over the next ten years. GPA's initial portfolio of 80 properties will grow to over 1,000 as it takes on increasing responsibility for managing the general purpose central government estate. ■

Spokesperson

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<https://www.gov.uk/government/groups/government-property-unit-gpu>

Is smart working heralding the slow 'death' of the traditional office?

Alison White, co-founder of PLACEmaking, shares her thoughts on the extent to which modern working practices are slowly eroding the outdated office culture of previous generations

With small, medium and large enterprises now more than ever aware of the cost of providing, servicing and maintaining often grossly underutilised office space, the time is right for a total rethink the role and purpose of the 'office'. Whilst utilisation of the traditional office space was always significantly lower than people thought, modern work patterns are gradually heralding the slow 'death' of the traditional office.

Those changing work patterns are often referred to as smart working, which is being adopted across the private and public sectors – and at pace. Whilst a drive to reduce the cost of an office estate is not the sole motive for embracing smart working, the realised benefits deliver both tangible financial savings and other significant non-tangible advantages.

What is smart working?

Smart working means providing people with the tools – the culture and leadership, workspace and technology – that enable people to choose when, where and how they do their jobs.

Technology has led to the automation of previously manual administrative tasks and remote access to internet-based services enables a greater number of jobs to be carried out remotely from the office. As a result, more of us have a greater choice of where and when we work. This has reduced our dependency on the tradi-

tional office environment and as fewer of us are working in the same space 9-5 and five days a week, common office practices associated with an administrative structure, control and hierarchy begin to seem outdated and irrelevant.

The trouble is, if the traditional office is not what we want anymore, then how do we agree what to put in its place? The 'office' means different things to different people: whilst we might not spend a great deal of time in it the notion of losing something that is so familiar for something comparatively unknown is no doubt exciting for some, but unsettling for many.

How do we ensure the voices of all four generations that make up the modern workforce are heard and how do we engage with them to ensure that the transition from a traditional way of working to a new solution is successful, business practices are updated, productivity is increased, and the health and well-being of people improved? If we are committed to modernising the workplace (and we must be), then we must also be fully prepared to help people through this transformational change.

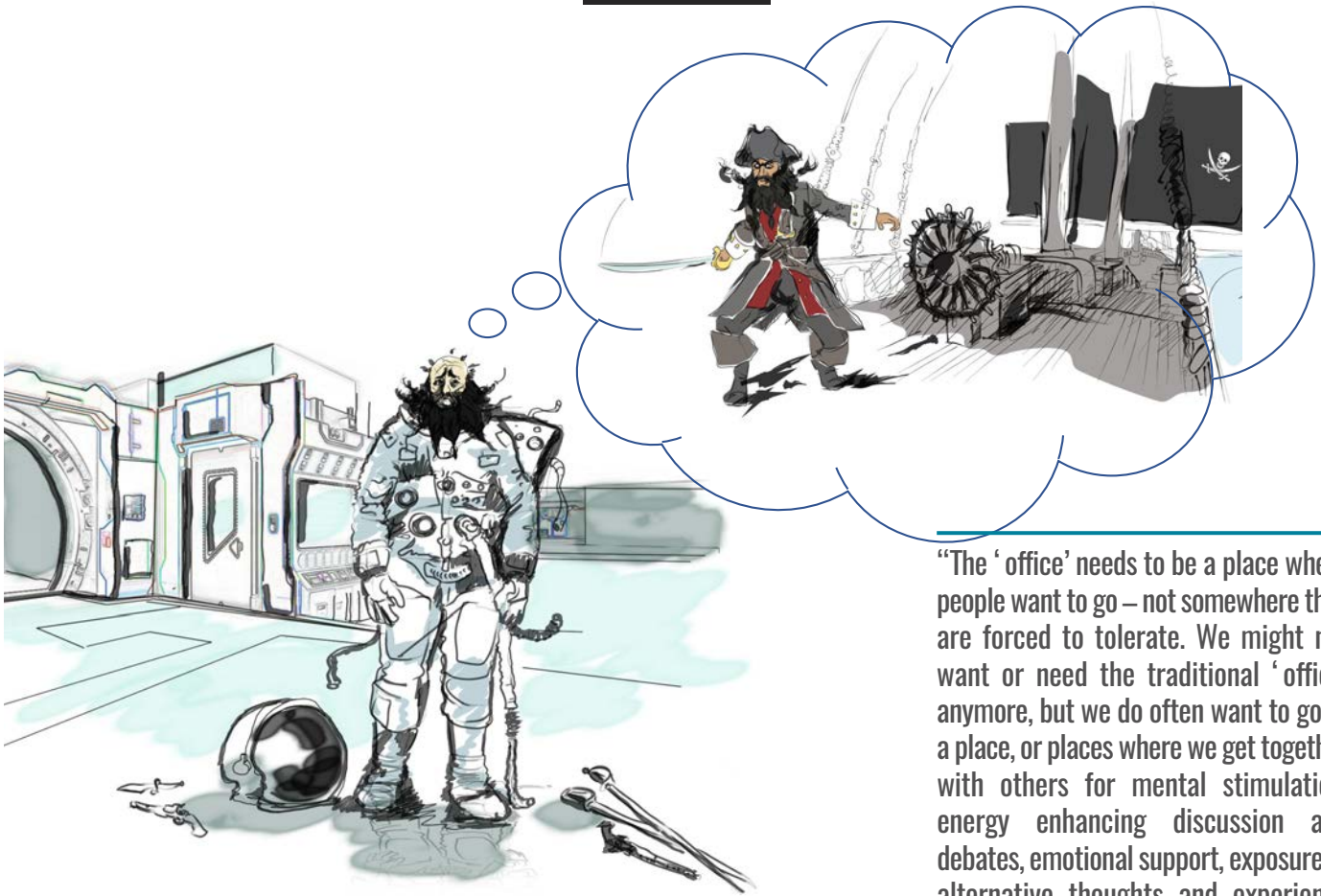
Changing working practices

Many embedded working practices evolved in the past when the pace of change was slower and therefore rarely challenged. When mass processing of paper-based information

was workforce dependent, the organisational 'machine' only functioned when all employees arrived at, operated within and finished at set times. The early computers mechanised that process and sped up the output results. We maintained the same supervised, administrative work styles: pushing aside paper-based in and out-trays and slowly replacing them with computer terminals (initially), micro-computers (1975-78) and then PCs (1980-86). We might have changed the tools, but we maintained the same working practices, turning the computers 'on' in the morning and 'off' at the end of the typical human working day.

Of course, the functionality of today's computers bears no resemblance to those early versions and the processing power each of us carries around in our laptop or tablet was inconceivable back in the day of central IT suites, hard-wired to heat-generating desktop computers. Light years of technology transformation has happened within the working lifetime of many of us and yet, too many working practices and attitudes have been slow to adapt, and many offices still look and operate in the same way as they did prior to the introduction of business computing. It is almost that we have maintained the working practices of a pirate while we carry around the computing power of an astronaut.

With the pace of computing and associated business advancements, are we



“The ‘office’ needs to be a place where people want to go – not somewhere they are forced to tolerate. We might not want or need the traditional ‘office’ anymore, but we do often want to go to a place, or places where we get together with others for mental stimulation, energy enhancing discussion and debates, emotional support, exposure to alternative thoughts and experience simple personal reassurance.”

ensuring that our human resources are happily functioning with the changes they have already experienced and all eagerly looking forward to the impact of the next wave of change? If business leaders assume everyone in their business that they rely on to function productively responds to change in the same way, then they are as out of date as their offices. Simply shoehorning a pirate into a space suit does not make him or her an astronaut.

Four generations in the workplace

It is too simplistic to assume everyone perceives smart working and the associated flexibility of how, when and where we work as entirely desirable. The generic profiles of veterans, baby boomers and generations X & Y are familiar terms often used to describe the characteristics of the four generations that make up the modern work-

force (Jeffery G. Harber, 2011). The opinions and expectations of these four generational groups vary: unconsciously influenced by the social, economic and political context of when they were born, educated and first entered the workplace. Their value sets are different and what ‘work’ means to them, as well as what they actually expect from ‘going to work’ varies enormously. Their opinions about the need or purpose of the ‘office’; how an enterprise operates and what sorts of behaviours are acceptable is influenced by many things, including their generational profile. Appreciating what influences their views and reactions provide us with a framework for shaping how we communicate planned changes, how we understand their often-unconscious reaction to new challenges and how we help them prepare for and exploit the opportunities available from smart working.

Whilst the terms and definitions of veterans, baby boomers and generations X & Y are useful for academic research and data comparison, in our experience few people appreciate being identified by these age-related labels. Instead, we use other approaches to enable individuals to identify for themselves their own cohort group using, for example, music legends and icons. We can all relate to the key superstars that dominated our generational group, even if we were not specific fans. We select artists that are identified as influencing youth culture of a period of time yet have become or are becoming accepted and respected across generational boundaries. Being associated with such icons could, of course, defines each personal generational group, but being affiliated with a celebrated icon is a more positive badge of pride than simply an age-related label.

4 generations: characteristics & values



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Cross-generational discussion and an increased awareness of each other's career expectations – as well as changes experienced to the workplace environment, technologies and ways of working – breaks down barriers and forges better mutual awareness and empathies. In contrast to the traditional method of 'sheep dipping' – through classroom-based and one-size-fits-all training sessions – we help people identify their own engagement profile and their communication style preferences, ensuring everyone can self-select their own profiled 'roadmap' to access and engage with relevant information and sign-post them to communications activities that best suit their personal profile.

The benefit of this approach is that it is scalable to match to the size of any enterprise, the media used is adaptable (mix of electronic and/or face to face) and users have greater choice on when, how and how often they engage with the change process. With the entry point to the engagement tool being electronic, we can track and

report levels of engagement and monitor selection preferences which in turn, informs the design, specification and targeted investment of our engagement and communications strategies. This increases the consistency and quality of information provided, boosts accuracy in targeted engagement and reduces the wastage of time, therefore delivering more value for money.

The future

And what about generation Z, the next generation yet to enter the workforce? How are we preparing for their arrival into the world of work? What will their expectations be and what will have influenced their opinions about and requirements of the workplace? These are the children of the current generations X and Y who themselves should have been profiting from the flexible working arrangements associated with smart working. Is generation Z witnessing how their parents have been supported to embrace the advantages of smart working, have more choice on when and where to work and are

enabled to balance work with other responsibilities and interests?

Or are their parents the unlucky ones who have had change forced on them and share horror stories of how they lost their own desk and were forced to work from home? Does generation Z assume they will be forced to work 9-5 in large office blocks in city centres, negotiating streets choked with the same pattern of rush hour traffic every day? Will they be disappointed on their first day of work to be directed to a desk, with poorer technology on it than they have at home, in a cluttered and uninspiring office and will they be supervised by someone with poor management skills influenced by a limited awareness of how work is changing? How quickly that generation will realise that the world of work hasn't quite matched their expectations.

On the horizon is more change and recognising a landscape of constant change is the destiny of any enterprise if it is to be sustainable. Business leaders need to balance the opportunities and risks that on-going change brings and accept that imposing change, as it was done in the past, is no longer viable. They need a workforce that accepts and expects change if the business is not to be exploited by it. That baton of responsibility for understanding the need for change needs to be handed from the employer to the employee.

And so where does this leave the topic of "the slow death of the office". The 'office' can no longer be regarded as an expensive necessity, subject therefore to property driven rationalisation focused initiatives. Attempts to convince people that the technology advances they are witnessing and

experiencing is not being matched by new working practices and alternative types of 'office' solutions are fundamentally flawed. Persuading people that the same desk-based solutions are still relevant, but they just need to have access to less of it, misses the point entirely and younger generations are explicitly rejecting such workplaces along with the outdated management practices that go with it.

"Now is the time to update and upgrade expectations about the workplace, how it operates and how we productively function in it. If more than 30% of your office space has desks in it or meeting rooms are the only alternative spaces available to get away from the desk, then it's time to review how your workplace is holding you back from achieving your business vision, objectives and expectations."

People can and will vote with their feet and with laptops under their arms, a mobile phone and remote access to internet stored information, they are finding alternative places to work and spending minimal time in their employer old offices. Look around any office on a Friday and it's practically empty and with average utilisation consistently measuring at under 45% in core hours, the real cost of out of date offices is more than the cost of real estate.

Forget the old image of the office made up of rows of desks, cellular offices and a few meeting rooms and ignore so-called property and facilities management experts whose mantra that minimising property costs, at all costs is a business key objective. A major cost of low office occupation is the loss of face to face interaction,

tacit knowledge sharing, networking and team bonding. Addressing such issues need a change of approach, rather than reinstating old management practices of presenteeism.

The 'office' needs to be a place where people want to go – not somewhere they are forced to tolerate. We might not want or need the traditional 'office' anymore, but we do often want to go to a place, or places where we get together with others for mental stimulation, energy enhancing discussion and debates, emotional support, exposure to alternative thoughts and experience simple personal reassurance. As such, we need an enriched range of work setting to select from and make use of that directly to help us achieve our objectives and complete our tasks. We need places that reinforce our personal role as part of a collective enterprise, with a greater emphasis on informality and shared contribution and less on hierarchy and stiff formality. We might not want cramped and cluttered offices, but we also don't want to be isolated, sit in our pyjamas at home or beg tablespace in a local coffee shop all the time either. Employers who invest in new thinking and new work environment will find attracting and retaining the talent they need to sustain their businesses all the easier.

Our expertise and skills enable PLACEmaking to deliver end-to-end professional services, developed to support our clients achieve their change objectives, including:

- Workplace change management;
- Communications & engagement solutions;

- Interior architecture & design;
- Strategic asset management;
- Digital and technology advisory and;
- Programme management.

Now is the time to update and upgrade expectations about the workplace, how it operates and how we productively function in it. If more than 30% of your office space has desks in it or meeting rooms are the only alternative spaces available to get away from the desk, then it's time to review how your workplace is holding you back from achieving your business vision, objectives and expectations.

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The UK's current housing crisis: Can your empty property portfolio provide a social dimension?

Vacant property expert, Stuart Woolgar, CEO of Global Guardians, discusses the country's current housing crisis and the section of people who cannot buy, nor are they eligible for social housing

Housing in the UK is both in crisis and confusion, with arguments raging how best to solve the problem.

House purchase

The government says it is stimulating house purchase for first-time buyers by cuts to Stamp Duty and the Help to Buy scheme and pushing developers to build more affordable housing. However, the recent analysis by the Local Government Association (LGA) shows we are experiencing the biggest fall in home ownership in the last 20 years, with the key 25-34-year-old group dropping from 65% to just 27% on the property ladder. Why? Simply because house prices have risen around seven times faster in real terms than incomes.

At a recent housing conference, the Prime Minister said she wanted to break the 'vicious circle' where most young people can only get on the property ladder with their parents' help; this was an unacceptable situation and the provision of more affordable housing was now a priority for the government to restore the dream of home ownership to millions across the country amid a lack of supply. However, house prices are unlikely to suddenly drop by a large amount so sizeable deposits for mortgages will still, somehow, have to be found.

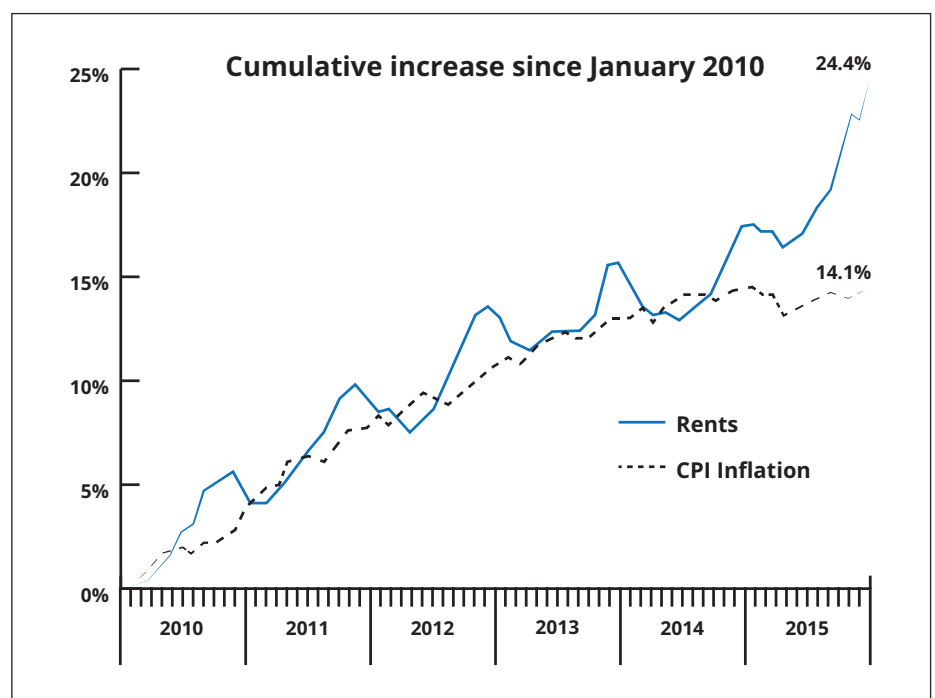


Image: © ISL Property Services

The rental sector

In 2017 the Royal Institution of Chartered Surveyors (RICS) predicted that rents will increase by just over 25% in the coming years. With the already huge increase in the cost of renting a home over the past decade, combined with the above problem for house purchase, this means there is a large cohort of people who can neither afford to buy their own home because they don't earn enough and don't have enough disposable income to save for a deposit because their rents are so high, nor are they eligible for social or affordable rented housing because they earn too much.

Tackling the problem

Two years ago, a leading thinktank produced a report which suggested that allowing disused commercial land and buildings in London to be redeveloped could provide up to 420,000 additional homes for the capital by 2036. Figures compiled by the Policy Exchange found there were more than 500 hectares of empty or under-utilised industrial land across London alone, the equivalent to 750 football pitches, as well as a significant amount of vacant retail space in outer London.

They believed that if the government were to commit £3.1 billion a year to

Case study: The Excalibur Estate in Catford, south east London

A good example of putting out of date buildings to good social use while redevelopment is planned and executed is the old Excalibur Estate in Catford, south east London. This 12-acre site is home to 187 prefab bungalows built hurriedly at the end of WWII when there was an acute shortage of housing due to the Blitz. With an intended lifespan of 10 years, these homes remain decades on.

After years of consultation, in 2011 plans were finally approved to redevelop the site but still became bogged down in ongoing delays and objections by heritage groups and the new development is now scheduled for completion by 2021. However, while all the discussions have been ongoing, these old properties still have the potential to provide much needed low-cost housing for many people.

When Global Guardians gradually took over the vacated properties, they refurbished them to modern standards and they are providing inexpensive homes to an increasing number of local people while at the same time keeping the Estate secure and safe from squatters and ASB, as well as generating savings for the Estate owners in terms of security, insurance and maintenance costs and generating council tax income as well. It is proving a win-win situation for all parties.

finance the purchase of this land or provide the finance to the local authority who owns it, maybe alongside a private sector investor partner/developer, in a PPP for example, around 21,000 homes could be built each year. Rental income from the homes and the sale of equity stakes could allow the government to recoup its money within 20 years and this scheme would be the largest government investment and delivery on housing since the 1970s.

Since the Government Property Unit (GPU) is pushing on with its target to reduce the UK public sector's estate from 800 to 200 by 2023, a real opportunity exists for the public sector to lead the way and kick-start some of the proposals now on the table to tackle the housing crisis.

However, there is a real opportunity being missed across the country, which has in fact been picked up by the Greater London Authority in their recent investigation to find one of several solutions to the capital's chronic housing shortage. This is the use of property guardians in otherwise vacant buildings: buildings that are currently sitting, awaiting development, with or without planning permission, or simply up for sale.

The use of property guardians, who pay a far lower 'licence fee' to occupy an otherwise empty property, residential or commercial, than the market rate for the area, could give a whole section of people, the 'squeezed middle' in the property sector as described above, an opportunity to actually save money to put towards a deposit on a home of their own.

At Global Guardians, we have many examples of people who have done that, simply by being a property guardian for a few years. All our guardians live in accommodation that is safe, secure, clean and heated with utilities and domestic facilities far better than in a lot of rented accommodation, with the benefit of regular monthly inspections to ensure the property is maintained to rigorous standards.

It is such a simple and social solution for a whole section of the population who are currently frustrated with their accommodation lifestyle and it has the dual effect of lessening the financial burden that a property has for its owner, even if it is lying vacant or simply being gradually refurbished. As property owners, insurance and rates or council tax still must be paid, as well

as security to keep it free from squatters, criminal damage or ASB of all types. This financial benefit is a key one, especially for local authorities or housing associations as well as government departments, where budgets are permanently under pressure.

With the public sector thinking outside the box like the GLA for more social solutions to the current housing crisis, hopefully, more of the 'squeezed middle' can be helped. It won't solve the housing crisis, but it is certainly a contribution that should be actively considered.



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Is the UK Industrial Strategy fit for the future?

Lawrence Conway, Institute of Economic Development (IED) board member and Chief Executive of South Lakeland District Council, shares his views on the UK Industrial Strategy and asks if it is fit for the future

I must admit I was in shock for a short time after the EU referendum vote and its outcome of a decision to leave the EU. The shock was not about the outcome per se, as there would always be opportunities inside or outside Europe.

I had always believed that the EU market was the UK's natural home market. It wasn't about integration, trade deals and tariffs; it was a vital extension to our island economy plugging us into an economic marketplace of 511 million people with a GDP of \$18 trillion on our doorstep.

“To deliver on such a strategy will also require an architecture beneath to ensure we deliver on the promises and actions we set out with. That architecture, or structure, must be relevant and agile. It must match how business works in a place – be that nationally, regionally or locally.”

Maintaining links to the EU economy is necessary for our nation's ambitious growth plans based on a future knowledge and technology-based economy. We would be ready for that future, strategy or no strategy.

We have survived for decades without any real joined-up economic strategy and policies and we still came out high on the list of the world's best performing national economies. This is a testament to our home-grown innovation and entrepreneurial enterprise and spirit and our ability to compete in world markets.

Our response to this historic event has been a flurry of activity and the publishing of the UK Industrial Strategy and its five pillars to success. The document has had relatively positive reviews. Not for a nailed down direction of travel or a positive vision of the UK's economy



Lawrence Conway

post-Brexit, but rather for the fact that at least we now have one irrespective of the finer details yet to be hammered out. For this, at least, I am grateful.

A strategy, implemented with commitment, will bring focus, direction and confidence to any economy. If we look at the very best the world has to offer – their national economic strategies, their national infrastructure plans, their nations skills development, their eye on the future, their ability to look after their citizens – we have a number of countries we can look to for intel: Germany, China etc. They all set out a future and stick to a plan.

I have not included the US just yet, as I think we need to give them a little more time to see how their latest initiatives come to fruition. Not just for their own economy, but for the rest of the world too. Who does now lead the world in global issues such as climate change, growth and technology?

Our very own UK Industrial Strategy is clearly necessary to articulate a future narrative and vision to galvanise and focus the application of our abilities and potential. Without such a strategy, to include strong investment in infrastructure, skills and knowledge base and devolved spending powers and public-sector infrastructure decision-making processes to focus investment on where it is needed, we are at risk of floundering in our resolve, our direction and our use of resources as a nation. A Northern Powerhouse or Midlands engine would ultimately be consigned to the fate of The Northern Way and many others before them.

To deliver on such a strategy will also require an architecture beneath to ensure we deliver on the promises and actions we set out with. That architecture, or structure, must be relevant and agile. It must match how business works in a place – be that nationally, regionally or locally.

We must recognise that it is both the horizontal and vertical elements of business and community that make a place successful. Geography, local economic structures, clusters and linkages, culture, environment and administration are all key factors in ensuring that we get the right structure to deliver the strategy. True functioning economic areas at the local, sub-regional and sub-national.

I think it's fair to say right now we have a bit of a mixed bag regards structure and governance.

For some, London, Manchester, the five elements above already exist in abundance, and much progress has been made in overcoming historical rivalries. For many others, this is not the case. The driver must be economic success, not ease of use for Whitehall and government.

It is also crucial that national strategies are linked together. Decent jobs, skills and housing generally lead to a healthier society. I am sure the departments of Brexit, Health, Education and Business meet regularly to bring their key ambitions and policies into alignment.

“Our response to Brexit has been a flurry of activity and the publishing of the UK Industrial Strategy and its five pillars to success. The document has had relatively positive reviews. Not for a nailed down direction of travel or a positive vision of the UK’s economy post-Brexit, but rather for the fact that at least we now have one irrespective of the finer details yet to be hammered out. For this, at least, I am grateful.”

I know from a private sector viewpoint, as that is where I spent my formative years, the outlook and success criteria are very different from those within the public sector where I now happily reside. But the end game is the same.

Providing confidence and leadership, enhancing social responsibility and an environment where everyone has a chance to make the best of their circumstances, is the job of us all. It is our collaborative task and challenge to ensure we achieve this ambition for our communities whatever the future may bring. ■

Lawrence Conway

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Skills – edging closer to demand-led provision

Director of Swindon and Wiltshire LEP, Paddy Bradley tells us why the skill levels of the current and future workforce are crucial in determining whether a business will look to invest in a new base in an area

The skill levels of the current and future workforce are crucial factors in determining whether a business will look to invest in a new base in an area. The Swindon and Wiltshire Local Enterprise Partnership covers the geography of the County of Wiltshire and is home to a number of globally renowned businesses who have chosen our area to establish their UK bases. Honda of the UK Manufacturing Ltd (HUM), is based in Swindon. It is the only Honda plant in the world to produce the Civic in all its variations and it does so at the rate of 600 a day, about one car every 90 seconds.

On its website, HUM identifies why it moved to Swindon in 1985: “Excellent people to begin with. A workforce that made Swindon the manufacturing centre of the Great Western Railway – and set the standard for excellence in engineering. There’s also an outstanding infrastructure and first-rate communications links...” The existence of a greenfield site, perfect for their needs is also a reason but comes third behind the skills of the work force and good connectivity.

A highly-skilled and adaptive workforce is at the heart of any area’s inward investment offer. As the UK leaves the European Union and anti-globalisation political philosophies begin to take hold in some countries, the UK and its constituent regions need to raise its competitive game. Ensuring we have

true demand-led skills provision is the best way to improve our productivity and make an area such as Swindon and Wiltshire an attractive investment proposition. The focus needs to be on foreign direct investment, but there is competition between the regions and what attracts businesses from outside the UK, will also draw businesses from one part of the country to another.

“We have ambitious plans for our area and seek to achieve our growth trajectory by collaborating with partners who share our vision of employers in the driving seat, determining skills provision in our area. We are open to new ideas to help deliver the high-skill workforce of the mid-21st century.”

New markets, transforming technologies and disruptor businesses demand a workforce with the skills required by a business need. This challenge is beginning to be met at a national level by the move from the vagaries of apprenticeship frameworks to the more tightly defined, industry-led apprenticeship standards, which place employers at the forefront of policy formation. The Department for Education (DfE) recently announced its £170 million scheme to develop between 10 and 15 Institutes of Technology (IoT) which aim to develop technical excellence amongst learners to degree level. In a very good move, the DfE stipulated that anchor employers must be identi-

fied for each IoT and those employers must be at the forefront of leadership and governance of the new institution.

The Swindon and Wiltshire Local Enterprise Partnership is a strong supporter of this direction of travel set by central government. At a local level, we have been championing demand-led skills provision since 2014, when we achieved a deal with the government to help us develop degree-level skills provision determined by the requirements of our local businesses. Currently, through our Higher Futures programme, we are working with 109 businesses across multiple sectors. We are now widening the scope of the programme to embed it fully in our Growth Hub (www.growthhub.swlep.co.uk) to act as a triage service for all skills support.

Swindon and Wiltshire is an area of demographic and industrial growth. We need skilled personnel to design and build the housing, industrial and commercial developments and road infrastructure to meet growing demand. SERCO has responded to our strategy for the use of European funding to win £4 million from our allocation to stimulate growth by working with 82 local businesses in the construction sector and train 503 learners in qualifications up to degree level.

One in three businesses in Swindon, North Wiltshire and south-east

Bridging the local skills gap



1. Higher Futures



SWINDON & WILTSHIRE LEP



Brokering University level courses to meet business needs in the region.

Impartial guidance on apprenticeships and organisational development.

Supporting **109** local businesses across multiple sectors.

The **triage** service for skills support through the Growth hub.



3. Institute of Technology (IOT)



1 in 3 Swindon businesses face a skills gap issue



Combination of **5** HE Institutes & FE Colleges



8 Key Local Businesses

gfirst LEP

Swindon & Wiltshire
LOCAL ENTERPRISE PARTNERSHIP

= IOT

A STEM based higher education offering aligned to local industry needs

2. Skills Support for the Workforce

serco

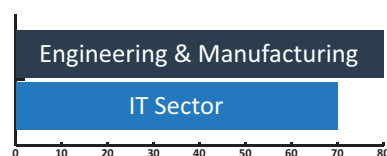


£4 million ESIF investment.

Supporting **82** local businesses within the construction sector.

Engaging **503** learners in the construction industry.

4. Creating a Higher Education Strategy



Data provided by UKCES Working Futures, suggests % required for new roles in these sectors requiring level 4+ skills.

Creation of a LEP wide HE strategy to address the long-term issue and highlight options.

Gloucestershire, face the challenge of meeting a current or imminent skills gap. This is not unusual across the UK. We have responded to the call for IoT bids by working with colleagues from the Gfirst LEP in Gloucestershire and two local authorities, five local further education colleges and regional universities and eight key local businesses to submit a strong application based on the development of science, technology, engineering and mathematics skills.

We are proud of our partnership working and regardless of the outcome of the bid, we will use the ideas and mutually beneficial relationships to continuously improve our degree-level skills provision. We are a market-oriented organisation and, lacking the presence of a large higher education

institution in our area, we are beginning to tackle the challenge by coordinating demand to improve supply.

There is a fundamental economic need at the core of this work. Engineering and advanced manufacturing and IT are amongst the most productive sectors in our area. To maintain that productivity and competitive advantage, 80% of jobs in engineering and manufacturing and 70% in IT will be at degree level or higher.

We have ambitious plans for our area and seek to achieve our growth trajectory by collaborating with partners who share our vision of employers in the driving seat, determining skills provision in our area. We are open to new ideas to help deliver the high-skill workforce of the mid-21st century.

If this has got your attention and you would like to discover more, please contact:

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The impact of welfare reform on social housing tenants and housing associations

Sue Ramsden, Policy Leader for Welfare at the National Housing Federation tells us about the impact of welfare reform on social housing tenants and housing associations

Since 2010, we have witnessed a period of radical change to the welfare system, on a scale that hasn't been seen in over sixty years. Governments have revolutionised the delivery of the benefits system, with the introduction of Universal Credit and made major changes to benefits entitlement. These changes have particularly impacted on people of working age living in social housing.

There is no disputing the impact the deductions from benefit for perceived spare rooms have had across the country. Two-thirds struggled to find the money to pay their rent¹ and downsizing was difficult because of a lack of smaller properties. The household benefit cap meanwhile, is applied regardless of local rent levels and family circumstances, exasperating arrears and poverty for some families.

The rise in the national minimum wage has helped put some money into the pockets of low-income families, but the cumulative impact of such welfare reforms on people's ability to rent a home has been difficult.

Cuts to the welfare budget were made without fully considering the effect it would have on housing affordability or the government's ambition to increase housing supply. Housing associations need certainty over their income if they are to build desperately needed new homes. Building more affordable homes is something that must be put at the heart of government policy on reducing welfare spending on housing.

The most significant transformation to the welfare system comes in the form of Universal Credit, which combines six benefits into one. The principles behind

Universal Credit were good ones – simplifying the system and making work pay – but it faces challenges.

Universal Credit in its current form is less generous than the Tax Credit system meaning families that work will still remain poor.

The programme was also designed with an expectation that people have savings or wages to tie them over the first six-week assessment period (now five weeks). In reality, many people come from low and weekly paid work or the existing benefits system so don't have these savings. Housing associations are finding that many tenants struggle to maintain rent payments particularly in this first period and our evidence so far shows higher levels of arrears for people in receipt of Universal Credit compared to Housing Benefit.

“Cuts to the welfare budget were made without fully considering the effect it would have on housing affordability or the government’s ambition to increase housing supply. Housing associations need certainty over their income if they are to build desperately needed new homes. Building more affordable homes is something that must be put at the heart of government policy on reducing welfare spending on housing.”

The government’s ‘test and learn’ approach to implementation means the DWP is open to acknowledging problems and implementing changes. As a result, we have seen recent improvements in the administration of Universal Credit, with more families now receiving the correct amount of money on time.

Changes after April 2018 also mean that the six-week wait has been reduced to around five weeks and there will be a two-week run on of housing benefit to help some tenants. We anticipate that these changes will help reduce the level of rent arrears, but we still need to better understand the relationship between Universal Credit and arrears levels and how best to support tenants over this period.

Though there have been positive changes, challenges remain. For example, a five-week wait does not mirror the world of work and though tenants can request an

advance on future payments, this is a loan that must be paid back from future payments.

It’s essential the government continues to listen and adapt the system, ensuring they put the people who depend on this money at the heart of the process.

Of particular concern to us at the moment is the level of deductions that can be made to pay back debt before families receive their Universal Credit payment – this could be government debt, Council Tax or rent arrears or debt with utility companies. Currently, up to 40% of someone’s personal benefit allowance can be taken to pay off such debt, including 20% for rent arrears. From speaking to our members, we know this is causing hardship and leaving some people unable to manage their day-to-day living, including ongoing rent payments. The government need to provide more flexibility around the level of deductions to ensure debts can be repaid at a rate that does not push people deeper into poverty.

The welfare system must be modified to ensure it doesn’t leave tenants at risk of debt, poverty and eviction or leave housing associations with arrears that threaten their financial stability. We know that a secure and decent home is often the starting point to help people back to work and building more affordable homes is the most effective way of cutting the overall benefits bill. Housing associations, therefore, are well placed to achieve both. ■

1 Ipsos Mori Impact of welfare reforms on housing associations, January 2014

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Modernising welfare payments in the UK

Director of Public Sector at Mastercard, Sam Mazloum explores why modernising welfare payments can be transformative for government and service user – and is not as difficult as it sounds

The UK public sector disburses over £100 billion in welfare payments every year, supporting millions of individuals and families with a wide range of needs and circumstances.

Traditional methods used to make welfare payments can be both expensive and limiting for the department as well as the service user, especially when compared to the opportunities offered by new payment products and services driven by the UK's flourishing fintech sector.

Working together with over 200 local and central authorities, Mastercard and its customers are delivering programmes that support a range of services and government policy. These offer a real alternative to existing welfare disbursements. At the centre of these programmes is the ability to save financially, cut out inefficiencies in processes and improve visibility over transactions, whilst at the same time increasing the level of care provided to everyone being supported.

Close the cash office

Cash management is expensive. Whether supporting an emergency need for an individual or a whole community, or those with no recourse to public funds, prepaid cards offer a simpler, safer and more versatile way of getting funds to people when they need it most. With card acceptance

ubiquitous in the UK, ATM access to withdraw funds in cash can also be restricted. The result is improved visibility of how funds are being spent and management information that can support safeguarding.

If a card is lost or stolen it can be simply cancelled and replaced, reducing the risk of crime associated with cash for the service user. If further funds need to be added to a prepaid card, this can be done without the need for the service user to visit the cash office or for public servants to make a home visit.

Prepaid cards remove the need to distribute cash. Where necessary, cash payments into your organisation can be made through the Post Office and local convenience stores. More and more councils and government departments are closing their cash offices. If you haven't yet done so, it might be time to start thinking about it.

Reach more people and simplify direct payments

The introduction of the Care Act and the subsequent move to direct payments for longer-term care needs is providing better outcomes for service-users.

Direct payments have traditionally been made to personal bank accounts, but this presents local authorities and

clinical commissioning groups with some challenges. To audit the service, it requires the individual to save bank statements and receipts and invoices and send them in monthly. The process is time intensive for the organisation and burdensome for the individual.

Prepaid programmes enable public sector organisations to provide transaction accounts that have the same functionality as basic bank accounts and more. Because the programmes are run by public sector organisations with the consent of the individual, they can automatically access financial information needed for audit, whilst at the same time saving the service user the burden of sending paper statements and receipts.

In addition, for many individuals, it can be challenging or impossible to get an account at one of the high street banks and therefore limits the number of services users that electronic direct payments can be made to. With prepaid programmes, the public-sector organisation is responsible for elements of the Know Your Customer process which means they can easily be provided to everyone regardless of their situation. This, combined with enhanced controls and alerts to support more vulnerable service-users, increases the number of people that direct payments can reach.

Universal Credit roll-out can support financial inclusion

By the time Universal Credit is fully rolled out, it will account for approximately £80 billion in payments. 20 per cent of those that will receive it do not have a transaction account today. For this group, benefits will more than likely be paid through the Post Office Card Account. POCA is not an account that enables payments, but one that simply allows an individual to withdraw funds in cash from the Post Office.

“Traditional methods used to make welfare payments can be both expensive and limiting for the department as well as the service user, especially when compared to the opportunities offered by new payment products and services driven by the UK’s flourishing fintech sector.”

Prepaid transaction accounts allow users to set up direct debits and standing orders, make card purchases in-store and online, check balances and expenditure online and withdraw cash using the ATM network. These accounts also can ring-fence funds for core spend such as rent and utilities and at the same time, they do not provide an overdraft or cheque facility, reducing the likelihood of unmanageable debt.

Initial trials using Mastercard prepaid cards to deliver Universal Credit have been extremely positive. The report on the Kent programme concluded that it: “demonstrated that prepaid cards have the potential to promote financial inclusion and independence, helping people manage their money and debts and widening options for financial management”.

The evidence shows that prepaid transaction accounts are a proven

alternative form of electronic payments that should be used to support the roll-out of Universal Credit, not just for those who don’t have a bank account today, but for everyone that wants greater control and smarter management of their finances.

The Department for Work and Pensions could reduce some of the risks associated with Universal Credit and simultaneously improve the financial health of a significant proportion of the population by moving beyond the prepaid pilots and into full roll-out.

Local authority case study: Surrey County Council Challenge

Surrey County Council (SCC) provides benefits to members of the community that require special care, such as, young carers and those who are mentally and physically disabled. In the past, funding recipients were required to open a bank account to receive payment. This was an extremely, time intensive process as it required a great deal of administration on behalf of the council.

Solution

SCC partnered with Mastercard and Prepaid Financial Services (PFS), an electronic payments provider, in February 2015 to transform its direct payment programme for special care clients. Due to the nature of prepaid cards and the flexibility they provide, the council has evolved its usage to now include its deputyship and young carers programmes. Currently, there are more than 600 recipients enrolled in the programme with plans to expand the service in the next 12 months.

Results

From SCC’s perspective, prepaid card usage has had major benefits to the

Council’s everyday activities. All reconciliations can now be completed in one day compared to the 45 days needed previously. From a financial perspective, the cost-savings have been significant. From April – September 2016, SCC identified £400-450,000 of unused funds and reallocated the funding to other initiatives. Not only has SCC managed to streamline their services to be more cost efficient, users also enjoy an increased amount of flexibility and control over their care.

“For SCC, the prepaid card is so much more than just a piece of plastic. We now have all the information readily available to us in real-time, making it easier for us to do our job and provide a more flexible and streamlined service. Ultimately, this new transparent way of working has resulted in cost and time-savings”, comments John Amans, East Area Finance Team Manager, Adult Social Care at Surrey County Council.



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Bercow: Ten Years On: The experiences of children and young people with SLCN

I CAN detail how their new independent report presents a real and updated picture of the experiences of children and young people with SLCN and their families, ten years on from The Bercow Report

Very few weeks pass by without us seeing the publication of the latest new report or review; a 'must read' for everyone. How many of these do you see however that have a focus on absolutely crucial skills, evidenced to have an effect on children and young people's education, their employability and their mental health?

Tuesday 20 March 2018 saw the launch of *Bercow: Ten Years On*, an uncompromising review of support for children with speech, language and communication needs (SLCN) in England. A decade on from the original, government backed publication, *The Bercow Report: A Review of Services for Children and Young People (0-19) with Speech, Language and Communication Needs*. This new independent report from I CAN, the children's communication charity and the Royal College of Speech and Language Therapists (RCSLT) presents a real and updated picture of the experiences of children and young people with SLCN and their families.

Given what we know about the prevalence of SLCN, this report is particularly important. 7.6% of children have a developmental language disorder that persists throughout school and impacts on learning and on their social and emotional development; at least two pupils in every classroom.

In some deprived areas of the UK, this figure is much higher – as many as 50% of children start school without the language they need to learn, learn to read or make friends. With clear evidence that shows the significant impact of SLCN on children and young people across the age range and on learning, socialisation and later life chances, never has it been more important to ensure the support that is needed is in place.

However, informed by evidence from more than 2,500 people, *Bercow: Ten Years On* shows that sadly, this is not the case. In fact, the report heard from many people that their experience of services is poor; that for families the journey to try to get support for their child is a "long, harrowing and tortuous" one; that systems do not prioritise speech, language and communication, or support for those who are struggling. Key findings from the report show:

- **Communication is crucial** to children's life chances. Yet awareness of its importance among the public and decision makers is not sufficient. This impacts on how well families can access the information they need – 77% of parents and carers said information about SLCN was either not easily available or not available at all.
- **Strategic system-wide approaches to supporting SLCN are rare.** Very often SLCN does not feature in national or local policies. In fact, 95% of people felt that central government's contribution to raising standards and improving outcomes for children and young people with SLCN is either not clear or in need of strengthening.
- **Services that are inaccessible and inequitable.** Too often support for children's SLCN is planned and funded based on the available resources, rather than what is needed, leading to an unacceptable level of variation across the country. Only 15% of people said that speech and language therapy was available in their area as required.
- **Support that makes a difference** is based on the evidence of what works. However, service design and

Just **15%** of people feel that speech and language therapy for children is suitably available.

#Bercow10

cuts frequently do not take account of the evidence we have. We heard, for example, from areas where support was only available to children younger than five, from services that only supported children with the highest need, that didn't offer training.

- **Too many children with SLCN are being missed** and are not getting the vital support they need. Worryingly, only 12% of parents said their child's difficulties were identified by a professional.

Thankfully, the picture is not a completely bleak one. Ten years after the original report, data from *Bercow: Ten Years On* tells us that the expertise of school and early years staff to identify and support children and young people's speech, language and communication has improved, although there is still a way to go.

The report also contains evidence of where things are working well in a series of good practice examples. A common thread that runs through these is the presence of strong leaders with a never-ending commitment to improving services for children and young people and a determination to design approaches based on evidence.

Of course, this isn't the end of the story for *Bercow: Ten Years On*. The report and [website](#) include recommen-

dations for government and local leaders to ensure change takes place and is sustainable and embedded. I CAN and RCSLT have made a commitment to ensure these are enacted. Alongside this, there are also calls to action for those involved in supporting children and young people and signposts to helpful information so that practitioners, children and young people and parents and carers can take bold first steps to change things locally.

Some of these may be for you. So, if you've not yet read *Bercow: Ten Years On*, be sure to add it to your 'must read' list. ■

Bercow: Ten Years On Project Team

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Specific Language Impairment (SLI) versus Speech Sound Disorders (SSD)

The important differences between Specific Language Impairment (SLI) in children and Speech Sound Disorders (SSD) in children are placed under the spotlight by Mabel L. Rice, Fred & Virginia Merrill Distinguished Professor of Advanced Studies at the University of Kansas

Around the world young children are expected to learn the language they overhear in conversations around them. This is a robust, spontaneous ability of humans, unlike, for example, reading, which must be explicitly taught. One prominent scholar of children's language acquisition once put it this way: "...there is virtually no way to prevent it from happening short of raising a child in a barrel."¹

Although true of most children, children with Specific Language Impairment (SLI) are the exceptions to this assumption. These are children who do not have overt neurodevelopmental disorders, hearing impairments, or other obvious causes of developmental disorders and who live in ordinary families. Yet they are later than other children in learning a language and are at risk for persistent low language abilities into adulthood. The best estimates for the prevalence of SLI are 7-10% of children at school entry (5-6 years).^{2,3}

SLI is often confused with Speech Sound Disorders (SSD) in children. Between one and five years of age children are learning two distinctly different parts of the human language capacity. One is the production of speech sounds needed in their native language. In the beginning, children can produce more sounds than they need for the language or languages

they are hearing. Their first job is to refine them to match the ones they need and to drop the ones that may not matter and to develop the motor control needed to do that.

Humans at birth are equipped with motor movements for breathing, sucking and swallowing (basic functions for survival), along with a wide range of sounds. Some vocalisations serve communicative purposes, and some are biological (such as burps or coughs). Between one and two years of age, babies master more refined tongue, lips and palatal movements needed for speaking the words and sentences of a language. This requires a fine-tuned synchrony of muscles, sound perception and the cognitive centres of the brain. The output is a sequenced speech pattern, such as what we hear in a phone conversation.

The second part of the human language capacity is more covert, a matter of cognitive processes in the brain that do not require a speech production system. For example, deaf children can acquire a language system that can be expressed in physical signs of the hands, face and body postures. Language emerges in young children first in short utterances that lengthen with age. In English, language emerges as one or two words at a time, which relatively quickly expand to phrases or sentences.

SSD can be obvious to adult listeners of young children. Young children's attempts to talk can be unintelligible, especially when they are very young. If unintelligibility persists as children age, it becomes noticeable and a matter of concern because it is not "typical." Some mispronunciations are understandable but regarded as immature, such as "wabbit" for "rabbit", "thoup" for "soup", or "bawoon" for "balloon." Scholars have tracked the order in which children learn their speech sounds and have developed age norms for evaluating whether a child meets age expectations⁴. The prevalence of SSD in 4-6-year-old children in population-based cohorts is approximately 3-6%⁵ and the condition appears to resolve in 75% of children by age 6⁶.

People often assume SSD is the same as SLI, such that children's speech abilities reflect their underlying language abilities or vice versa. This is not true. In the most precise study of a population-based sample of 5-year-old children, the co-occurrence of speech and language impairments, once adjusting for age expectations, was estimated at less than 2%⁵. For the children with SLI, speech impairment was evident in approximately 5-8% of the children. The authors concluded that SSD and SLI are independent; they are not likely to co-occur. Thus, SSD is not a diagnostic marker of SLI and presumably, the two condi-

tions do not share a common causal pathway.

The non-overlap of SLI and SSD carries implications for public health services and for scientific studies of the nature and origins of SLI and SSD.

- A big issue for public health services is that children with SLI are likely to be overlooked as needing language intervention services, perhaps in part because of the fact that SSD may be obvious to adults/caregivers, but SLI is not⁷.
- SSD is likely to resolve with age (children are likely to “outgrow” it) whereas SLI is likely to persist into adulthood⁷.
- At school entry, SLI predicts later reading impairments⁸ whereas SSD predicts weakly, if at all, once adjusted for co-occurring language impairments.^{9,10}
- Scientific studies of children’s communication problems in medical conditions should differentiate between SLI and SSD. A recent study of children exposed to Human Immunodeficiency Virus (HIV) is the first report of SSD outcomes compared to primary language impairments (i.e., without other developmental disorders). The risk for language impairments in the children was higher than population norms but the risk for SSD was not elevated.¹¹

Examples of how children talk can illustrate the differences between SLI and SSD. Consider two 5-year-old boys. They are talking about a picture of red rabbits. One, dressed in purple, has an SSD, apparent in his mispronunciations of the speech sounds needed to say “why are the rabbits red.” Within his speech system, he

says “why ah de wabbits wed?” The substitution of w/r in “rabbit” and “red”, along with the omission of the final /r/ in the word “are,” are not unusual speech errors in the speech of young boys.

Such errors are quite noticeable although they often do not interfere with adults’ understanding of the intended meanings. The other boy, dressed in green, asks a question formulated in the adult grammar as: “why is/are that rabbit/those rabbits red?” The boy says “Why that red?”, a sentence consistent with the grammar rules for children this age with SLI⁷. He demonstrates a deficiency in sentence structure, with the omission of the obligatory copula form of BE (“is” or “are”) and the substitution of a pronoun (“that”) for the common noun “rabbit.” Furthermore, the specification of singular versus plural for the noun phrase is vague because the noun information is underspecified. His articulation of speech sounds is at adult levels and his meaning is effectively conveyed.

Although the speech sound errors of the child with SSD are likely to be noticed and to generate attempts by adults to correct the problem, the grammar errors of the child with SLI are less likely to be noticed or understood as flags for concern. Yet it is the child in green who is at higher risk of adverse developmental outcomes than the child in purple, who is more likely to “outgrow” the SSD and less likely to encounter problems with literacy, school achievement, or long-term persistence of subtle but very important elements of grammar and vocabulary. Our research and our service systems will be improved by increased recognition of the important differences between SLI and SSD.

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Canadian education and Indigenous peoples

Vice President of the Canadian Society for the Study of Education, Dwayne Donald shares his expert perspective on Canadian education and research on Indigenous peoples

Over the past decade in Canada, Canadians and Indigenous peoples have together been critically scrutinising the character of the historic and current relationships linking them. This broad social, cultural, educational and political movement was instigated by the Truth and Reconciliation Commission on Indian Residential Schools that began in 2010. The Commission brought focus on the painful history of Indian Residential Schools in Canada and the multiple intergenerational traumas suffered by the peoples and communities subjected to them.

Indian residential schools were founded in the 1880s in Canada based on the belief that Indigenous children needed to be removed from their families and communities and forced to assimilate to more modern ways of living if they were to become useful citizens. In this way, their usefulness as citizens was understood as dependent on how well they could learn to imitate Canadians.

This institutional and societal practice of pathologising Indigenous peoples and their children is deeply rooted in Canadian culture and tremendously influential in the formation of policies and initiatives intended to address the educational needs of Indigenous peoples and communities. Up until very recently, most educational initiatives focused on Indigenous themes and issues were couched in logic that denies the oppressive history and instead characterise the educational struggles of Indigenous peoples as resulting from their own separate cultural preoccupations. Such work is founded on the assumption that Indigenous students will be more motivated to stay in school if they are provided opportunities to connect in some way with their own cultures and languages.

Ironically, however, failure in school is also considered a consequence of Indigenous children clinging to

ancestral cultures that render school meaningless to them. By persistently framing the educational struggles of Indigenous children as their own strange cultural problem, Canadian educational policymakers and leaders have effectively hidden their own complicity in the perpetuation of colonial violence against Indigenous peoples. By fixating on the problematics of Indigenous cultures, they have failed to consider Canadian culture as also part of the problem.

“...there is an urgent need to expand the realm of teaching and learning in Canadian educational institutions so that people can be provided with meaningful opportunities to come to terms with the difficult implications of the Calls.”

Canadian educational policymakers and institutions have recently been challenged to shift this unethical relationship and initiate a different kind of relationship with Indigenous peoples when the Truth and Reconciliation Commissioners issued 94 Calls to Action to redress the damaging legacies of the residential schools and advance processes of reconciliation in Canada.

The Calls to Action (2015) seek to facilitate depth engagement with Indigenous themes, experiences and worldviews as a societal commitment while simultaneously fostering ethical exploration of the possibilities such engagement provides in imagining new ways of living together that are not fully circumscribed by colonial logics. Educational institutions across the country and at all levels are expected to implement measures in response to the Calls on an ongoing basis.

Thus, there is an urgent need to expand the realm of teaching and learning in Canadian educational institutions so that people can be provided with meaningful opportunities to come to terms with the difficult impli-



cations of the Calls. There are three general ways to understand this need. First, Canadians have not been taught oppressive colonial histories involving their own country and naturally resist seeing themselves and their nation implicated in them. This resistance, its various manifestations and the pedagogies associated with helping people unlearn colonialism in the Canadian context need to be better understood.

“Indian residential schools were founded in the 1880s in Canada based on the belief that Indigenous children needed to be removed from their families and communities and forced to assimilate to more modern ways of living if they were to become useful citizens. In this way, their usefulness as citizens was understood as dependent on how well they could learn to imitate Canadians.”

Second, thoughtful attentiveness needs to be given to the experiences of Indigenous students participating in these reconciliation processes and how it feels for them to be the subjective data of their own studies.

Third, careful consideration needs to be given to the possibility that foundational Indigenous wisdom traditions can provide insightful reconciliatory guidance on how to reimagine education and reconceptualise the human being at the heart of the educative processes in Canada. The hope is that responses to the Calls to Action from educational institutions and policymakers in Canada can be inspired by the very knowledge systems that the Indian Residential Schools were designed to eradicate. ■

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Non-Indigenous individuals' responsibilities within higher education contexts

Dawn Zinga, from the Department of Child and Youth Studies at Brock University explore the responsibilities of non-Indigenous individuals within higher education settings and the inequalities that exist

As a non-Indigenous scholar working in the area of Indigenous education, I spend a lot of my time thinking about my own role in perpetuating inequality within higher education and answering questions posed by non-Indigenous faculty, staff, and students. These questions usually fall into two broad categories. The first category consists of questions about why I am raising an issue or why something is important, while the second category tends to focus on questions about what individuals can do now, so that they know about the inequities that exist. These two categories of questions point to some interesting aspects about the responsibilities of non-Indigenous individuals' within higher education settings. One of the first responsibilities is to become educated about the realities of Indigenous peoples and related the systems of inequality. The second responsibility that I will focus on is what to do with the knowledge that you gain when you become educated.

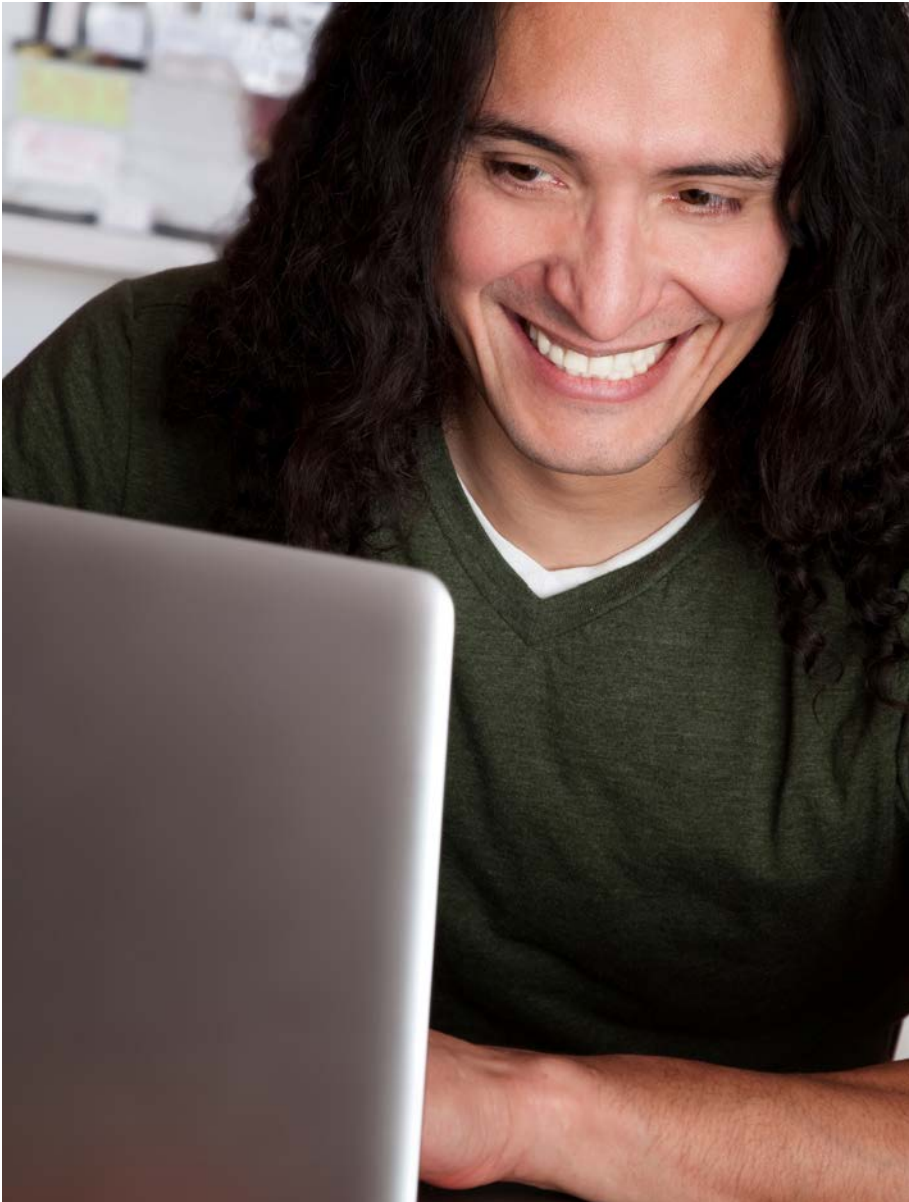
Starting with myself, I am a several-generations-removed immigrant to the ancestral lands on which I reside and I have experienced a position of some privilege in the mainstream structures of society, such as education, health services, and other governmental systems. While I grew up in a blue-collar home and experienced



the discrimination that can be associated with class and being a girl, I was afforded many privileges and rarely had cause to question that I belonged in the classrooms that I occupied. I frequently saw myself and my life experiences reflected in the classroom and my experiences within society. From a young age, I had a questioning mind and often challenged teachers about why some voices and some life experiences were not represented in the curriculum or were represented in very narrow and proscribed ways. Through my own search for knowledge and the generous teachings of my Indigenous colleagues, I became aware of the systems of racism and inequity experienced by individuals who are

minoritised by the mainstream systems of privilege and discrimination that continue to be reinforced throughout society and particularly within systems of education. In my role as a university professor, I am also responsible for exposing undergraduate and graduate students to these systems of inequity and to challenge their taken-for-granted assumptions.

Some of my students resist any challenges to their understanding of society and the status quo and remain facing the first responsibility of education. Other students engage in the teaching but sink into guilt and seem paralysed by the immensity and



complexity of the issues they have just learned exist. The second responsibility of what to do with the knowledge once you have learned it is easier to address than the resistance to learning that the world does not necessarily operate in a way that you thought that it did, and that with or without your knowledge, you have occupied a position of power and privilege. The first thing for non-Indigenous individuals to realise is that guilt is an emotion that will not be helpful. It must be experienced but in the end we are not responsible for the actions of those who preceded us, but we are responsible for how we address the legacy

that was left behind. Essentially, non-Indigenous individuals must focus on how to act on the knowledge that has been gained.

Non-Indigenous individuals have a choice. They can choose to close their eyes to uncomfortable realities and continue on perpetuating them or they can choose to use their individual voices to make a difference. Using one's voice can be as simple as speaking up when an inequality is being perpetuated, or challenging a policy that negates other people's experiences or lived realities. It can be exposing others to knowledge they

may not be aware of or supporting someone when that person's viewpoint is being shut down as invalid or irrelevant. Sometimes it can be listening to another perspective and being open to being challenged and educated about how your own actions or lack of action may have reinforced inequalities or alienated Indigenous individuals.

Addressing these two responsibilities within educational contexts can lead to educational settings in which Indigenous students and other Indigenous individuals feel welcome and accepted. It can open up important spaces to talk about ways of moving forward together towards positive change that does not reproduce or perpetuate systems of inequality. While I have focused on higher education contexts, this can also be extended to other educational contexts. Making a choice to address these responsibilities daily is a choice to move beyond resistance and guilt to positive action and strong relationships that can help us all negotiate a new future of education for all students.

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The crucial role of apprenticeships in the UK

Chief Executive of The Association of Employment and Learning Providers (AELP), Mark Dawe details the crucial role of apprenticeships in the UK today

For all the political turmoil since the general election of 2015, the one thing that hasn't changed is the UK government's commitment to advancing social mobility even if the recent report on the Social Mobility Commission by the Education Committee in the House of Commons exposed divisions about how the issue was being addressed.

Apprenticeships are rightly considered a key driver for social mobility and the introduction of the apprenticeship levy on large employers last year was meant to generate a big increase in apprenticeship opportunities for young people – to put them on the road to a successful career. This may still happen which is why the Association of Employment and Learning Providers (AELP) is an unequivocal supporter of the levy and believes that for the foreseeable future, the levy's proceeds should remain ringfenced to fund only apprenticeships rather than other forms of training.

But there is no escaping the fact that the latest official apprenticeship statistics do not make for happy reading. Starts on the programme in England were just 27,000 last November, a staggering 40% decrease on the number 12 months before. In respect of social mobility, the biggest concern should be the falling number of new apprenticeship opportunities for 16 to 24-year olds and at intermediate and advanced levels (levels 2 and 3). In fact, since the levy reforms were introduced, the number of apprenticeship starts at level 2 have halved while starts for 16 to 18-year olds have fallen by 38%. The Education Committee chair Robert Halfon MP agrees with our concerns about this and now Ofsted's Chief Inspector Amanda Spielman has added her influential voice to those who believe that the government needs to take action.

Our proposal to ministers is that until April 2019, SME employers outside the levy's scope should not be



Mark Dawe, Chief Executive of the Association

required to make a financial contribution towards the cost of training new apprentices aged between 16 and 24. The waiver should also apply to the levy paying employers who hire additional apprentices beyond their levy entitlement. We would also like to see a new incentive to encourage more progression from intermediate to advanced levels, again involving the waiving of the financial contribution when an apprentice moves on from level 2 to a level 3 programme.

Traditionally the majority of apprentices have been employed by SMEs, but for the 15-month period of January 2018 until April 2019, the government has allocated an initial £450 million for the apprenticeships of non-levy payers which is less than half of the 12-month budget allocated to them a year ago. The levy payers also get the first claim on taking back money from the levy pot and therefore, smaller businesses are now wrongly a secondary priority in driving forward employer engagement with the apprenticeship programme. To rectify this, a guaranteed £1 billion annual budget for non-levy employers is required to ensure that there are apprenticeship opportunities available across the whole of the country and in all sectors.

Delivering apprenticeship training for non-levy paying SMEs is still undertaken via a contracting process between the Education and Skills Funding Agency and training providers. Last autumn, after a previous disastrous attempt was scrapped by skills minister Anne

Milton, a government procurement exercise took place to decide which providers would deliver the training for SMEs until April 2019. Unfortunately, it was another botched exercise with a controversial marking system that left many good and outstanding specialist training providers without contracts.

Many areas of the country and particular sectors are, therefore, about to experience a shortage of specialist provision which will impact negatively on employers and the young people wanting to do an apprenticeship. In our view, all government registered providers should immediately be given access to funding apprenticeships for all employers. The government also needs to address other barriers to employment engagement in the programme, such as more flexibility in the rules that govern off-the-job training. The disappointing outcome to the non-levy contract procurement is leading to more subcontracting in the supply market and the rules surrounding this practice need to recognise the new realities while ensuring that money is not being taken away from frontline training.

In yielding a billion pounds more for the programme's budget, the apprenticeship levy is potentially a game-changer in the efforts to boost Britain's productivity, as a vehicle for improving social mobility and for 'growing our own people' to fill post-Brexit skills shortages. The introduction of new standards has given us an opportunity to improve the quality of apprenticeship training, while the increase in the number of apprenticeships at higher and degree level is now giving young people a genuine choice over whether or not to go to university, knowing that apprenticeships mean no student debt and that the apprentices are earning while learning. But we cannot deny that damage is being inflicted on the social mobility agenda because of the way the levy is being implemented and this is why ministers need to act now. ■

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The future of the common agricultural policy (CAP)

Commissioner Phil Hogan shared his views on the future of the EU's common agricultural policy (CAP) during a speech he recently made at the Berlin Green Week to the political leaders of Germany's farmers

Green Week is obviously a great occasion and opportunity for political and farm association leaders to come together, but it is also an opportunity for tens of thousands of farmers and consumers to come together and engage about the latest developments in food and agriculture, whether that is in terms of market developments or policy developments. I have succeeded in being at Green Week every year since I was appointed Commissioner.

“Standing still is not an option. Agriculture is a dynamic industry, constantly adapting to new challenges and, while farmers have over the millennia, shown themselves to be adaptable and indeed ingenious, our job, as policy-makers, is to provide them with the legislative and regulatory framework within which they can show that adaptability and ingenuity.”

The conference was appropriately titled the “Future of the CAP.” Before discussing what that future might look like, let us agree on one thing – the CAP has a future, not alone because of the Treaty objectives which underpin it and which continue to be relevant today, over 60 years since they were first included in the Treaties of Rome, but because the CAP is a living, evolving policy that changes to meet new and emerging challenges and adapts to ensure that it continues to provide appropriate support to millions of farmers in this country and throughout the European Union.

Since its inception, the CAP has had several manifestations and has seen profound change during a period of more than half a century when the continent of Europe has emerged from near post-war ruin to a time of unparalleled peace and prosperity.

Today, Europe is the biggest trader of agricultural produce, with Germany more than playing its part. After a

record year for agri-food exports in 2016 (€131 billion of exports and €112 billion of imports), the strong trade performance continued in 2017. The EU's trade balance in agri-food products has now been positive for seven years in a row. This has brought significant benefits to our sector and there is huge potential to continue to do so in the future.

There are many reasons behind these impressive figures, including the high standards and quality of our food. But, it is also because of the competitiveness of European agricultural production. As agricultural trade becomes more global, the competitiveness of Europe's production will become increasingly challenged.

We have to prepare for this and maintain our competitive edge through investment in research, innovation and technology. I have seen at first-hand the developments in technology and their application in the field. What impresses me about what I see is not alone the work that is going on in the laboratories and workshops, but how we translate that work into concrete results that benefit farmers.

The CAP has and will continue to prioritise investment in research and innovation, with the aim of improving the competitiveness of European farmers who, in an increasingly market-orientated policy, will in the future have to secure more of their income from the market into which they sell their produce.

However, that increased focus on market-orientation is in no way to understate the importance of the CAP in terms of providing income support and a safety net for farmers. It is precisely for that reason that, in our Communication of the Future of Food and Farming, the Commission has restated its commitment to the maintenance of direct payments. The Communication



Image: © European Union, 2017

says that, “direct payments remain an essential part of the CAP in line with its Treaty obligations.” We have also confirmed that we are keeping “the existing two-pillar structure which, in our view, serves our farmers and rural areas well.”

“While there is always room for greater efficiency in the way in which we do our business, this argument is simplistic and does not acknowledge the very real pressures caused by taking necessary measures in the areas of migration, security and defence.”

We know that farmers are facing challenges, whether that it is in the form of extreme weather events – several of which we saw last year – price volatility or diseases. At least 20% of farmers lose more than 30% of their income, compared with the average for the previous three years. As I said at the EU’s Outlook Conference in December 2017, I know of no other profession or occupation which has to live with such income uncertainty.

Standing still is not an option. Agriculture is a dynamic

industry, constantly adapting to new challenges and, while farmers have over the millennia, shown themselves to be adaptable and indeed ingenious, our job, as policy-makers, is to provide them with the legislative and regulatory framework within which they can show that adaptability and ingenuity.

My view is that the current broad architecture of the CAP works quite well and, after the reform of 2013, my sense among farmers and public authorities is that there is an element of ‘reform fatigue’ and a desire, particularly among farmers, to be left alone to get on with their work without the tedium of excessive red tape and unworkable rules that prevent them from reaching their potential, both because of the production restrictions and the fear of contravening the myriad of complex rules and regulations.

It is precisely for this reason that I have described the Commission’s Communication, adopted in November 2017, as an “evolution rather than a revolution”. Indeed, I’m pleased to see that there is a widespread acknowledgement that this is what we have achieved.



Phil Hogan, Commissioner for Agriculture & Rural Development

Of course, I'm not so naïve as to think that this acknowledgement automatically translates into full support for the proposal. I have listened carefully to the reactions of various stakeholders to the Commission's proposal and this is another important opportunity to hear your views and to see how I can address some of those concerns.

“The proposal reflects what I believe to be a universally accepted conclusion that a “one-size-fits-all” approach doesn’t work in terms of agricultural production in Europe. What the Commission is proposing is not, as some of the critics, like to label it “the renationalisation of the CAP”.”

Following the adoption of the Communication, our focus has now shifted to the preparation of a legislative proposal, which I hope will be adopted very shortly after the Commission publishes its proposals for the next MFF, which is scheduled to happen at the end of May.

Given the obvious connection between the future of the CAP and the future financing of the EU, I am working to

see how we can address the budgetary gap caused by the UK's departure and, at the same time, provide funding for the new challenges of migration, security and defence, without having a disproportionate impact on the funding of the CAP.

It is important to make the point that the future funding of the EU is NOT a matter for the Commission, but a matter for the Member States and it is they which must decide whether they are prepared, as I believe they should, to increase their national contributions to the EU budget. I know that there are critics of such an approach who instead argue that the EU budget has to become leaner and more efficient. While there is always room for greater efficiency in the way in which we do our business, this argument is simplistic and does not acknowledge the very real pressures caused by taking necessary measures in the areas of migration, security and defence.

I hope that you can bring whatever influence to bear on those whose decision it will ultimately be whether to support a higher level of MS contribution to the EU

budget. As President Juncker said in January, “we need a budget of more than 1% of GDP if we are to pursue EU policies and fund them properly”. He went on to say that “countries need to stop thinking in terms of net contributors and net recipients”. I hope that this is the kind of constructive attitude that will characterise the forthcoming discussions on the MFF.

Before I conclude, I should say something about what is described as the new “delivery model” for the CAP post-2020. It seems to be the issue around which most of the debate is focused and I understand that. It is a debate worth having, but it is also a debate that needs people to stand back from some of the misinformed rhetoric which is already evident.

The proposal reflects what I believe to be a universally accepted conclusion that a “one-size-fits-all” approach doesn’t work in terms of agricultural production in Europe. What the Commission is proposing is not, as some of the critics, like to label it “the renationalisation of the CAP”.

Instead, it is an approach consistent with the principle of subsidiarity, as enshrined in Article 5 of the Treaty and with the ‘Task Force on Subsidiarity, Proportionality and “Doing Less More Efficiently”’.

The Task Force, which will report to President Juncker by 15 July 2018, will make recommendations on how to better apply the principles of subsidiarity and proportionality, identifying policy areas where work could be re-delegated or definitely returned to the Member States, as well as ways to better involve regional and local authorities in EU policy-making and delivery.

Our proposal ensures a very clearly defined role for the Commission which will set high-level objectives at the EU level. These will revolve around the Treaty objectives as well as those identified in the Communication. They will then be translated into a set of specific objectives, which will be concrete priorities. Each of the specific objectives will be accompanied by a set of results and qualified output indicators, which will allow MS to define the targets.

The MS will be required to prepare a CAP Strategic Plan, which will be subject to approval by the Commission,

similar to the way in which RDP plans are currently subject to Commission approval. This is a very important aspect because nobody has suggested that Pillar II of the CAP has been renationalised. The CAP Strategic Plans and their approval by the Commission will ensure EU added-value and will preserve a functioning agricultural internal market.

“Today, Europe is the biggest trader of agricultural produce, with Germany more than playing its part. After a record year for agri-food exports in 2016 (€131 billion of exports and €112 billion of imports), the strong trade performance continued in 2017. The EU’s trade balance in agri-food products has now been positive for seven years in a row. This has brought significant benefits to our sector and there is huge potential to continue to do so in the future.”

I hope that I have given you some flavour of the motivation to make this proposal as well as address some of the emerging concerns about the future of the CAP. I look forward to hearing your views and I want to assure you of the Commission’s openness and to mine, to hearing and considering your views in more detail.

This article is based on a speech given by Commissioner Phil Hogan at Berlin Green Week on “Future of the CAP” Berlin, 18 January 2018. ■

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https://ec.europa.eu/commission/commissioners/2014-2019/hogan_en

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The importance of animal welfare: European precision and sustainable livestock farming

Daniel Berckmans and Tomas Norton from M3-BIORES, Catholic University of Leuven together explore the importance of animal welfare and livestock farming in Europe

Animal welfare is important from an ethical viewpoint and to realise a more efficient livestock sector. We need a more efficient production: more animal product for less feed input, less manure and fewer emissions.

For over 40 years, the *European Commission* has been promoting animal welfare by gradually improving the lives of farm animals. The development of welfare assessment schemes is a long journey – with difficult balancing between practical constraints against scientific validity and reliability. The practical implementation of a feasible, affordable and common way to assess or measure animal welfare in the field seems to be even more difficult. After the first approaches by the so-called *iceberg indicators for animal welfare*, the approach of the EU Welfare Quality® project was the next step. This generated a method for qualitative assessment of animal welfare based upon behaviour scored by observers visiting farms. These previous methods are important since they can be used as a reference for animal welfare at the farm level to develop further steps in realising a European monitoring and management system for animal welfare.

The following step is the so-called *Precision Livestock Farming (PLF)* technology. PLF aims to deliver a tool for



Figure 1: The SOUNd MONitor (SOMO) for infection monitoring in pigs

management of livestock by continuous and automated real-time monitoring of production/reproduction, health and welfare of livestock and the environmental impact. PLF assists livestock producers by combining ICT with cameras, microphones, sensors on or around the animal and intelligent algorithms analysing animal behaviour in real-time.

The biggest advantages are continuous monitoring 24 hours a day/7 days a week throughout the life of the animal, a fully automated method, based on the use of objective quantitative data, rather than qualitative information, a technology-based method that is same in all farms. This method is not prone to subjectivity by individual experts, it's cheaper than

costly man-hours, a more hygienic method than experts travelling between farms and continuous dataflow is available for early warning and management actions.

It has been over 27 years now since this technology – for the monitoring animals with sensor and ICT – has been under development in laboratory conditions. The European Committee for Precision Livestock Farming since 2003 has already organised seven European conferences on PLF. ECPLF2019 will be organised in Cork, Ireland. The first Asian European Conference was organised in 2016 in Chongqing China and the first USA conference focusing on PLF is the 2018 ILES conference, taking place this year.



Figure 2: The eYenamic system for real-time monitoring of broilers' behaviour

Instead of developing more technology, the EU-PLF project Bright Farm by Precision Livestock Farming, EU Grant Agreement no.311825 was testing this PLF approach on real farms. The technology was installed in 20 farms all over Europe: 10 farms with fattening pigs, five broiler farms and five dairy farms. For each species, 60 production cycles were monitored. The farmers from 12 different countries were trained to get familiar with the technology and gave feedback during several workshops.

The main conclusion of the EU-PLF project is that the demonstration of the real-time monitoring of livestock concept is realistic. Though there is scepticism regarding the working capacity of this technology in commercial farms, the sound, image and sensors installations in the harsh conditions of livestock houses were operational during the test of three and a half years and worked well continuously 24 hours a day/7 days a week. The project generated 120 terabytes image data, five million sound files from 5,475 measuring days.

Another important deliverable of the project was the *PLF-Blueprint* for inter-

ested farmers and other stakeholders, including an e-course for researchers (see European Association for PLF, www.ea-plf.eu). The project also started *four new high-tech companies* in four different EU countries showing that the livestock sector can turn into a high-tech sector to implement PLF technology and services. The Soundtalks *Pig Cough Monitor* (Figure 1) detects the infection of pigs by sound analyses and detected problems up to 10 days before the farmer has noticed them.

The real-time Fancom eYenamic system for broilers (Figure 2) using image analysis detected 95% of all problems (light, feed/drinking systems, climate, light, etc.) in the broiler house during the fattening period. The GEA *Cow view system* was used in five barns with milking cows monitored continuously in terms of the position of each individual cow – creating alerts for animals that need farmers' attention.

The PLF systems showed the potential to give *tangible benefits* for farmers by saving man-hours in control actions and preventing days of production losses by early warnings, based upon

real-time analysis of animal behaviour. Farmers are also appreciating the *non-tangible benefits*, such as getting more peace of mind, chances for a different lifestyle with the family and being able to show transparency to the community, all of which are very important.

The project also showed that farmers need training and help in using this modern technology, a *PLF service industry* will create a modern more sustainable livestock sector.



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Agriculture, forestry and rural development in Portugal

The background and current work of Luís Capoulas Santos, Minister of Agriculture, Forestry and Rural Development is placed under the spotlight by Open Access Government

Luís Capoulas Santos, Minister of Agriculture, Forestry and Rural Development in Portugal has been in office since November 2015. Before we look at his current role, it's worth providing his background prior to attaining that position. He was born in Montemor-o-Novo, in 1951 and many years later, he graduated in Sociology from the Universidade de Évora.

He also worked in the Ministry of Agriculture for many years, from 1977 to 1991. After that, he was a member of the Assembly of Republic by Évora district between 1991 and 1995, then again from 2002 to 2004, plus he was re-elected in 2015.

Between 1995 to 1998, he served as Secretary of State of Agriculture and Rural Development and from 1998 to 2002, he was Minister of Agriculture, Rural Development and Fisheries. In addition, he was a member of the European Parliament between 2004 and 2014 and spokesman for the Agriculture Affairs of Socialist and European Democrats Group.

Other impressive positions he has held include his time as vice-president of Euro-Latin-America Parliamentary Assembly and as rapporteur of European Parliament for the reforms of Common Agricultural Policy between 2008 and 2013.

Supporting farmers in Portugal

In late March this year, The Ministry of Agriculture, Forestry and Rural Development in Portugal paid a total amount of €37.3 million to Portuguese farmers through Institute for Financing Agriculture and Fisheries (IFAP). This payment includes €13.5 million that constituted the final payment to the farmers affected by the deadly fires that swept Portugal (and Northern Spain) during October 2017, after the control actions were carried out.

A few days after this, Minister Santos says that on the recent full payment of support to 23746 farmers affected by the fires: "Some 30 million are in payment against the presentation of their supporting documents", he adds, noting that 25 are from community funds (Rural Development Program 2020) and €5.5 million to support the recovery of vines.

"In late March this year, The Ministry of Agriculture, Forestry and Rural Development in Portugal paid a total amount of €37.3 million to Portuguese farmers through Institute for Financing Agriculture and Fisheries (IFAP). This payment includes €13.5 million that constituted the final payment to the farmers affected by the deadly fires that swept Portugal (and Northern Spain) during October 2017, after the control actions were carried out."

In other recent news, Minister Santos announced that the government will constitute the Public Enterprise for Forest Development and Management. He said that the key objective would be "to demonstrate how it is possible to profitably manage the forest, particularly in the minifundium areas".

The company "aims to demonstrate how the forest can be professionally managed, how it can yield and how to prevent fires", the Minister says, adding that the company will also seek to identify the rustic buildings. The Minister also points out that the contracts involving municipalities and other organisations in the forestry sector allowed for the creation of 26 reception and storage areas for burnt wood were signed during March.

The Minister for Home Affairs was also present at the debate on the report of the independent technical commission on the fires of October 2017 and



Luís Capoulas Santos, Minister of Agriculture, Forestry and Rural Development

announced the reinforcement of the means of fighting the fires.

Rural development in Portugal

Through the above examples, we can see that Luís Capoulas Santos, Minister of Agriculture, Forestry and Rural Development strongly supports those working in the rural sector in the country. This is also evidenced by the government's clear support for the tornado-hit farms in Esposende, Portugal. The ordinance signed by the Minister himself and recognises that the tornado that reached the coastal zone of the municipality of Esposende on 14th March this year was an "adverse climatic phenomenon".

This measure is part of the Rural Development Program PDR 2020, providing support totalling €3 million and is intended for the holders of agricultural holdings located in the parishes of Belinho and Mar, where the damage of more than 30% has occurred. The support is for equipment and rural buildings, the replenishment of animals, multi-annual plantations to support agricultural activity in the country. The support is for 100% for losses up to €5,000; of 85% for losses between €5,000 and €50,000; and 50% for damages

between €50,000 and €800,000. The minimum support limit is €100 and added to that, the thresholds are cumulative.

A point worth considering is the government's National Irrigation Program, presented in March 2018. The National Irrigation Program is an initiative that will create more than 90,000 hectares of irrigated land by 2022, with a public investment of €534 million. The National Irrigation Program is financed through the Rural Development Program (PDR 2020), the European Investment Bank (EIB) and the Council of Europe Development Bank (CEB). The future of Portugal's rural sector looks bright, despite the fires of October last year. ■

For more details, please visit <https://www.portugal.gov.pt/en/gc21/ministries/agriculture-forestry-and-rural-development>

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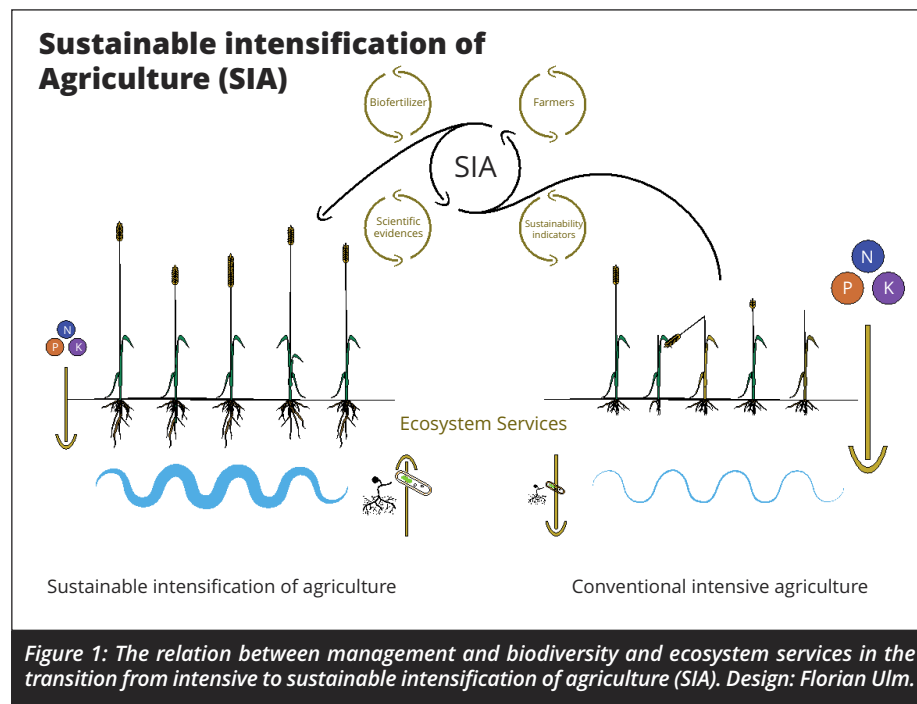
The sustainable intensification of agriculture in Europe

Cristina Cruz, Professor Auxiliar at Faculdade de Ciências da Universidade de Lisboa (FCUL) shares her thoughts on the sustainable intensification of agriculture (SIA) in Europe

The sustainable intensification of agriculture (SIA) is intended to strengthen food production with minimum negative environmental impacts and zero increase in land degradation. According to the European Commission (COM-2017/713), this is its latest objective for European agriculture.

However, sound supporting evidence of its advantages and tools for its implementation are not currently reaching the farmers, which may explain farmers' low engagement with the concept. It is, therefore, essential to understand the interactions of above- and below-ground biodiversity with various farm management systems and their relationship with the ecosystem services provided. A relevant question is to understand whether soils that have been subject to intensive agriculture will increase and improve below-ground biodiversity, which would represent a key justification for the promotion of SIA as a management tool to support ecosystem function.

In Europe, where agriculture is already very intensive, SIA can only be achieved through the development of new techniques targeted at increasing the efficiency of use of the available resources in order to produce healthy food outputs with minimal disturbance to agro-ecosystems' components. For this, we need to bring research and innovation out of the



labs and into the fields and markets, to better link what we know with what we grow.

Soil, the pillar of food sustainability, is a biological system. The support and sustenance of soil's functionality and provision of ecosystem services, related to natural, societal and productive capital, is its biological community, which, in highly managed systems, is the first to be destroyed by high levels of fertilizer, pesticides and herbicides and soil mobilisation. The recovery of a functional soil biota may represent an opportunity to increase sustainable productivity and mitigate the environmental impacts of conventional (intensive) farm systems (even though in certain EU locations this would imply a de-intensification).

Agriculture is the principal factor responsible for the 33% increase in EU ecological footprint over the last 40 years. However, at the same time, EU farmers are the guardians of environmental sustainability since they care for the natural resources (soil, water, air and biodiversity) of 48% of the EU's land, on which all of us depend. High opportunities for SIA are found on 34% of the arable area in the EU. All the results obtained in our research indicate that biodiversity is a key to sustainability of agrosystems and that it is possible to convert intensively managed farms into sustainable ones by increasing below- and above-ground biodiversity.

However, the actors of this change must be farmers and to achieve this,

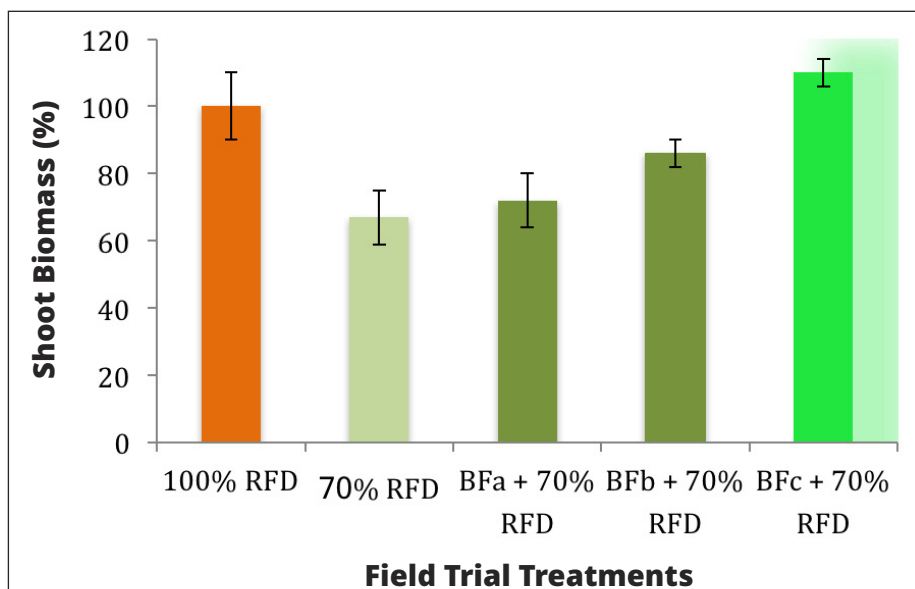


Figure 2: Results of the field trial using 3 biofertilizers (BFa, BFb and BFc) prototypes and 70% of the recommended fertilizer dose (RFD). Field trials were performed in Alentejo, Portugal, using maize (Sincero variety). Vertical bars represent standard deviation (n=3).

they require access to this evidence in order to implement the necessary strategies to promote biodiversity and consequently farm sustainability; they need tools to convert intensive farms into more sustainable ones and indicators of that change; and they need knowledge of changing farm management, since it also involves socio-economic issues (Fig. 1). Thus, implementing the sustainable intensification of agriculture has social, scientific and technical dimensions.

In line with the SIA concept, farms rely on their natural resource capital that includes a self-sustaining and hence resource-efficient, nutrient acquisition strategy, which depends on the close interaction of plant roots with their microbiome. The plant microbiome is known to supply plants with nutrients such as nitrogen and phosphorus and increase plant tolerance to biotic and abiotic stresses. SIA may compensate for some of the reduced inputs, through enhanced soil microorganism-mediated nutrient mobilisation. This advantage would justify SIA promotion at the EU level as an attractive farmland management alternative.

However, in highly managed conventional agrosystems, the soil biological community is the first to be destroyed. Of the techniques for recovery of those soils, not many are economically viable in the farming context. Due to the influence of plants on soil microbial composition, the best way to restore soil ecology is by increasing plant diversity. It has been proven that crop rotation or crop cover are practices that stimulate crop productivity through soil enrichment.

The use of old crop varieties or the introduction of new varieties with stronger interactions with the soil biota may also contribute to the stimulation of soil vitality. However, there are situations where a stronger intervention is needed, where bio-fertilisers may be an important tool to recover soil biota, nutrient use efficiency and plant health.

Many small and big companies are intensively working to produce the best possible biofertilizer. Bioclub, a project financially supported by FCT (PTDC/AGR-PRO/1852/2014), has a multi-actor team involving international (Israel, India, The Netherlands

and national (from Universidade de Lisboa) scientists, as well as companies (Soilvitae, Trichodex, Fertiprado), to develop a biofertilizer able to reduce mineral fertilizer application in 30% without affecting productivity. The first three biofertilizer prototypes were designed and produced and are being tested in field trials, which have had promising results (Fig. 2). At the moment we can say that at least one biofertilizer prototype (BFc) allowed the reduction of the recommended dose of fertilizer (RFD) by 30% without decreasing maize productivity.

More field trials are being performed with various crops (wheat, tomato, peas) in close collaboration with farmers, adjusting the experimental design to answer their questions. This challenge has been very rewarding from the scientific and social point of view. We are convinced that by the end of the project (in two years) we will have solid evidence that the combined use of bio- and mineral fertilizers may provide the fine tuning necessary to increase the resource use efficiency of EU agricultural systems where intensification is already very high.

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Animal medicine: Science in the legislative driver's seat

Roxane Feller, AnimalhealthEurope Secretary-General shares her thoughts on the role of science in the legislative driver's seat where animal medicine is concerned

Animal medicine, alongside its human counterpart, is a heavily regulated industry sector, comprehensively reliant on scientific assessment before products are permitted for use. And, rightly so. Animal health products impact all levels of society, from animal welfare to public health, from food safety to the health of our countryside, right down to protecting our relationship with the animals that share our homes and lives. It is therefore normal that, before any new animal medicine can be placed on the market, a stringent scientific and independent review has to be carried out by the authorities to ensure it is safe, of high quality and efficacious.

In Europe, the EU registration process ensures that only those products of a defined standard, which have been thoroughly tested and carefully reviewed by independent scientific experts, reach the marketplace. And when this registration system in Europe is fair, based on science and predictable, the availability of medicines and vaccines can be maintained to the benefit of Europe's animals, vets, farmers and pet owners.

The vast range of specific requirements inherent to the animal medicines sector, such as a large number of different species, a range of different diseases and the difficulty to administer treatments, requires a significant research and development effort. The requirements of safety, quality and efficacy demand complex and exhaustive scientific programmes to provide all the necessary data for regulatory approval, which are time- and cost-intensive. Research and development programmes needed to take a new product from inception to the market can cost up to €150 million and can take between five and 11 years to complete.

With EU legislation on 'veterinary medicinal products' and 'placing on the market of medicated feed' in the final stages of revision, the animal medicines sector in Europe recalls the importance to ensure that new regulations overseeing animal health products encourage advances in R&D. A robust regulatory system that is supportive of business innovation goes a long way to ensuring wider access to and availability of more animal health solutions across Europe.

Since its first ever inception with the 1965 EC Medicines Directive, which laid down the criteria for safety, quality and efficacy, the EU has established effective and rigorous procedures and rules to ensure the protection of animals, people and the environment when it comes to licensing medicines. Manufacturers of animal medicines are eager to continue to prevent and manage animal disease in Europe and this needs a business and regulatory environment that, at the same time, is based on scientific evaluation, supports benefit-risk assessment and is conducive to innovation.

In the years succeeding the introduction of revised rules in 2004, Europe-based animal medicines companies recorded a 20% drop in investment in new product development. This was reported as being partly due to the amount of R&D budget that must be diverted to defending and maintaining existing licensed products and the costs of manufacturing, compliance and variations.

It is also partly due to the introduction of the 'global marketing authorisation concept' which has meant that all innovations to an existing product, excluding adding an additional species, do not have any data protection. This is a major disincentive to introduce

improved formulations, for example, such as re-formulations to improve ease of administration and user compliance. Practically all studies have had to be re-done when a product formulation is changed, incurring significant costs and administrative burden. As a result, companies are less inclined to invest in the costlier products, such as much-needed innovations in antibiotics.

With the added influence of the socio-political debate in this particular area, the ensuing sense of unpredictability has led to companies who once spearheaded the present portfolio of modern antibiotics, not wishing to invest in new solutions that might be banned for veterinary use and reserved for human use only at some unknown point in the future.

The new EU rules set out to encourage greater innovation by reducing administrative burden and improving the functioning of the internal market. For industry, it is pertinent that a combination of: (a) a science-based risk-benefit system; and (b) adequate protection periods for technical documentation when developing new products, improving formulation, or adding a new species, etc., remain a central focus in the new legislation. In conjunction with a new pragmatic system to overcome the lack of harmonisation in the authorised summary of product characteristics for the same products and a reduction in information that must appear on the immediate label to decrease costs for multi-lingual labelling, the animal medicines sector can ensure its response to Europe's need for new and improved animal disease prevention and treatment options.

To ensure that manufacturers continue investing in the development of new solutions, it is essential that EU rules remain both science-based and predictable. Respect for the procedure put in place is important and its sustained independence, objectivity and credibility must not be undermined by non-scientific considerations as the rules are revised. For any medicine, the potential benefits must be weighed up against the potential risks. There is no such thing as zero risks in any field. Unfortunately, social and political pressures sometimes expect that.

If other criteria, such as socio-political considerations, are influencing the rule-making, then this creates an impediment to predictability, affordability and ultimately, availability. Non-science-backed decision-



Roxane Feller, Secretary-General

making can lead to restrictions in the vet's armoury as they may be denied access to the full range of modern medicines potentially available to them. In the case of products which are essentially a 'public good' like animal medicines, the decision-makers primary consideration must be the impact of their decision on the vet's ability to prevent and treat animal disease.

About the author: Roxane Feller is Secretary General of AnimalhealthEurope, the representative body of manufacturers of animal medicines, vaccines and other animal health products in Europe. With membership covering 90% of the European Market, AnimalhealthEurope represents innovators and generics alike, as well as large, medium-sized and small companies. ■

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How right-sizing regulation can optimise plant protection

Greg Rosenthal of the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service explains how right-sizing regulation can optimise plant protection

The idea of right-sizing regulation is a guiding force for USDA's Animal and Plant Health Inspection Service (APHIS). Part of our mission is safeguarding U.S. agriculture and natural resources against invasive pests and diseases and facilitating the safe trade of agricultural products. The scale and complexity of this work is vast. In 2017, APHIS helped safeguard more than \$98 billion worth of U.S. agriculture production and facilitate agricultural exports valued at over \$138 billion.

The role of regulations

APHIS' regulations are a crucial tool for mission success. Our regulations prevent devastating foreign pests and diseases from entering the United States on imported agricultural products. Should a pest or disease enter our country, regulations or other regulatory means allow us to take decisive action to prevent its spread.

The balance: most effective, least restrictive

Of course, there is another side to regulations. Some regulatory actions can create burdens on producers and the industries they supply. That is why we constantly seek the most effective – and least restrictive – approach possible.

To make sure we are hitting the mark, APHIS officials meet yearly with representatives from various commodity sectors to discuss the opportunities and challenges they face. We also reduce burdens by constantly applying cutting-edge science, technology and data analysis to streamline inspection methods, commodity treatments, pest detection, pest management and export certification. In addition, APHIS uses existing regulatory flexibilities and non-regulatory solutions to right-size regulation.



Inspectors with USDA's Animal and Plant Health Inspection Service ensure that imported plant parts comply with science- and risk-based regulations that are designed to keep invasive pests and diseases out of the United States.

Regulatory flexibility

The status of plant and animal pest and disease conditions worldwide constantly changes and import requirements must keep up. That can be challenging, however, when each change requires a time-consuming rulemaking process. To respond faster, APHIS has begun moving specific import requirements for certain commodities out of the Code of Federal Regulations (CFR) and into online regulatory manuals. More general import requirements remain in the CFR and the CFR

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Image: USDA Photo by R. Anson Eaglin



Invasive pests can infest the millions of sea containers that carry agricultural commodities around the world. USDA, working with our Canadian partners and the maritime industry, have formed the North American Sea Container Initiative to develop and promote the use of voluntary guidelines for effectively cleaning and disinfecting sea containers to reduce this risk.

refers to the manuals for specific requirements. That allows us to change these requirements when needed through a much faster notice-based process, which includes a public comment period.

Non-regulatory solutions

We are eager to look beyond rulemaking to solve plant and animal health problems through other means whenever possible, using solid science and industry best practices. In 2016, we used this approach when we confirmed that bacterial leaf streak, a disease affecting corn plant leaves, was present in several states throughout the U.S. Corn Belt. We knew that regulating the disease would be neither practical nor possible.

Instead, APHIS worked with our partners to identify best management practices to effectively control the disease. At the same time, APHIS gathered scientific evidence on this little-known pathogen to help build a strong case for the safety of U.S. corn, protecting \$6.3 billion in U.S. corn exports from trade disruption.

We also collaborate with industry, states, academia and others to promote voluntary programmes that protect U.S. agriculture. For example, APHIS and the seed industry are developing a Seed Health Regulatory

Framework. It will make international seed movement safer by promoting the worldwide use of consistent and equivalent requirements that reduce pest risk.

Through our Offshore Certification Programs, we verify that overseas nurseries and other facilities that export large-volume, high-demand plants, cuttings, seeds and other products to the United States meet minimum production and sanitation standards. This offshore work is an effective way to prevent harmful plant pests and diseases from entering our country.

Everyone wins

APHIS constantly strikes that critical balance of taking the most effective and least restrictive approach. This allows us to regulate at the speed of commerce and relieve industry burdens wherever possible – without compromising our mission. ■

Greg Rosenthal Communications Specialist

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Biological pesticides and the future of sustainable agriculture

Cooperative Extension Specialist at the Department of Botany and Plant Sciences, University of California Riverside, Dr Philippe E. Rolshausen shares his thoughts on biological pesticides and the future of sustainable agriculture

Crop yield and quality of marketable fruit are corner stones of any farmers' business model. To that end, chemicals have been widely deployed in agriculture to fertilise soils and plants or to kill pests and pathogens that are limiting factors to optimum productivity.

However, the 20th century dogma that chemicals could be used blindly without restrictions has found its limits in today's era. Concerns about their excessive use on human health and environmental pollution have shifted the farming philosophy to a more sustainable approach. Here, we will review some of the key discoveries that have advanced the field of biological pesticides and discuss how new technologies could shape the future of sustainable agriculture.

Synthetic agrochemical products have been successful for decades to manage pests and pathogens. An agrochemical is categorised by its active ingredient and metabolic target. One the major negative side effect of over-using chemicals with a similar mode of actions is the selection of resistant strains within microbial populations. Examples of resistance to fungicides and bactericides in fungal and bacterial pathogen populations are well documented, but often growers manage the problem by rotating their chemistries, adopting disease forecast models to reduce chemical input and adapting



their management practices to minimise disease pressure.

However, in extreme events, farmers have no chemical alternatives to manage a disease. For example, resistance to the neonicotinoid insecticide in psyllid populations has been clearly established in the United States and it no longer suppresses populations of psyllids below desirable levels. This has become a major threat to the citrus and potato industries because this insect feeds on plants and transmits bacterial pathogens (*Candidatus liberibacter* species) that cause diseases known as Huanglongbing and Zebra Chip, respectively.

In recent years, there has been a shift in consumer mentality, with an

increased demand for organic food and food products. US farms produced and sold \$7.6 billion (up 23% from 2015) in certified organic commodities, according to the U.S. Department of Agriculture's National Agricultural Statistics Service. As a result, there has been an increase of organic farms (over 14,000; up 11% from 2015) and a total acreage (5 million acres, up 15% from 2015).

Conventional farms also tend to be more mindful of their farming practices. To that end, biological pesticide application, which consists of using beneficial microbes or microbial products to control disease, improves soil and crop health and has been deployed in a broader capacity because of their low environmental

impact. For example, one of the many benefits is that resistance cannot develop against microbes.

The first biological control ever discovered in the early 20th century was the bacterium *Bacillus thuringiensis*. Some strains produce toxins that are lethal to insect pests and those have been commercialised, as either a biological insecticide or an insect-resistant genetically modified crops. Because of the toxin host-specificity, it is regarded as environmentally friendly.

Another key example of biological pesticide is *Agrobacterium radiobacter* strain K84 registered in the late 20th century as a biological control agent of grown gall caused by *Agrobacterium tumefaciens*, a soil-borne pathogen that affects a broad spectrum of crops. *A. radiobacter* strain K84 releases a toxin that alters the ability of the pathogen to reproduce.

Despite those key scientific discoveries that became commercial successes, biological pesticides only remained adopted in niche markets where synthetic chemicals were not registered, not effective, or not economical. Thus, the discovery of new biological pesticides remained marginal because of the widespread adoption of cost-effective synthetic chemicals. Nowadays, this trend is reversed. The commercialisation of chemical pesticides is declining whereas biopesticide has become a booming market.

One of the major game changers for biological pesticides discoveries was the advent of 'Omics' technologies. The traditional microbiological techniques that were utilised in the 20th century did not allow for a high throughput screening of organisms. In addition,

most organisms are not culturable, so the microbial techniques only recovered a small range of the plant-associated microbes and most bacteria and fungi were overlooked. Plants host an infinite number of microorganisms and looking for the 'good ones' at the time was comparable to finding a needle in a haystack.

"In recent years, there has been a shift in consumer mentality, with an increased demand for organic food and food products. US farms produced and sold \$7.6 billion (up 23% from 2015) in certified organic commodities, according to the U.S. Department of Agriculture's National Agricultural Statistics Service."

In today's era, 'Omics' technologies have allowed us to profile the microbial communities living inside and outside of plants and better understand the complex plant-microbe and microbe-microbe interactions and their biological functions. These new technologies can reveal in a high throughput capacity taxa, genes, metabolites or proteins that have potential antimicrobial attributes.

In my laboratory, we are using these technologies to identify solutions to two important bacterial diseases of grapes and citrus, namely Pierce's Disease and Huanglongbing, respectively. Those global emerging diseases are huge threats to crop production because they can rapidly kill a vine or tree. We have been exploiting a natural phenomenon occurring in vineyards and orchards whereby some vines or trees under high disease pressure are not symptomatic.

Because plants are of the same genetic make-up (same variety grafted on the

same rootstock) we hypothesise that the residing microbial communities cause the disease tolerance that we observe. Our approach is to collect plant tissue samples from both symptomatic and asymptomatic plants and deploy a culture-dependent approach with traditional microbial techniques and culture-independent approach using a next generation sequencing-based platform, so we capture all the organisms associated with those plants.

The computational analyses of the DNA-database provide the seeds for obtaining a greater understanding of the factors that shape the plant microbiome, as well as identifying the microbes that potentially play a role in plant health and disease suppression or exacerbation. Those potential beneficial microbes can be cross-referenced in our culture collection and recovered for downstream evaluation in *in vitro* and *in planta* bioassays. This approach provides opportunities for the patenting of novel technologies and for the development and commercialisation of new science-based bioproducts.



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USDA: Protecting Americans from foodborne illness

Acting Deputy Under Secretary for Food Safety at the United States Department of Agriculture (USDA), Carmen Rottenberg explains how the Food Safety and Inspection Service protects Americans from foodborne illness

The Food Safety and Inspection Service (FSIS) is the public health agency in the United States Department of Agriculture (USDA) responsible for protecting the public's health by ensuring the safety of the nation's commercial supply of meat, poultry and processed egg products. (Our partner agency, the U.S. Department of Health and Human Services' Food and Drug Administration, has jurisdiction over other foods, such as fruits, vegetables and dairy products.)

FSIS ensures food safety through the authorities of several federal laws. The Federal Meat Inspection Act (FMIA) was passed in 1906. The FMIA requires that slaughter and processing take place under sanitary conditions and bans the sale of adulterated or

misbranded meat and meat products. The FMIA was followed by the Poultry Products Inspection Act (PPIA) in 1957.

Both laws require continuous federal inspection of slaughter operations and that state inspection programs be at least equal to federal standards. The Egg Products Inspection Act (EPIA) of 1970 and the Humane Methods of Slaughter Act (HMSA) of 1978 complete the set of major laws, providing FSIS with the authority and obligation to carry out its mission to protect public health and prevent foodborne illness.

Secretary of Agriculture, Sonny Perdue, has made agricultural trade a key priority of his tenure at USDA.

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*Carmen Rottenberg
Acting Deputy Under Secretary for Food Safety*

As we look to imported product, FSIS has a robust equivalence system in place to ensure that countries seeking to export to the U.S. meet the same rigorous standards we expect of our domestic producers. For meat, poultry and processed eggs to be imported into the United States, a foreign country's inspection system must be found to be equivalent to the U.S. system. This equivalency status is not permanent but must be confirmed by periodic audits. 100% of meat, poultry and processed egg products imported into the U.S. is re-inspected at point-of-entry. This inspection may also include sampling to test for pathogens and banned chemical substances.

At FSIS, we never lose sight of our mission to protect public health by preventing foodborne illness. In his first speech as Secretary of Agriculture, Secretary Perdue named food safety as one of the top priorities. Our mission and goals line up perfectly with Secretary Perdue's vision and the new USDA Motto to "Do Right and Feed Everyone!" ■

As the U.S. continues to expand into markets overseas, at FSIS we are keenly aware of the role that food safety plays in an increasingly global agricultural marketplace. Food safety is the critical underpinning of this global economy.

Carmen Rottenberg
Acting Deputy Under Secretary for Food Safety

United States Department of Agriculture (USDA)
www.fsis.usda.gov
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Techniques for monitoring broiler embryo temperature

Dr E. David Peebles from the Poultry Science Department at Mississippi State University details the accurate determination of embryo temperature and its relationship to the functional characteristics of broiler hatching eggs

Eggshell temperature has been routinely used in commercial settings to pragmatically estimate internal egg temperature (Lourens et al. (2005) and to serve as a subsequent indicator of embryo body temperature (Janke et al., 2004). However, because eggshell temperature is influenced by the thermal conductivity of the eggshell and the pattern and velocity of air flow within the incubator (Lourens et al., 2011; Ozcan et al., 2010), it may not precisely reflect actual internal egg temperature.

“Further technological advancements and refinements of transponder implantation and temperature recording procedures may increase the practicality of temperature transponder use in commercial settings.”

Direct measurement of the internal temperature of eggs has been used to more accurately assess the level of heat production and the body temperature of embryos during incubation (Janke et al. (2004). Various methods that have been employed to directly measure internal egg or embryo temperature have exhibited certain limitations, which include physiological invasiveness, egg contamination, the alteration of embryo metabolism and an increase in embryo mortality (Janke et al., 2004; Turner, 1990).



Nevertheless, Pulikanti et al. (2011a) have successfully inserted transponders into the air cells of broiler hatching eggs between 12 and 14 days of incubation without any associated adverse effects on eggshell porosity or embryogenesis or any noted physiological stress to the embryo. This relatively non-invasive procedure has allowed for the accurate determination of embryo temperature through the last week of the incubational period. This procedure also enables investigators to detect variations in embryo metabolism and subsequent heat production that other external methods, such as those used for measuring eggshell temperature, are unable to detect.

Relationship of embryo temperature to the functional characteristics of eggshells

Pulikanti et al. (2011b) used temperature transponders to record the temperature of the air in the incubator immediately surrounding the egg. At the same time, they implanted transponders in the air cells of those same eggs to record their internal temperature. These concurrent temperature readings were used to more accurately calculate the water vapour pressure gradient across the shell and for the subsequent precise calculation of absolute and relative (adjusted to egg weight) eggshell water vapour conductance.

Pulikanti et al. (2012b) later employed these same methods to further compute the conductance constants of eggs, in which the length of incubation was included as a variable in the calculation. Accurate determinations of the above variables are necessary in research studies where the specific functional properties of the eggshell are required.

“Further work conducted by Pulikanti et al. (2012a) showed that a higher relative eggshell conductance, calculated using internal egg temperature from transponder readings, results in an increase in embryonic metabolism which then leads to an increase in growth and yolk sac absorption.”

Relationship of embryo temperature and the functional characteristics of eggshells to the physiological characteristics of embryos and posthatch broilers

Pulikanti et al. (2011b) reported that the internal temperature of live embryonated eggs exceeded those of non-embroned eggs between 10.5 and 18 days of incubation. The temperature difference increased from approximately 0.025°C on day 10.5 to 0.80°C on day 18, with the average difference over the entire period being 0.50°C. The semicircadian patterns in temperature observed were more accurately detected by transponders that were implanted in the air cells of the eggs.

Further work conducted by Pulikanti et al. (2012a) showed that a higher relative eggshell conductance, calculated using internal egg temperature from transponder readings, results in an increase in embryonic metabolism which then leads to an increase in growth and yolk sac absorption.

Pulikanti et al. (2013) also later confirmed that embryo temperature and subsequent relative eggshell conductance can influence physiological variables in birds during both the middle and late posthatch grow out periods. For example, it was shown that relative body and breast muscle weights on day 48 posthatch were positively correlated with relative eggshell conductance and eggshell conductance constant values and that relative breast muscle weight was negatively correlated with embryo temperature. These reports indicate that accurate determinations of embryo temperature and associated eggshell functional characteristics are necessary in determining the physiological status of the embryo and in predicting the posthatch performance of broilers.

Summary

Further technological advancements and refinements of transponder implantation and temperature recording procedures may increase the practicality of temperature transponder use in commercial settings. This methodology has the potential to provide commercial hatchery managers with a more accurate means by which to regulate incubation conditions to better suit the broiler embryo and to subsequently lead to increased production profits.

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National Institute of Food and Agriculture (NIFA)

The work of the National Institute of Food and Agriculture (NIFA)
is examined here by Open Access Government

The National Institute of Food and Agriculture (NIFA) is a federal agency within the United States Department of Agriculture (USDA). The agency administers federal funding to address the agricultural issues impacting people's daily lives and the nation's future. To provide both leadership and funding for programmes that advance the progression of agriculture-related sciences, NIFA invest in and support initiatives that ensure the long-term viability of agriculture. They do this while applying an integrated approach to ensure that ground-breaking discoveries in agriculture-related sciences and technologies reach the people who can put them into practice.

NIFA collaborates with leading scientists, policymakers, experts and educators in organisations throughout the world to find innovative solutions to the most pressing local and global problems. These collaborations create

spaces for constant scientific progress, made through discovery and application. Among the most important progressions in 2018 NIFA focuses on:

- The advances in the competitiveness of American agriculture;
- Bolstering the U.S. economy;
- Enhancing the safety of the nation's food supply;
- Improving the nutrition and well-being of American citizens;
- Sustaining natural resources and the environment and;
- Building energy independence.

It is clear to see that NIFA programmes aim to cover a wide spread of issues, while also serving as a vital contributor to science policy decision-making. NIFA has taken significant strides toward enhancing the impact of food agriculture, natural resources and human sciences in recent years and now more than ever it is vital to strike the balance between practising sustainable agriculture while also increasing productivity and production efficiency. The U.S. Department of Agriculture is propelling its scientists to develop research-based technologies that can make this possible.

February 2018 marked the announcement of The U.S. Department of Agriculture's (USDA) NIFA support for the Alfalfa Forage and Research Program (AFRP) with approximately \$2.1 million in available funding to support AFRP. This programme funds research and extension programmes that improve alfalfa forage, seed yields and helps producers apply best practices.

"Alfalfa research helps ensure there are dependable and affordable supplies of forage available for dairy and other livestock producers around the country," states NIFA Director, Dr Sonny Ramaswamy. "This crop is also a part of conservation production systems that help protect fields from water erosion and provide a natural supply of nitrogen to the soil for use by other crops." Their principal goals are to increase alfalfa yields and quality; improve harvest and storage systems; develop methods to estimate forage yield and quality to support marketing while reducing producer risks and; explore new and novel uses for alfalfa.

Success in previous projects across America spurs on scientists to become innovators who explore new ways of tackling problems from all angles. For example, January 2017 saw several announcements regarding NIFA and the diverse allocation of funding and collaborative research:

- Four grants totalling more than \$13.6 million allocated to combat a scourge on the nation's citrus industry, citrus greening disease, aka Huanglongbing.
- \$18.9 million in funding for eligible 1890 land-grant colleges and universities to obtain or improve agricultural and food sciences facilities and equipment. The 1890 Facilities Grant Program helps the eligible institutions educate the future workforce in the food; agricultural and human sciences job sectors.

- The availability of \$8.8 million in funding to support agricultural science education at Hispanic-serving institutions (HSIs). "Hispanic students earn only 8% of the degrees awarded in science, technology, engineering and math (STEM)", states Director Ramaswamy. "These investments help HSIs promote STEM education and agricultural industry careers to all their students, including Hispanic students."

In the same vein, NIFA tackles a few "challenge areas" using collaborative research and funding. The AFRI Resilient Agroecosystems in a Changing Climate Challenge Area is one of these and focuses on understanding the interaction between climate variability and agricultural production systems, so that we can develop the plants, animals and management systems that will be robust and productive under changing environmental conditions.

Research results from this challenge area will lead to improved management systems and crop varieties that consider the risks associated with a more variable environment. Another long-term outcome of this challenge area is reducing the environmental impact, while maintaining a productive food, feed, fibre and fuel system. This is a prime example of studies exploring maximised productivity alongside minimised environmental damage, it is becoming more and more obvious to the agricultural sector that environmental impacts need to be minimised, while also developing new ways to deal with the results.

Overall, it is evident that these above initiatives and programmes support their aims. In a press release, we find out that: "NIFA's mission is to invest in and advance agricultural research, education and extension that solve societal challenges." Their programmes propel cutting-edge discoveries from research laboratories to farms, classrooms, communities and back again. Through three main federal-funding mechanisms, NIFA supports programmes that address key national challenge areas. ■

<https://nifa.usda.gov/announcement/usdas-national-institute-food-and-agriculture-announces-support-increasing-alfalfa>

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Transformative research on Cowpea: Innovative trap crop development and deployment

Louis E. N Jackai and Beatrice N. Dingha from the Department of Natural Resources and Environmental Design at North Carolina A&T State University discuss their transformative research on Cowpea for increased and sustained production and use in the USA, with this first article focussing on innovative trap crop development and deployment

Cowpea, *Vigna unguiculata* Walp., is an important source of protein and vitamins. It is widely grown in the Southern USA and in most tropical and subtropical countries worldwide. Cowpea was historically used as a forage crop for horses and cattle (speculated source of the name cowpea), and is utilised primarily as a fresh market and frozen or canned vegetable in Southern USA but is consumed mostly as a dry pea (for example “blackeye pea”) on a global basis.

In the Southwestern USA, especially in California and Texas, about 45,000 t of dry cowpea (“blackeye” and other types) is produced annually, on about 20,000 ha. Roughly a third of the production is exported to Europe, Middle East and elsewhere; North Carolina grows only about 2,000 acres, much below its actual potential.

Cowpea has other uses, including as cover crop (especially in organic systems) for soil health enhancement and as an animal feed supplement. Cowpea consumption by humans and livestock is known to have significant health attributes, some yet to be fully understood or exploited; for example, the potential for cowpea extract to reduce proliferation of triple negative

breast cancer, a very aggressive form of cancer, as well as increasing immune system defense in ruminants against gastrointestinal parasites among other effects (Adjei-Fremah, 2017).

Cowpea is also attractive to pollinators, such as honey bees and other pollinating arthropods foraging for nectar as they carry out important ecological services that are critical for a productive and sustainable agroecosystem. Many varieties of cowpea have high-yield potential (>3,500 kg/ha), superior seed quality and various levels of resistance to insect pests and diseases.

Both small and commercial production can be profitable; fresh market production is primarily by small growers, while dry seed production is mainly a large commercial enterprise. However, the various benefits and uses of cowpea cannot be realised without adequate control of field and storage pests that can destroy an entire crop.

Production constraints

Pests on cowpea are indeed a bane worldwide. Realising the potential of cowpea as a crop, soil health enhancer, livestock feed or any other use will be difficult to achieve without our ability to minimise the damage and preva-

lence of insect pests and diseases. Entomologists, Drs Louis Jackai and Beatrice Dingha and their colleagues at North Carolina A&T State University in the USA have been working on the pest problems of small organic and conventional growers who produce 95% of the cowpeas in North Carolina.

The university is the only institution in the state that has a cowpea research programme focused exclusively on pest management. There is a good reason for this focus. Results from recent studies (funded by USDA-NIFA and USDA-ARS) to determine the factors that limit the expansion and use of cowpea indicate that insect pests, especially pentatomid pests, such as the brown marmorated stink bug (BMSB) and a weevil, the cowpea curculio (Cpc), may be among the most limiting challenges.

Cowpea as a trap crop for an emerging invasive pest

Research conducted at two locations, Greensboro, NC (in the Piedmont) and Goldsboro, NC (in the Coastal Plain) revealed that BMSB, a severe pest on fruit, ornamentals and vegetables and the Cpc present inverse population trends, with the former limiting production in the Piedmont zone and the latter in the Coastal Plain. This was most evident in 2014, when our research

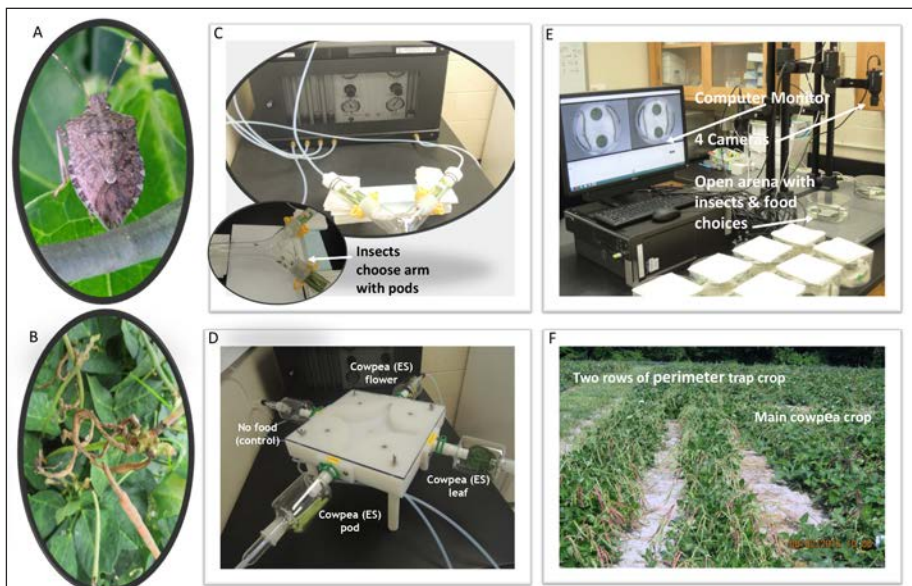


Figure 1: The brown marmorated stink bug (A) causes severe damage to cowpea (B). Several field and laboratory techniques are used in the discovery of a suitable trap crop for this insect including response to plant odors (Y-tube (C) and 4-arm (D) olfactometers and other behaviors related to attraction to a host plant source (using the Noldus Observer XT video system, E). One of the best cowpea trap crop varieties (ES) is shown in F as a 2-row peripheral trap.

showed a near crop failure from BMSB damage in the Piedmont and from the Cpc in the Coastal Plain region.

A broad range of laboratory and field experiments (Fig. 1) have since shown that a few cowpea varieties are particularly attractive to BMSBs and as such, can be used as decoys to attract and divert the pest away from a desired main cowpea crop, thus serving as a sink. This is the textbook definition of the trap crop concept (Hokkanen, 1991; Shelton and Badenes-Perez 2006; Parker et al., 2013), in this case an intra-specific trap crop that uses the same crop species both as trap and main crop.

This finding has many small vegetable growers excited about the long-term possibilities of minimising the use of high-risk pesticides leading to increased food safety and farm profits. In a spin-off from the initial grant, we started to examine the potential of using cowpea as a trap crop in other cropping systems to divert populations of BMSB from high-value crops (such as soybean, corn, sunflower and possibly peppers, tomato and fruit trees – the latter have not yet been tested) to a cowpea trap crop on

which the pest can then be killed, with an appropriate insecticide or other method that would result in less environmental and human health risks, while obtaining reasonable crop yield.

The future of trap cropping and other pest management approaches for BMSB suppression

Crop protection using tactics such as trap cropping can take a long time to figure out *where* (field location; conventional wisdom of periphery trap placement may not always be optimal), *when* (time of trap crop introduction) and *how much/and for how long* (trap density/retention).

In some situations, multiple trap crops have produced better yields (Parker et al., 2016); using both perimeter and strip trap crops, our work and that of others, has produced great success in using a single trap crop variety. Traps work because of the olfactory responses that are triggered by semiochemicals (plant odours) that guide the insects to the trap crop.

The same compounds (single or mixtures) may also be present in the main

crop, as in crucifer trap cropping, but their concentrations and gene expression may make all the difference. Ongoing work in our laboratories will try to understand these dynamics to make trap cropping more efficient and predictable. This approach is the nexus to sustainable pest management in organic systems and overall ecosystem sustainability; indeed, continued research funding from USDA and other sources as well as innovative ideas hold the key to future success of this and similar pest management tactics.

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Finding new solutions to agricultural problems in the U.S.

Open Access Government looks at the work of the Agricultural Research Service (ARS) in finding new solutions to agricultural problems in the United States

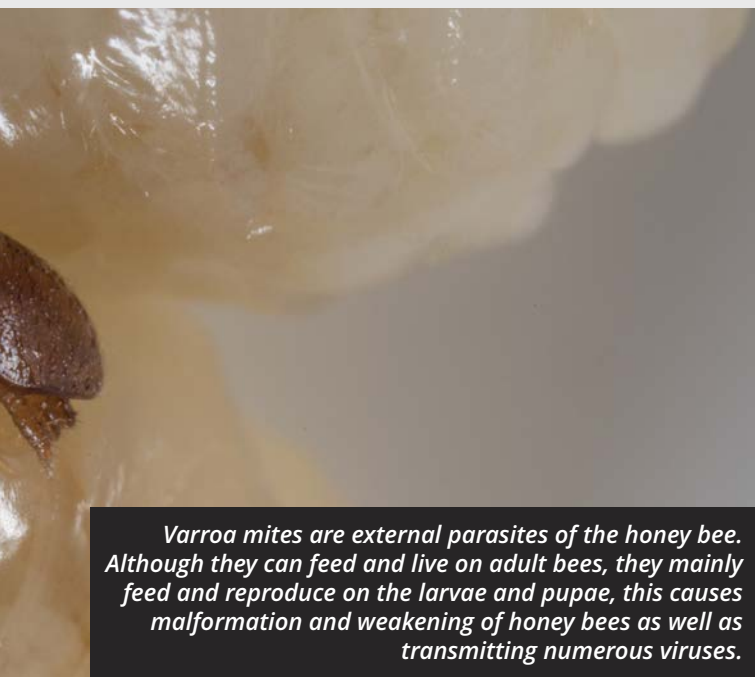
The Agricultural Research Service (ARS) is the U.S. Department of Agriculture's (USDA's) chief scientific in-house research agency. ARS is one of four agencies in USDA's Research, Education and Economics mission area. Their principal purpose is finding new solutions to agricultural problems that affect Americans every day from the field to the table, with the vision to "lead America towards a better future through agricultural research and information."

Their methods to solving agricultural problems are focalised through their four national programme areas: nutrition, food safety and quality; animal production and protection; natural resources and sustainable agricultural systems; and crop production and protection. Formed in 1953, the ARS has come a long way since then, rapidly growing in scope. Today, the organisation includes 690 research projects within 15 national programmes, 2,000 scientists and post docs, 90+ research locations, including overseas laboratories and a \$1.1 billion fiscal year budget.

The ARS states that each dollar invested in agricultural research results in \$20 of economic impact.

ARS scientists regularly collaborate with research partners from universities, companies, large organisations and numerous different countries. An example of this is the \$1 million Funded International Consortium to Seek Honey Bee Disease Controls, which took place in March of this year. Agricultural Research Service (ARS) entomologist Steven Cook is leading this consortium of scientists, who together are attempting to seek new controls for Varroa mites, the honeybees' number one problem.

Along with the Bee Research Laboratory, (a part of ARS's Beltsville (Maryland) Agricultural Research Centre), Cook will be the principal investigator of a group that will include scientists from the United States, Canada and Spain. ARS is the in-house research agency of the U.S. Department of Agriculture (USDA). Laboratory and field studies will be conducted at



Varroa mites are external parasites of the honey bee. Although they can feed and live on adult bees, they mainly feed and reproduce on the larvae and pupae, this causes malformation and weakening of honey bees as well as transmitting numerous viruses.

compound so that it poses little to no danger to human or animal cells, but can still kill germs.

“Honey bees specifically pollinate about 100 crops in the United States. Varroa mites have become resistant to many commercially available chemical control agents in recent years.”

The ARS pride themselves on their mission, that is constantly striving to ensure high-quality, safe food and other agricultural products; assessing the nutritional needs of Americans; sustaining a competitive agricultural economy; and enhancing the natural resource base and the environment. Furthermore, they hope to provide economic opportunities for rural citizens, communities and society as a whole; and supply the infrastructure necessary for creating and maintaining a diversified workplace.

With the recent death of the ARS Hall of Fame Scientist Ernest James Harris, we are called to remember some of the terrific work that has been done in the past, not just in the present day. Harris was internationally known for finding innovative ways to control fruit flies that threaten crops around the world and his technologies have been key to eradicating foreign fruit flies in California, Florida and other U.S. mainland states, as well as keeping areas free of these pests that would require costly quarantines and interfere with millions of dollars of agricultural exports.

The ARS website itself stated that: “he was a particularly strong role model for other African-American scientists and was known to his ARS colleagues in Hawaii for his positive attitude, kindness, gentle demeanour and humility”. These kinds of scientists are exactly the kind of hard-working innovators that the ARS trust to carry out their research and make progress in the U.S. Department of Agriculture. ■

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facilities in Alabama, Georgia, Maryland and Ohio, as well as in Alberta, Canada.

In addition, laboratories in Nebraska and Spain will see scientists using advanced methods to work out an understanding of the molecular mechanisms by which Varroa mites develop resistance to various chemical controls. Honey bees specifically pollinate about 100 crops in the United States. Varroa mites have become resistant to many commercially available chemical control agents in recent years.

Recent additional research conducted by the ARS includes the work to counter the resistance of a common soil bacterial compound named Tunicamycin, which causes infection in both humans and animals. The ARS Website printed a press release on March 29th, 2018 regarding this research and stated that: “Researchers have known of tunicamycin for decades and were initially excited by its medical and veterinary prospects – especially to overcome the resistance of some germs to penicillin-based drugs like oxacillin and methicillin.

The problem was, tunicamycin also blocked a key protein in human and animal cells, undercutting its potential use in the ground war on germs.” An ARS-led team of scientists and colleagues at the agencies National Centre for Agricultural Utilization Research (NCAUR) in Peoria, Illinois and the Chinese Academy of Sciences are working to devise a method to retool the

Texas 2012: An entire field of corn is lost due to drought conditions

Global research on drought

Professor Robert Aiken, Research Crop Scientist from Northwest Research–Extension Center provides his expert thoughts on the fascinating global research taking place on drought, including the vital role of satellite imagery

As a field agronomist from Northwest Kansas, I'm attending the 15th Ogallala Aquifer Program workshop in Lubbock, TX with irrigation engineers, hydrologists, economists and other water scientists, focused on extending the life of the aquifer to sustain rural economies (<https://ogallala.tamu.edu/>). The tension in the conference is palpable. "164 days since last measurable precipitation in the Texas High Plains." "This wheat crop is on the ropes." "If we don't get rain soon..."

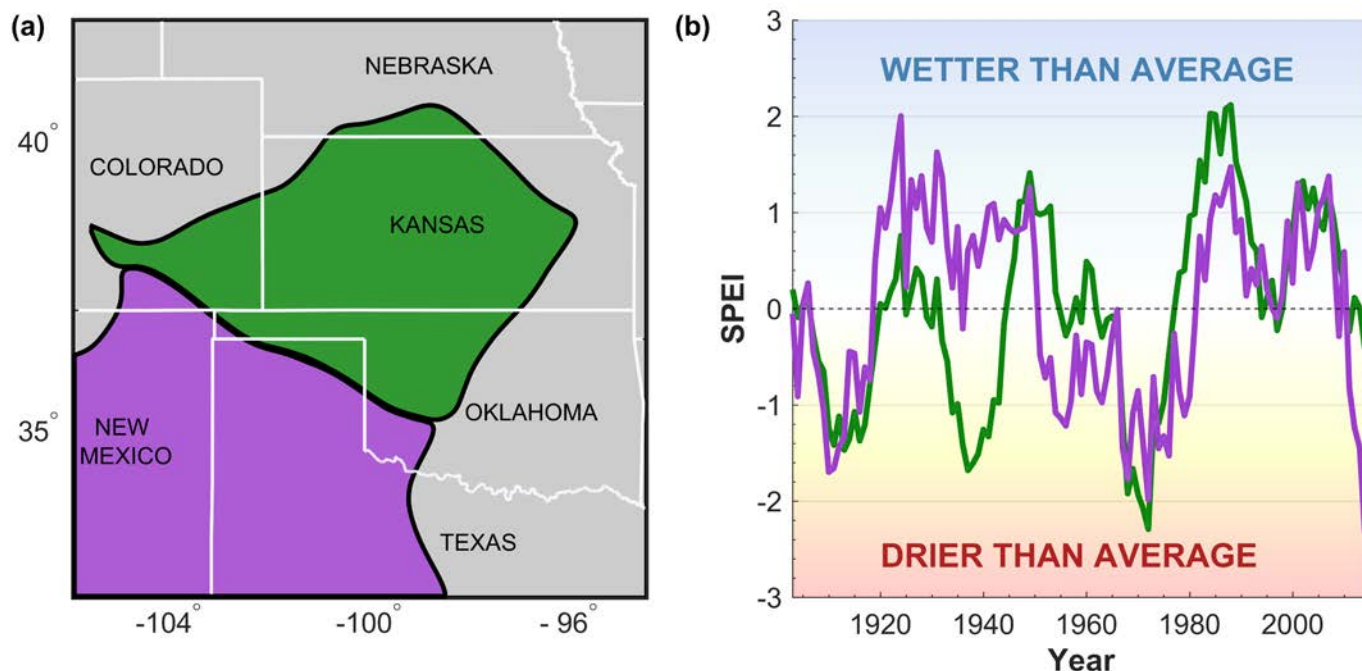
We all recognise drought. The dull green vegetation; the pallor of dust-filled skies; the dry scratchy throat and persistent cough. Agriculture? Drought stops agriculture in its tracks. Here in the High Plains, agriculture affects a third of the regional econ-

omy. In Sub-Saharan Africa, drought affects the core food supply, leading to rural exodus and civil unrest. In Northwest India, drought amplifies the frequency of heat-related deaths. In Cape Town, South Africa, a two-year drought threatens the water supply for the four million residents. Drought touches our lives and communities in myriad ways.

Wayne Palmer published his drought index in 1965, considering drought cycles of the 1930s and 1950s. His metric uses monthly precipitation and atmospheric demand for water, contrived to report the deviation of soil water supply from 'normal' conditions. The concept of 'normal', or the long-term average weather is central to many drought indices used today. The [United States Drought Monitor](#)

displays its index using fire colours – yellow, orange, red. Drought metrics provide early warning of impending disasters.

The American Meteorological Society hosted four sessions on drought and food security in its 2018 meetings. One of several global-scale drought monitoring programmes utilises satellite imagery to calculate and map the energy balance for land surfaces. This accounting scheme uses physics to sum inputs and outputs in terms of radiation, evaporation and warming/cooling of air and land. The thermal band from satellites, representing the surface temperature, conveys critical information of surface water availability. Warmer sectors indicate dry surfaces, while the wet regions display cooler temperatures.



(a) Two selected sub-regions in the Great Plains for spring drought variability and (b) their corresponding drought time series (filtered using a 10-year running average) for the period 1903-2015. Climate data used to calculate the drought index was retrieved from the Climatic Research Unit (CRU) TS v. 3.24.01 (Harris et al. 2014¹). The drought index is the Standardized Precipitation Evapotranspiration Index (SPEI) on a three-month time scale (Vicente-Serrano et al. 2010²). Positive values of the SPEI represent wetter than average conditions and negative values represent drier than average conditions. There are notable differences in the drought conditions of these adjacent sub-regions during the 1930s (Dust Bowl era) and the period 2010-2015 (b). These temporal differences in drought variability across relatively short spatial distances provide evidence for the delineation of each sub-region and consideration in drought monitoring and climate change analyses.

Globally, agencies use these techniques to detect and report incipient and ongoing drought. These early warnings and updates inform emergency drought responses. Earth scientists recognise drought as an integral component of the hydrological cycle. The question remains: Has climate change affected the frequency, duration or extent of drought?

Zach Zambreski, a young, bright, dedicated meteorologist, tackled the problem of long-term drought dynamics in his graduate research (Kansas State University, Agronomy). He employed Empirical Orthogonal Functions (EOF, a type of principal component analysis) to characterise monthly drought metrics of the U.S. Great Plains over the 20th century (1903 to 2015). He then correlated the EOF with each of the localised time series of drought metrics

to identify regions with similar historic patterns of wetting and drying cycles. Analyses such as this provide benchmarks against which climate change trends can be usefully compared.

This afternoon our groundwater conference closes. The overnight thunderstorm relieves the tension – for the moment. We muse about La Nina effects, the wet winter conditions in the Northern Great Plains and prospects for wheat harvest. Likely, there are similar conversations within the railroad companies, considering where to position their box cars to transport the wheat crop to export shipping terminals. As earth scientists, we recognise the tools at our disposal to identify and quantify drought. Collectively, as a global society, are we prepared to mitigate the effects of drought?

¹ Harris, I., P. D. Jones, T. J. Osborn, and D. H. Lister, 2014: Updated high-resolution grids of monthly climatic observations - the CRU TS3.10 Dataset. *International Journal of Climatology*, 34, 623-642, doi: 10.1002/joc.3711.

² Vicente-Serrano, S. M., S. Beguería, and J. I. López-Moreno, 2010: A Multiscalar Drought Index Sensitive to Global Warming: The Standardized Precipitation Evapotranspiration Index. *Journal of Climate*, 23, 1696-1718, doi: 10.1175/2009jcli2909.1.



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The nutritional quality of minor cereals and their role in the human diet

Ismail Çakmak of Sabanci University sheds light on the nutritional quality of minor cereals and their importance in the human diet

The HealthyMinorCereals project aims to boost cultivation and consumption of five minor cereal species – rye, oats, einkorn, emmer and spelt. Nutritional quality of these minor cereals has been studied to highlight their importance in the human diet.

In recent years, there has been a growing interest and awareness about consuming healthy and nutritious foods. In this regard, particular attention is being paid to the consumption of cereal-based foods, because cereal grains contain many diverse nutritionally-valuable compounds and biologically active antioxidants (Shewry and Hey, 2015, Food Energy Sec. 4:178-202; Masisi et al., 2016, Food Chem. 196: 90-97). Various epidemiologic studies are available – demonstrating that regular consumption of cereals is associated with a reduced risk of chronic diseases such as cancers and cardiovascular diseases.

In fact, cereal grains potentially exhibit higher protective and beneficial impacts against diseases than what is usually reported. According to Adom and Liu (2002; J. Agric. Food, 50: 6182-6187), the antioxidative activity and health impacts of cereals are underestimated due to the fact that only easily extractable antioxidants are examined, and these represent only a small fraction of the antioxidant pool in grains.

Indeed, most of the total antioxidants

in the grain are in a bound form which cannot be extractable or isolated by common extraction methods. For example, the percentage of bound phenolic compounds in cereal grains usually ranges from between 70 to 90% of the total phenolics as shown in oat, barley and wheat which occur in a bound form (Adom and Liu (2002; J. Agric. Food, 50: 6182-6187; Cömet and Gokmen, 2017, Comp. Rev. Food Sci. Food Saf. 16: 383-399; Arigo et al., 2018, Food Chem. 245:829-837).

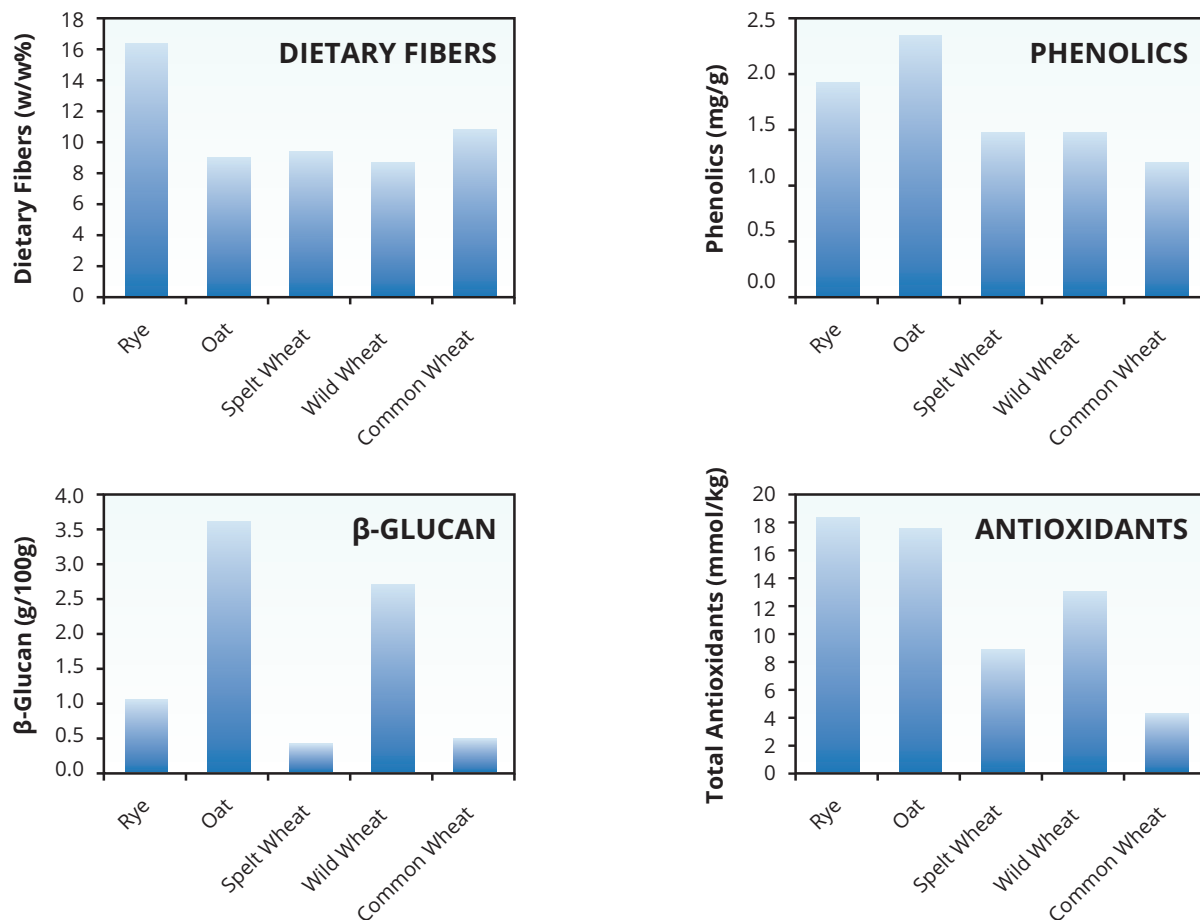
It is suggested that bound antioxidants exert their biological effects for longer periods of time in body than soluble ones (Durazzo, 2017, Foods, 6, 17; doi:10.3390/foods6030017; Cömet and Gokmen, 2017, Comp. Rev. Food Sci. Food Saf. 16: 383-399).

The antioxidative bioactive compounds present in cereals include phenolic acids, dietary fibres, carotenoids, β -glucan and several other phytochemicals such as tocopherols, alkylresorcinols, flavonoids, phytosterols and selenomethionine. Most of these antioxidative compounds have a high potential to remove highly toxic free radicals and thereby minimise oxidative stress – and inflammation-related chronic diseases. These protective effects are most likely related to individual and/or combined (synergistic) effects of the antioxidant compounds found in cereals (Fardet et al. 2008, J. Cereal Sci. 48:258-276; Lee et al., 2015, J. Medical Food, 18:1179-1186).

To measure the antioxidative capacity of foods containing different antioxidants, total antioxidant assays are often employed which reflect the sum of the antioxidant activity of individual antioxidant compounds. Cereal species, as well as genotypes of a given cereal species, differ largely in their concentration and composition of nutritional compounds and antioxidants. Some cereal species contain unique antioxidants and some antioxidants occur at much higher levels in certain cereal species.

“In recent years, there has been a growing interest and awareness about consuming healthy and nutritious foods. In this regard, particular attention is being paid to the consumption of cereal-based foods, because cereal grains contain many diverse nutritionally-valuable compounds and biologically active antioxidants.”

For example, oat contains the highest levels of β -glucan of all cereals studied. The avenanthramides with their strong antioxidant capacity are unique to oat (Boz, 2015, Czech J. Food Sci. 33:399-404; Rasane et al., 2015, 52:662-675). Rye is typically rich in phenolic antioxidants including phenolic acids, alkylresorcinols and lignans (Bondia-Pons et al. 2009, J. Cereal Sci. 49:323-336). Einkorn wheat is known for its generally high amounts of lipophilic antioxidants, such as tocopherol and β -carotene (Antognoni et al., 2018, Nutrients, 1232; Ziegler et al.,



Total dietary fibres, phenolics, antioxidants and β -glucan within various genotypes of rye, oat, spelt wheat, wild wheat and common wheat

J. Functional Foods, 20:594-605).

The HealthyMinorCereal project studied over 600 different genotypes of rye (n:54), oat (n:200), spelt (n:300), wild and primitive wheat including Tr. monococcum, Tr. boeoticum and several Aegilops (n: 64) to collect information about their antioxidant capacity. For comparison, also 12 modern (widely cultivated) wheat cultivars were included in the analyses.

The genotypes of each cereal species have been evaluated, based on the results of total phenolics, total antioxidant activity (based on measurement of Trolox equivalent antioxidant capacity) and β -glucan. Additionally, also dietary fibre data have been included

in the analysis programme. The results from our study are presented in the figure above. More details will be published on the project website: www.healthyminorcereals.eu.

“It is suggested that bound antioxidants exert their biological effects for longer periods of time in body than soluble ones.”

Contact

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EU aquaculture: Supporting the farmers in the water

Karmenu Vella, European Commissioner for Environment, Maritime Affairs and Fisheries explains the Commission's support for EU aquaculture and supporting farmers in the water

40 years ago, the famous French Commandant Jacques-Yves Cousteau stated: "We must plan the sea and herd its animals using the sea as farmers instead of hunters." His vision is now becoming reality: in 2014, for the first time in history, humans consumed more farmed than wild-caught fish.

And this is just the beginning: the world population is forecast to reach 10 billion people by 2050 and demand for protein is expected to grow by 70%. This will create an increasing appetite for ocean-derived food: seafood is not only very healthy but, in some parts of the world, essential to fighting hunger and malnutrition.

Fisheries alone will not meet this demand. In 2013,

according to UN-FAO, 58% of the wild stocks were fully fished and more than 30% were not fished sustainably. While we must continue to promote sustainable fisheries, if we are to get more seafood, it has to come from farming.

"I'd like to think that the EU aquaculture will continue the growing trend, not only due to improved regulatory environments or the support from EU Funds, but also thanks to our joint efforts to improve the understanding of farmed seafood among consumers."

After more than a decade of stagnation, it is, therefore, encouraging that EU aquaculture is finally starting to grow again. Together with national authorities, the EU



Image: © European Union

The scientists give us clear messages: by far the biggest potential for increasing seafood production is through the farming of marine species. The key is also to ensure responsible and sustainable practices and move to lower levels in the food chain (less predatory fish, more shellfish). The importance of the Blue Bio-Economy Forum, set up by the European Commission, is also underlined. This confirms that we are on the right path.

“The world population is forecast to reach 10 billion people by 2050 and demand for protein is expected to grow by 70%. This will create an increasing appetite for ocean-derived food: seafood is not only very healthy but, in some parts of the world, essential to fighting hunger and malnutrition.”

is simplifying licencing procedures, putting Maritime Spatial Plans in place and encouraging investment in the sector. These actions are delivering: 4% growth in volume and 8% in value between 2014 and 2015. In fact, by 2015, the sector was generating more value than ever before.

In parallel, thanks to EU-funded research, the sector is spinning out innovative businesses: traditional aquaculture is now complemented with techniques such as aquaponics (cultivating plants and fish together) and integrated multi-trophic aquaculture (cultivating several species together), but also venturing into new markets such as cosmetics, pharmaceuticals, and food additives.

Despite these positive developments, we can do even more to enable our aquaculture sector to take full part in shouldering the larger challenges surrounding us. As one of the world’s biggest seafood markets, more than 60% of our consumption is sourced outside the EU. And with magnitude and influence comes global responsibility. That is why I asked the High-Level Scientists advising the European Commission to produce the “Food from the Oceans” report.

I’d like to think that the EU aquaculture will continue the growing trend, not only due to improved regulatory environments or the support from EU Funds, but also thanks to our joint efforts to improve the understanding of farmed seafood among consumers.

Since 2015, our “Farmed in the EU campaign” has reached thousands of students across Europe. After a remarkable campaign in Spain, I am pleased that Ireland and Lithuania will also launch national campaigns in 2018. It is only with the support of our own citizens and their confidence as consumers, that our farmers in the water, can play an exemplary role at the global scale. ■

Karmenu Vella

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ec.europa.eu/commission/commissioners/2014-2019/vella_en

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Is local governance ready for climate change?

A group of researchers from the Climate Service Center Germany (GERICS) ask if local governance is ready for the effects of climate change

On 4th November 2016, the Paris Agreement entered into force. It called into memory the emotional scenes of Laurent Fabius, holding hands with fellow diplomats whilst being applauded by an audience of exuberant political representatives from across the globe. The sense of hope was palpable, and many people felt that now, finally, things were going to change.

The Paris Agreement, famed though it is, is by no means the only piece of global climate legislation in place. In fact, a study by the Grantham Institute on Climate Change and Environment revealed a 20-fold increase in global climate change laws since 1997. This is an indication of a shift in mindset among the upper echelons of the political establishment. Yet what is actually happening at the local level? On the ground, where river-banks are bursting, sea-level rise is causing coastal erosion and houses are being swept away by landslides?

While it is the role of national and supranational political bodies to pass legislation, the actual implementation of legislation remains distinctly local. The construction of wind farms, solar panels or energy-efficient housing for mitigation, as well as the design of flood defences, appropriate drainage systems or erosion protection for adaptation, is largely in the hands of local governments. This highlights the need for strengthening the capacity of



While it is the role of national and supranational political bodies to pass legislation, the actual implementation of legislation remains distinctly local.

local governments for implementing climate change legislation. Before even that, however, important questions need to be dealt with: how can the capacity of local governance to implement climate change legislation be evaluated in the first place? And is there a need for increasing governance structures to support local governmental structures?

In an attempt at addressing precisely this issue, a group of researchers (Mañez Costa et al., 2014; Carmona et al., 2017; Celliers, 2017) from the Climate Service Center Germany (GERICS) developed the Capital Approach Framework. With its conceptual roots in a number of different

sustainability approaches, the methodology was developed to assess governance performance, including the ability of communities and governments to respond to natural hazards.

To facilitate the measuring of governance performance, the Capital Approach Framework is divided into five capitals (social, political, human, financial and environmental capital), assessed by factors that are measured by indicators. Each indicator is assessed through gathering existing data and insights, knowledge and perceptions of local stakeholders. The answers, collected in binary, ordinal, or cardinal unit measure, can then be aggregated to assess each indicator,

measuring the factor and evaluating the overall capital. For example, stakeholders can be asked whether they are aware of any climate change adaptation plans or strategies at the local government level. This indicator serves as a measurement of the “Regulatory Framework” factor, feeding into political capital. Another example would be whether local government members have the possibility of taking part in capacity building exercises, feeding into the “Human Resources” factor, in turn revealing information on the strength of Human Capital.

Through applying the Capital Approach Framework, a governance baseline is established, and strengths and weaknesses are identified in the functioning of local governance. This is not only useful for informing decision-makers and policy-planners on deficits in current local governance but can also serve as a baseline to monitor effects of decisions and policies in adaptive governance the future. This may further contribute to improving the response of local governance to climate change.

The versatility of the Capital Approach Framework is illustrated by the various regions and contexts it has been applied in. It was used to analyse the governance performance of a multi-sector partnership in dealing with drought in the Júcar River basin, Spain. Findings indicate the positive effects of polycentric governance on drought management in the area, in particular promoting transparency in the decision-making and policy-planning process.

In South Africa, it has been used to assess the performance of local governance for water management in an informal settlement in Durban. Again, it was found that the integration of affected communities into the decision-making and policy-planning process was insufficient, whilst also establishing a lack of trust amongst stakeholders.

The Capital Approach Framework has further been adapted to assess coastal governance systems. For the WIOMSA project “Emerging Knowledge for Local Adaptation”, it proved highly valuable in establishing the capacity and readiness of local governance in implementing climate change adaptation. It has therefore been applied in Kenya and South Africa and laid the foundation for policy briefs given to local governance stakeholders.

More recently it has been used in Mauritius, helping to identify the gap between national and local government when it comes to the transfer of climate change information, compounded by a lack of know-how at the local level to implement recommendations handed down from the national government. In a two-day workshop in Mauritius, held during March 2018, the results of this study have been presented back to the participating governance members for validation, with very interesting results and discussions. On the whole, participants agreed with the findings, with much intense deliberation on areas in current local governance processes in need of improvement that needed a greater emphasis and possible policy recommendations.

The Capital Approach Framework has been shown to be particularly versatile and efficient in gathering large amounts of information relevant to local governance and climate change adaptation. It is really important to continue and to increase research of this nature at the local level. Which preconditions are necessary for the successful implementation of climate change? Which mechanisms might be developed to support local governments? And could this approach be developed to become a self-assessment tool for local governments implementing climate change adaptation to monitor the effects of decisions and policies? These questions are essential, as it is at the local level where the battle against the impacts of climate change may be won or lost.



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Canada's plan to reduce carbon emissions and strengthen their clean growth economy

Minister of Environment and Climate Change in Canada, Catherine McKenna details the country's plan to reduce carbon emissions and strengthen their clean growth economy

In mid-February, thousands of Canadians gathered in Ottawa for the 40th edition of Winterlude, one of the country's most famous winter festivals.

They skated along the Rideau Canal, the UNESCO World Heritage Site that runs through the heart of the national capital. They fuelled their excursions with cinnamon-flavoured deep-fried dough called Beaver Tails and *tire d'érable*, a dessert of frozen maple syrup.

And at Ottawa City Hall, they attended an exhibit of photos of Sirmilik National Park, a 22,000-square-kilometre protected area on Baffin Island in Canada's extreme north. The photos were taken by students who travelled through that magnificent region last summer. They captured Sirmilik's unquestionable beauty. But they also served as a sobering reminder.

It is in this region where the unprecedented challenge of climate change is most readily visible. While Canada's temperature increases are outpacing the global average, temperatures are rising even faster in the country's northern areas.

While Winterlude celebrates Canada's unique, winter culture – Canada's High Arctic is warming at three times the rate of the rest of the country. So, the Sirmilik exhibit was a perfect complement to Winterlude because Canadians see climate change with increasing awareness and concern.

The Government of Canada is committed to doing its part to achieve the global goals set out in the 2015 Paris Agreement. Canada was one of the first countries to sign and ratify the historic pact.

Our country's goal? To reduce greenhouse gas emissions by 30% below 2005 levels by 2030.

As a first step, Canada undertook a broad process that involved all provincial and territorial governments, as well as Indigenous leaders. We wanted to develop a comprehensive national plan to address climate change.

People across the country helped inform this groundbreaking strategy through town hall meetings from coast to coast and an interactive website.

The result was the Pan-Canadian Framework on Clean Growth and Climate Change, which was adopted on December 9, 2016. The Pan-Canadian Framework outlines over fifty concrete measures to reduce carbon pollution and help us adapt and become more resilient to the impacts of a changing climate.

The Framework will foster clean technology solutions and create good jobs that contribute to a stronger economy. A plan to price carbon pollution is at its centre. Our national carbon-pricing approach, announced two years ago, will require all Canadian jurisdictions to have prices on carbon pollution in place by the end of 2018.

Of course, the Framework includes other components. For example, last December, we outlined a design for Canada's Clean Fuel Standard. It will lead to new regulations requiring the use of cleaner fuels in vehicles, industries and buildings.

The Clean Fuel Standard is the single largest emission-reduction policy in Canada's climate and clean-growth plan. It could reduce Canada's greenhouse gas emissions by 30 million tonnes a year, by 2030.

In 2017, we also announced plans to accelerate the phase-out of traditional coal-fired electricity by 2030.

And to encourage countries around the world to take similar action, we launched the international Powering Past Coal Alliance with the United Kingdom.

Today, pollution from coal power contributes close to 10% of Canada's total greenhouse gas emissions. We also published draft regulations to cut methane emissions from the oil and gas sector by 40-45% by 2025. Reducing methane emissions will achieve the same reductions as taking about 5 million passenger vehicles off the road each year.

This is the lowest cost GHG reduction opportunity in the energy sector. Through the new methane regulations, Canada's oil and gas sector will become a global leader in responsible energy production.

Then there are our investments in infrastructure to support electric vehicles. Canada is investing \$182.5 million in green infrastructure and clean technologies and partnering with the private sector to support demonstration and deployment of new charging stations for electric vehicles, as well as refuelling stations for alternative fuels such as hydrogen and natural gas.

These measures take advantage of the fact that over 80% of Canada's grid is powered by non-emitting electricity. The Pan-Canadian Framework also commits provincial and territorial governments to work to improve efficiency in Canadian buildings and develop new building codes. The goal is to develop the net-zero buildings of the 21st century.

And in the area of clean technologies, our government will make smart and strategic investments in research and development and in supporting commercialisation.

The global market for clean technology is projected to increase significantly. Canadian companies are poised to provide solutions to global challenges.

Canada is home to 13 of the 2018 Global Cleantech Top 100 list that was recently revealed at the annual Cleantech Forum San Francisco. The government is working to help our private sector seize new opportunities with large investments in clean energy, green infrastructure and clean technology.

Meeting our climate commitments and investing in clean growth are central to our plan to grow our economy as we achieve our environmental goals.

Canada will continue to advance global momentum on climate action through its international efforts. The Powering Past Coal Alliance, which we helped kick-start is only the most recent such example.

Last year, we published final regulations of the Kigali Agreement – an amendment to one of the most successful environmental treaties ever, the Montreal Protocol, which Canada helped organise 30 years ago.

Kigali will reduce hydrofluorocarbons used in refrigerators and air conditioners that can be thousands of times more powerful than carbon dioxide in inducing climate change.

Canada is also helping developing countries access clean energy and climate solutions. In 2016, we committed to contributing \$2.65 billion over the next five years to this goal.

Governments everywhere want to protect their citizens from climate risks. They want to build resilient communities, protect investments, reduce costs and ensure people thrive in a changing climate.

Climate change is as much an economic issue and a social one as it is environmental. It is as much about transitioning to ways of living and working that do no environmental harm as it is about protecting our natural world from further damage. ■

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The key challenges around Europe's environment

We spoke to Catherine Bearder MEP about the many challenges around Europe's environment today, including the funding of Natura 2000 sites and the Convention on International Trade in Endangered Species

First elected in 2009, Catherine Bearder is respected as a passionate and committed local campaigner and a strong voice in Europe, as a member of the Liberal Democrats.

She is committed to protecting the natural environment in Europe, indeed Catherine is working hard to get environmental protection as a core element of European policy, not just as an 'add-on'. She has studied wild animals in the field in Africa, and as such, Catherine recognises the threats to the planet's biodiversity and what this will mean for us all if we lose any more. She has also fought to protect elephants and other animals from the catastrophic rates of poaching and is campaigning to stamp out the trade in wild animals caught for the pet trade.

We were fortunate to speak with Catherine to discuss her policies that concern the environment, including funding the Natura 2000 sites which provide vital protection to endangered species. She also sheds light on the report by the Convention on International Trade in Endangered Species (Cites) and the EU Action Plan against Wildlife Trafficking.

Funding the Natura 2000 sites

Catherine then sheds light on the European Parliament's vote on a Parliamentary Motion calling on EU governments to properly fund the Natura 2000 sites, which provide vital protection to endangered species. The Motion, which was voted in by over 600 votes, was a response to the European Commission's Nature Action Plan which was adopted to ensure that the Birds and Habitats Directives was more effectively implemented.

"The concept between Natura 2000 is wonderful, in that you take a large block of land and you map out sites that are continuous and give a recognised



Catherine Bearder MEP

movement of nature, migratory flows and water needs. When they have mapped out the whole of Europe in this way, that is only part of the job done.

"We also need to have the funding and political commitment behind that to achieve the goals of Natura 2000. The EU member states are falling on that because they are not funding it properly – it is one of the tensions in the European Union, of course, in that people are looking to member states but do not want to give up their functions. At member state level, it can be very difficult to think European-wide, which is something that we do in the European Parliament all the time.

"While it is a frustration, we can get over that if we ensure that proper funding comes through and we have good reporting and transparency so that the public can see what is happening. Building this into the next (Multiannual Financial Framework) MFF in 2021,



Natura 2000 site: Korneti-Pelli nature reserve, Latvia

which should have mechanisms in place so that member states do what they are signed up to do. That means funding those Natura 2000 properly and protecting them, by not allowing hunting, for example.”

The Convention on International Trade in Endangered Species

In Africa, 2016 figures show that elephant poaching has dropped beneath 2008 levels, when the increase began; but the outlook for elephants in Central Africa remains bleak as poaching levels remain high. Catherine Bearder MEP’s Report on the EU’s Action Plan Against Wildlife Trafficking, calls for a full and immediate ban on all ivory products in the EU. She chairs the cross-party group of MEPs who campaign against wildlife trafficking.

On the report by the Convention on International Trade in Endangered Species, Catherine tells us how it showed that ivory seizures have reached a ‘record high’ in 2016, while poaching has levelled off in many areas.

“The Convention on International Trade in Endangered Species (Cites) is a success story in one respect, in as much that customs officers are recognising that

endangered species are going through the European ports of entry and exit, plus technology in this area has advanced. While elephant poaching has been going on for years, clearly it is going to go down if there are fewer to poach, so it is a simple chicken and egg scenario.

“The real concern is that the fewer elephants that are left, then their ivory becomes more valuable. There are so many good people out there giving their lives on an almost daily basis, with game rangers being shot. We have lost some very high-profile people and one such person, Wayne Lotter the head of an animal conservation NGO was based in Tanzania and did some terrific work with local communities.”

EU Action Plan against Wildlife Trafficking

Catherine explains that what she hasn’t seen, are the figures of prosecutions and the locking up of poachers. The report, EU Action Plan against Wildlife Trafficking, is something that she raised in the European Parliament and the ACP-EU Joint Parliamentary Assembly. She also tells us about Ofir Dori who is doing terrific work in getting people behind bars, that is not with the local poachers, but with the middle and upper men. Catherine is keen to develop this point for us in her own words.



Large african elephant, Kenya

"Ofir has done sterling work with communities across Africa and in other countries. He comes from Great Apes Survival Partnership (GRASP) (1) and has been talking to African and other leaders about these source countries, who are having their timber taken away, as well as lizards and butterflies, which have been stripped out of the wild and put on the European market. So, we must work with them and close the markets here, so that is why I am for stopping all ivory sales, both old and new.

"We are finding that a lot of new ivory is buried for a few months to make it look like old ivory. While we have the market, we will have poachers. I would like Europe to say NO to ivory sales, so we can get over the issue of rare and artistically valuable items, but the junk stuff such as the cutlery, bangles, earrings and trinkets that grandma has on her shelf cannot be sold because they have no monetary value."

Catherine then reveals more about the EU Action Plan against Wildlife Trafficking, stressing that the European Parliament worked very hard with the European Commission to bring it forward. When the new Commission

came in four years ago, Catherine tells us that this subject wasn't really on their agenda and so she formed the cross-party group, MEPs for Wildlife. They had hearings, met the Commissioner and worked with officers in the European Parliament to encourage them to come forward with an action plan.

"I was very pleased to get a response to this action plan in European Parliament – two or three things were missing. One was concerning the European Union Agency for Law Enforcement Cooperation (Europol), who didn't have it in their serious and organised crime plans wildlife crime (Serious and Organised Crime Threat Assessment (SOCTA) – Europol). We knew that it is a very big part of organised crime as criminals only care about making money, whether that involves shifting guns, drugs or ivory.

"SOCTA now has the permission, budget and officers working on wildlife crime as part of their planning. We have a mid-term review of how that action plan is working and the ivory ban was another one – we confiscate animals when we find them and that is a big problem. We heard about a hyena which was kept for



The European turtle dove (Streptopelia turtur) are on a red list of endangered British birds

two years after it was discovered being illegally trafficked as a tiny cub. It takes two years for them to fully grow, so it had to be held at the airport until it was old enough to move.

“There is much legislation behind what happens to recovered animals, what do you do with rare species, where do you send them to? There is some evidence that where lizards and parrots are concerned, they are sent off to a rescue centre but within six months they have gone from there as they have been sold back into the trade again. There is a whole trail of legislation that still needs to come in to protect these animals.”

Environment funding after Brexit

In closing, Catherine stresses that she wants to look at what can be done about the issues discussed here at a pan-European level. Catherine believes that the real concern around Brexit is that funding will become even tighter than it is now, and the question arises: who will be monitoring the UK government once the country is out of the European Union? Also, who will prioritise the training of law enforcement and customs officers to keep an eye out for these things? The last word on this

point is explained to us by Catherine.

“We’ll lose LIFE Programme funding, something that is brilliant, for example, the Turtle Dove breeding programme in Otmoor, Oxfordshire. They have small amounts of funding so that they can plant strips of grain so that the turtle doves have food. Such money is from the LIFE Programme and I am concerned that after Brexit we will lose much of this cooperation and funding.” ■

¹ GRASP is a United Nations initiative committed to ensuring the long-term survival of chimpanzees, gorillas, bonobos, and orangutans and their habitats in Africa and Asia. More details at www.un-grasp.org.

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Wildlife conservation: Africa leading the way at the European Parliament

There are “winners” and “losers” in the conservation of wildlife in Africa! H.E. the Ambassador of Zimbabwe proclaimed in a conference: “Keep Calm and Let Africa Take the Lead! The EU- Africa Dialogue: Supporting communities in wildlife conservation” on the 6th of March 2018 at the European Parliament. He stated that Southern African nations were amongst the “winners”, in that they have increasing national wildlife populations.

At this conference, organised by MEP Karl Heinz-Florenz, President of the Biodiversity, Hunting, Countryside Intergroup of the European Parliament, representatives of the wildlife management authorities, parliaments, embassies and non-governmental organisations from Zimbabwe, South Africa and Namibia explained why the European Union (EU) must “Keep Calm and Let Africa Take the Lead” in decisions about the management and conservation of Africa’s wildlife.

Ali Kaka, Vice President of the International Union for Conservation of Nature (IUCN), the largest umbrella organisation for nature conservation organisations in the world, a national of Kenya, moderated the discussion and encouraged interventions and questions from the audience.

The panellists explained to an audience that included members of the European Parliament, representatives

from the European Commission and leaders in the hunting and sustainable use community on how hunting in Africa contributes significantly to wildlife conservation, habitat improvement and the fight against poaching and illegal trafficking. The speakers explained the importance of community-based conservation as the key to Africa’s success in bringing species populations back from decline while contributing vitally to the livelihoods of the communities.

The panellists included, Joanna Drake (Deputy Director DG Environment), Maxi Louis (NACSO, representing communities from Namibia), H.E. Prof Kaire Mbuende (Ambassador Namibia), H.E. Tadeous Chifamba (Ambassador Zimbabwe), Joanna Yawitch (Chairperson of the South African National Parks), Arnaud Goessens (Wildlife Conservation Society) and Wilfried Pabst (Zimbabwean landowner).

The Minister of Environmental Affairs of South Africa, Dr Edna Molewa addressed conference through a recorded video message. Minister Molewa reiterated South Africa’s approach to wildlife management should benefit both wildlife and people. “South Africa is committed to promoting responsible hunting that is conducted in line with the applicable legislation,” she said. Minister Molewa reported that trophy and meat hunters respectively contributed R1.9 and R8.6 billion (approx. between 129

and 584 million euro) to the economy of South Africa during the 2015-2016 hunting season. Hunting further contributes to food security in the form of healthy, free-range, lean protein of between 31,000 and 87,000 tonnes per annum.

Joanna Drake underlined that it is a cornerstone to involve local communities, which is a key element of the EU Action Plan Against Wildlife Trafficking and encouraged the organisations involved in sustainable use to continue their valued conservation work and to promote sustainable hunting.

Prof Kaire Mbuende expressed his concerns over some attempts to ban the import of trophies to the EU, which would have disastrous consequences, as 80% of Namibia’s wildlife revenue is coming from the hunting industry!

Maxi Louis added that despite the challenges Namibia is facing in terms of their wildlife management, such as drought, human-wildlife conflict, poaching and the issues of land use, the country has success stories, creating large connected landscapes, with proper governance and real benefit sharing.

Tadeous Chifamba highlighted that one of the biggest threats to wildlife in Zimbabwe is poaching. He stressed the importance of sustainable hunting, as a countermeasure and as its revenue going back to the local communities,

WINNERS AND LOSERS

"There are winners and losers in the conservation of wildlife in Africa, and Southern African nations are amongst the "winners" with increasing national wildlife populations."

H.E. Tadeous Chifamba, the Ambassador of Zimbabwe to the European Union proclaimed in a conference

Keep Calm and Let Africa Take the Lead!
The EU-Africa Dialogue:
Supporting communities in wildlife conservation

on the 6th of March 2018
 at the European Parliament.

Annie Schreijer-Pierik, Vice-President of the Intergroup "Biodiversity, Hunting, Countryside", gave important conclusions and closed the session.

The message that the panellists and participants in the event delivered to the EU was clear. Africa's wildlife management authorities and the leaders of sustainable use conservation-related organisations in Southern Africa are successfully managing and conserving their wildlife through sustainable use methods, including hunting. Decision-makers in the EU should work with Africa's leaders to continue, support, enhance and replicate their success.

The European Federation for Hunting and Conservation (FACE), the International Council for Game and Wildlife Conservation (CIC), the European Landowners' Organization (ELO) and Safari Club International (SCI) took pleasure to organise the event through collaboration and to give Africa and its wildlife conservation a stage and voice in Europe's capital city, Brussels.

motivates communities to live with their wildlife in harmony.

Willy Pabst described his success story in having created a wildlife paradise, clearly pointed out that trophy hunting was the foundation of his success, as it was providing the necessary income for securing the thriving of the wildlife in his sanctuary.

MEP Stefan Eck, Vice-President of the Animal Welfare Intergroup in the European Parliament, expressed his disapproval of trophy hunting, but at the same time, he acknowledged that to safeguard a healthy population of

wildlife the off-take of 1% of the population though trophy hunting could be an acceptable management tool. This could be the beginning of a constructive dialogue between trophy hunting opponents and trophy hunting supporters in the interest of conservation of wildlife.

MEP Bendt Bendtsen, Vice-President of the Intergroup "Biodiversity, Hunting, Countryside" Member Franz Obermayr expressed their appreciation for the important information received from the African delegates and stressed the necessity to repeat similar events periodically to hear the voice of Africa. MEP



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Biodiversity: The extraordinary variety of life on Earth

Pamela S. Soltis, Director of the University of Florida Biodiversity Institute provides a fascinating analysis of her department's research on biodiversity – that is, the extraordinary variety of life on Earth

Biodiversity – the extraordinary variety of life on Earth – is fundamental to a healthy, sustainable planet, yet the connections between biodiversity, ecosystem function and services that contribute to human well-being are less well understood. These 'ecosystem services' derive from healthy ecosystems and include clean air, clean water, flood resistance, protection from weather extremes, pollinators of crops, sources of foods, fibres and medicines, recreational opportunities and spiritual and cultural experiences, to name a few (Fig. 1).

The current concept of ecosystem services traces to the 2005 United Nations Millennium Ecosystem Assessment. Classification of ecosystem services – by function or other properties – provides a basis for quantifying and valuing these contributions. For example, the U.S. Environmental Protection Agency (EPA) defines 'final ecosystem goods and services' as components of nature, directly enjoyed, consumed, or used to yield human well-being, in contrast to 'intermediate ecosystem services', which are benefits that lead to the final service. The recognition of ecosystem services as final versus the intermediate is important for assigning economic value to these benefits.

Ecological economists note the effect of invasive species (>\$120 billion annually in the U.S. alone) and have begun to



quantify the economic benefit of ecosystem services, but the valuation of ecosystem services is complex and includes both market and non-market values. For example, both a market (or dollar) value assigned to a specific ecosystem or component thereof and non-market values, such as societal preferences, intrinsic value and improved public health, may contribute to the value of an ecosystem service.

Increasingly, representatives of local to national governments, as well as non-government organisations and the private sector, are incorporating the economic impact of ecosystem services into policy. Thus, sound research that integrates biodiversity and environmental science, social science and economics is required for appropriate valuation of ecosystem services. To this end, the U.S. President's Council of Advisors on Science and Technology (PCAST) in 2011 called for the improved accounting of

ecosystem services and greater protection of environmental capital, citing the need for further biodiversity science and application of informatics to enhance our understanding of ecosystem services and develop appropriate policy to protect them.

More recently, the International Platform on Biodiversity and Ecosystem Services (IPBES), with 118 member nations and modelled after the Intergovernmental Panel on Climate Change (IPCC), has begun assessing the scientific and social knowledge of Earth's biological diversity and how environmental change will impact ecosystems and human societies. Integrated, accessible science and technology platforms are needed to leverage novel planetary data, models and tools to create and link knowledge to policy.

To meet the scientific and societal challenges of a changing planet,

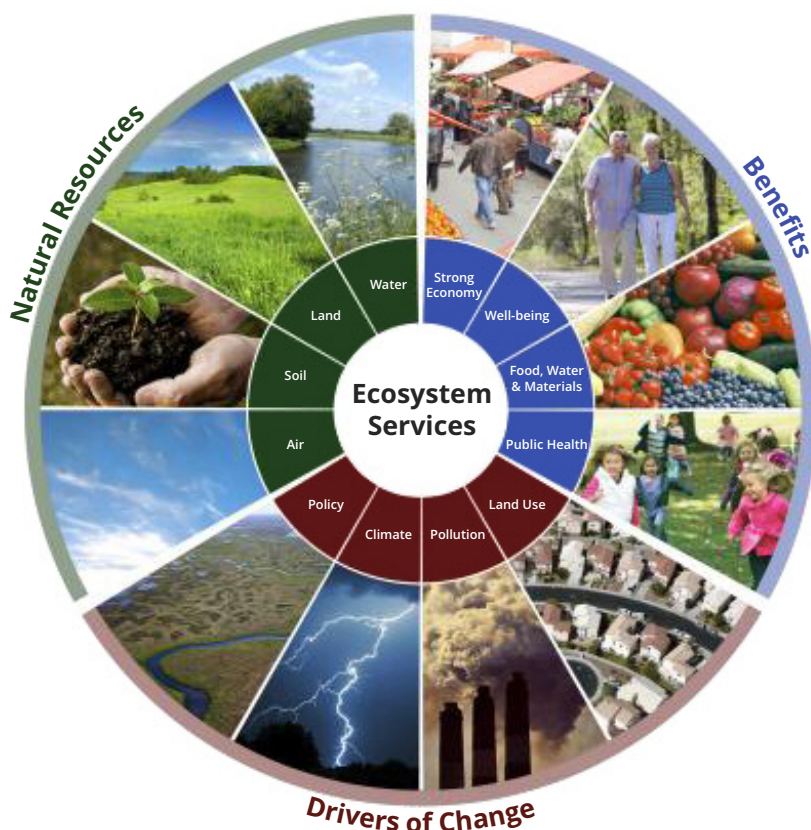


Figure 1. Diagrammatic representation of ecosystem services, showing the benefits themselves, the natural resources that provide the benefits and the drivers of change. (From the United States Environmental Protection Agency. *EnviroAtlas. Ecosystem Services in EnviroAtlas*. Retrieved: April 5th, 2018 from www.epa.gov/enviroatlas/ecosystem-services-enviroatlas)

including the identification and valuation of ecosystem services, the University of Florida (UF) Biodiversity Institute promotes interdisciplinary, integrative biodiversity science. The mission of the UF Biodiversity Institute is to conduct high-quality research and develop programs to advance three primary goals:

1. Initiate and lead large-scale, collaborative biological surveys to document and monitor biodiversity on a global scale;
2. Conduct collaborative and interdisciplinary research on biodiversity, with an emphasis on the use of Big Data;
3. Translate biodiversity science to solve major societal problems.

Research on ecosystem services of Florida's forests, grasslands and springs

is quantifying the economic value of these important resources and developing methods for valuation of ecosystem services that can be exported to other regions and resources worldwide.

By working with scientists, economists and social scientists at UF, elsewhere in the U.S. and abroad, we hope to bring greater appreciation for the many benefits that we derive from healthy ecosystems and demonstrate the significant cost – financial and otherwise – of lost biodiversity and deteriorating ecosystems.

The UF Biodiversity Institute was introduced in the August 2017, issue of *Adjacent Government*. Launched in 2016 to bring together scientists, social scientists and policy experts to address critical societal issues of the 21st century related to biodiversity,

the interdisciplinary UF Biodiversity Institute is accelerating synthetic research on biological diversity to serve stakeholders in Florida (a biodiversity hotspot) and globally through efforts to understand and manage biodiversity, develop relevant conservation, educational and outreach programs and shape policy to protect and enhance environmental capital. Newly synthesised knowledge from the UF Biodiversity Institute is available to individuals and organisations seeking validated biodiversity information.

Previous articles in this series have (1) introduced the UF Biodiversity Institute, (2) described how iDigBio, the U.S. national centre for digitisation of natural history collections, promotes digitisation of collections, serves digitised data (including images and other media) for biodiversity research and education, enables the use of digitised data in biodiversity science and engages with biodiversity resources worldwide and (3) outlined a strategy for integrated training in biodiversity and data sciences to meet the needs of a global 21st-century workforce.

Note: Supported by the UF Biodiversity Institute.

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Critical gaps remain in Europe's environmental performance despite improvements

Executive Director of the European Environment Agency (EEA), Hans Bruyninckx shares his thoughts on the critical gaps present in Europe's environmental performance

The European Union (EU) is making stronger progress towards a resource-efficient, low-carbon economy than in protecting biodiversity, natural capital and people's health. An annual European Environment Agency (EEA) environmental indicator report analyses whether the EU is achieving by 2020 a selected set of environmental objectives.

Looking beyond 2020, EU Member States need to accelerate progress in transforming key systems of production and consumption, including in food, energy and mobility, that have the greatest environmental and climate impacts.

The EEA 'Environmental Indicator Report 2017' gives an overview of the EU's progress towards 29 environmental policy objectives. These are relevant to the achievement of the 7th Environment Action Programme (EAP) three key priority objectives: natural capital; resource-efficient, low-carbon economy; and people's health and well-being.

The annual report draws every year on the same 29 indicators – updated with latest data – to provide an outlook on meeting each of the 29 objectives by 2020. According to the report, many indicators show positive past trends but meeting relevant targets by 2020 remains a challenge.

'Following the 2008 financial crisis, lower economic activity in the EU contributed to several of the positive environmental trends shown in the report's indicators. As economic growth is returning, increased efforts are likely to be necessary to maintain progress,' said Hans Bruyninckx, EEA Executive Director.

Looking beyond 2020, EU Member States need to accelerate progress in transforming key systems of production and consumption, including in food, energy and mobility, that have the greatest environmental and climate impacts'.

The 2017 report changed the prospects of meeting two selected objectives compared with the previous year's assessment. The EU outlook of meeting by 2020 the ammonia reduction commitment was revised from 'likely' to 'uncertain'. Ammonia emissions come mainly from agriculture. Also, the 2020 prospects of keeping the average annual rate of land take below 800 km² from 2000-2020 were revised from 'uncertain' to 'unlikely' to be achieved.

"The European Union (EU) is making stronger progress towards a resource-efficient, low-carbon economy than in protecting biodiversity, natural capital and people's health. An annual European Environment Agency (EEA) environmental indicator report analyses whether the EU is achieving by 2020 a selected set of environmental objectives."

Based on recent trends, the report also stresses that additional efforts are necessary to stay on track to meet the energy efficiency target while the EU is at an increasing risk of missing its objective of reducing the overall environmental impact from the mobility sector.

The updated results of this year's report confirmed the overall results of the 2016 assessment by key 7th EAP priority objectives:

Protect nature and strengthen ecological resilience:



The EU's natural capital is not yet being protected, maintained and enhanced in line with the ambitions of the 7th EAP. The 2020 outlook remains bleak overall for the selected set of objectives related to this priority objective.

“There have been substantial reductions in emissions of air and water pollutants in recent decades. However, key concerns persist around air quality and noise pollution in urban areas and chronic exposure of the population to complex mixtures of chemicals in products.”

Boost sustainable, resource- efficient, low carbon growth: The EU remains on track towards meeting its key climate and energy targets by 2020. Moreover, Europe's economy is growing faster than its use of raw materials, indicating better resource efficiency. However, efforts so far to reduce the environmental impact of production and consumption in key sectors of food, housing and mobility vary considerably in their success rates.

Effectively address environment-related threats to health and well-being.

There have been substantial reductions in emissions of air and water pollutants in recent decades. However, key concerns persist around air quality and noise pollution in urban areas and chronic exposure of the population to complex mixtures of chemicals in products. ■

Editorial originally published at <https://www.eea.europa.eu/highlights/critical-gaps-remain-in-europes>

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The threat of invasive species to biodiversity: Biological control of Himalayan balsam

Alan Gange, Amanda Currie & Nadia Ab Razak (Royal Holloway, University of London), Carol Ellison, Norbert Maczey & Suzy Wood (CABI Bioscience) and Robert Jackson & Mojgan Rabiey (University of Reading) discuss the threat of invasive species to biodiversity, including the biological control of Himalayan balsam

Invasive species are one of the main threats to biodiversity across the world, being second only to habitat destruction in causing biodiversity decline. In the UK, they cost the economy £1.7 billion annually, through costs of control, losses to agriculture and damage to infrastructure.

Himalayan balsam or *Impatiens glandulifera* is one such species; first brought to the UK in 1839 by Victorian plant hunters, from India and Pakistan. It was introduced as a garden ornamental, and is an annual plant, with attractive pink or white flowers and novelty explosive seed pods. Sometimes known as ‘policeman’s helmets’ due to the flower shape, its efficient seed dispersal helped it to escape from gardens and it is now the most common non-native plant species on riparian systems in England and Wales. It frequently forms large populations on riverbanks, reducing native plant diversity, stealing pollinators from native plants and reducing the abundance of decomposer fungi in soil. In autumn, dying plants choke waterways, while bare riverbanks in winter are more prone to erosion, ultimately leading to increased risk of flooding.

Due to the high cost of manual control and the problems of using herbicides

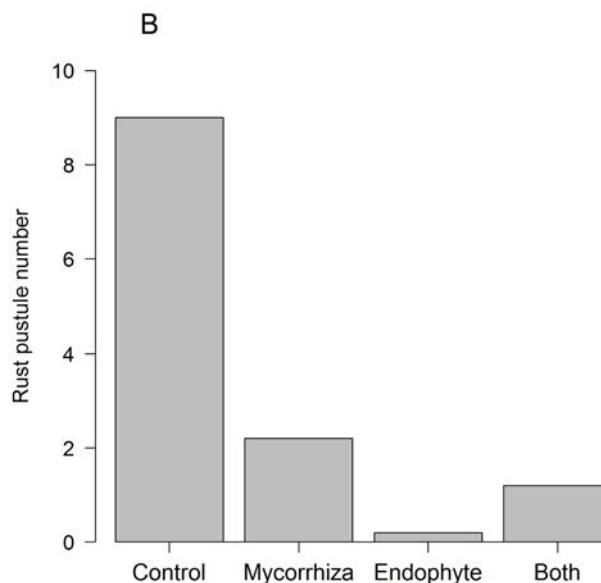
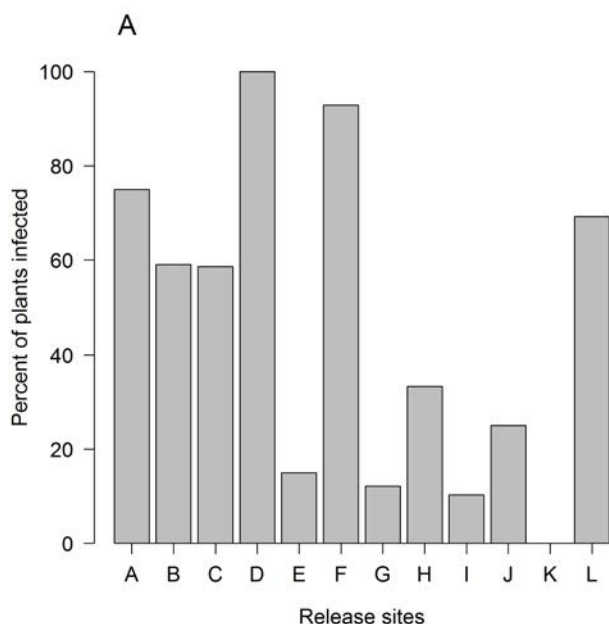


near water, the plant was selected as a target for a classical biological control programme, funded by a consortium of donors led by the Department for Environment, Food and Rural Affairs. This approach aims to diminish the competitiveness of invasive species by reuniting them with their natural enemies that exert control in their area of origin. CABI searched the native range of the plant and discovered a pathogenic fungus (called a ‘rust’) that only attacks balsam, reducing its growth and ability to reproduce.

Following a comprehensive plant screening programme, Ministerial

approval was given for the release of the rust in the UK in 2014; the first ever such release in Europe. In 2015, the Natural Environment Research Council funded Royal Holloway, CABI and the University of Reading to study rust establishment, identify factors that might hinder or enhance the efficacy of the pathogen and follow the impact on biodiversity restoration.

The establishment of the rust varied across the original 12 release sites. At some sites, the pathogen overwintered successfully and has spread, while at others, few or even no infected plants were recorded (Fig. A). There appears



to be variation in the resistance of different balsam populations to the rust and we are trying to determine what factors might contribute to this resistance and thereby enable us to break down this barrier to biological control.

“Invasive species are one of the main threats to biodiversity across the world, being second only to habitat destruction in causing biodiversity decline. In the UK, they cost the economy £1.7 billion annually, through costs of control, losses to agriculture and damage to infrastructure.”

Perhaps the most obvious factor is the genetic make-up of the plant. We discovered that balsam populations vary genetically, and the plant was introduced at least three times into the UK, from different areas in India and Pakistan. The fact that strains of the rust from one part of the Himalayas are unable to infect plants originating from a different area shows just how specific the pathogen can be. This provides confidence concerning the safety of the fungus, but it does mean that additional strains of the rust are needed to achieve full control in the UK.

However, we have also found that the process is much more complex and that the ability of the rust to infect the plant is affected by native fungi, present in the soil or the plant itself. Every living plant is colonised by a variety of fungi and bacteria that live within its shoots ('endophytes') and roots ('mycorrhizas'), collectively these are called the 'microbiome'. Mycorrhizas help plants take up nutrients from the soil, enabling a plant's defence system to be activated, through the increased nutrient supply. Meanwhile, endophytes produce chemicals in leaves that the plant can also use to defend itself against pests and diseases.

In a controlled study, we discovered that the presence of a mycorrhiza and/or endophyte seriously reduces the ability of the rust to infect the plant (Fig. B). This could explain why some populations of balsam appear to be partially resistant.

Biological control offers a safe, economic and sustainable alternative to chemicals. However, our research shows that the natural world is complex, and one must often unravel

intricate patterns to open up the full potential of this method and make it as effective as possible.

Concerning data availability, please contact a.gange@rhul.ac.uk.



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The wonders of the Baltic Sea

Susanna Kaasinen, Project Manager and Monika Stankiewicz, Executive Secretary at the Baltic Marine Environment Protection Commission – Helsinki Commission (HELCOM) explore the wonders of the Baltic Sea

The Baltic Sea is unique both by its characteristics and by the intergovernmental, cross-sectoral cooperation that was established over four decades ago to protect it. The special characteristics include shallow mean depth, low salinity as well as the unique flora and fauna adapted to the brackish water. In addition, the Baltic Sea is almost entirely land-locked, and the water exchange is very limited. The fragile sea is faced with multiple pressures from the 85 million people living in its catchment area and the industrial activities ranging from agriculture and chemical industry to the 1400 ships sailing the Baltic Sea daily ⁽¹⁾.

The Baltic Marine Environment Protection Convention – Helsinki Convention was first signed in 1974 and renewed in 1992. The Helsinki Commission (HELCOM) consists of the ten contracting parties (Denmark,

European Union, Estonia, Finland, Germany, Latvia, Lithuania, Poland, Russia and Sweden) that have signed the Convention. HELCOM works with various topics related to the protection of the Baltic Sea including agriculture, fisheries, biodiversity, marine litter, maritime spatial planning, shipping and response to oil spills. The stakeholders – HELCOM Observers – representing different interest groups, for example, environmental NGOs, the aquaculture industry and intergovernmental organisations, have an active role in HELCOM's work.

The Baltic Sea Action Plan, adopted in 2007, is an ambitious plan to restore the good ecological status of the Baltic Sea by 2021. There have been many successes in implementing the plan, such as covering almost 12% of the Baltic Sea with marine protected areas as well as submitting a joint proposal of the Baltic Sea and the

North Sea countries to International Maritime Organization for designating both seas as Nitrogen Emission Control Area (NECA) for ships. This is estimated to cut airborne deposition of nitrogen significantly. However, many actions are yet to be accomplished. With three years to the deadline, 68% of joint actions and 23% of national actions agreed in the Baltic Sea Action Plan and subsequent HELCOM Ministerial Meetings have been accomplished.

Despite many efforts, according to the first results of the HELCOM “State of the Baltic Sea Report” ⁽²⁾ in 2017, the good ecological status of the Baltic Sea has not yet been reached. Over 95% of the Baltic Sea area suffers from eutrophication due to inputs of nitrogen and phosphorus, which have been high in the past and are still excessive. The pressure from contaminants is high throughout the Baltic Sea and among the assessed hazardous substances, the flame retardant PBDE and mercury have particularly high concentrations. Achieving a good status of biodiversity in the long-term is a HELCOM priority, but the latest results show that many species are still under threat.

Reaching the goal of the Baltic Sea action plan is crucial to a variety of species and sea ecosystems. Furthermore, a healthy sea and sustainable use of marine resources are important for the people living by and of the sea. It has been estimated that reducing eutrophication of the Baltic Sea would increase citizen welfare by 4 billion euros annually.

While work still remains to implement the past commitments, there are also new emerging issues, such as underwater noise and the impacts of climate change, which require attention. Also, new international commitments, such as the United Nations Sustainable Development Goals need to be addressed.

To better tackle emerging issues, the Environmental Ministers of the Baltic Sea countries and the EU Commissioner agreed in the HELCOM Ministerial Meeting held on 6th March 2018 in Brussels, among other things, to develop an action plan on underwater noise by 2021, elaborate a Baltic Sea Regional Nutrient Recycling Strategy by 2020 and update the Baltic Sea Action Plan beyond 2021 based on the newest scientific

knowledge. The HELCOM members have also agreed to use the HELCOM platform in implementing the ocean- and water-related Sustainable Development Goals.

“Over 95% of the Baltic Sea area suffers from eutrophication due to inputs of nitrogen and phosphorus, which have been high in the past and are still excessive. The pressure from contaminants is high throughout the Baltic Sea and among the assessed hazardous substances, the flame retardant PBDE and mercury have particularly high concentrations.”

More efforts are still needed to achieve the good ecological status of the Baltic Sea. In the future, the effects of climate change will make this work even more challenging affecting processes both in the sea and in the catchment area. Strengthened cross-sectorial cooperation and strong political commitment are essential to reaching the goal of healthy Baltic Sea and securing it for future generations. ■

1 HELCOM 2018. HELCOM Assessment on maritime activities in the Baltic Sea 2018. Baltic Sea Environment Proceedings No.152. Helsinki Commission, Helsinki. 253pp.

2 HELCOM (2017). First version of the ‘State of the Baltic Sea’ report – June 2017 – to be updated in 2018. Available at: <http://stateofthe-balticsea.helcom.fi>

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Cracking down on plastic pollution

Samantha Harding, Litter Programme Director at the Campaign to Protect Rural England reveals her views on moving towards a deposit return system in the UK for bottles and cans, to crack down on plastic pollution

In March 2018, the UK Government announced that a deposit return system for bottles and cans will be introduced in England. This is a significant and positive step, as evidence from the 38 schemes that currently operate around the world shows that a well-designed deposit system will deliver some clear benefits.

DEFRA: Moving to a deposit return system in the UK

On the UK Government's plans for a deposit return scheme to crack down on plastic pollution, Environment Secretary Michael Gove said:

"We can be in no doubt that plastic is wreaking havoc on our marine environment – killing dolphins, choking turtles and degrading our most precious habitats. It is absolutely vital we act now to tackle this threat and curb the millions of plastic bottles a day that go unrecycled.

"We have already banned harmful microbeads and cut plastic bag use, and now we want to take action on plastic bottles to help clean up our oceans."⁽¹⁾

According to the Department for Environment Food & Rural Affairs (DEFRA), UK consumers get through an estimated 13 billion plastic drinks bottles each year, but more than three billion of these are incinerated, sent to landfill or left to pollute the countryside, streets and our marine environment.

¹ <https://www.gov.uk/government/news/deposit-return-scheme-in-fight-against-plastic>

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It will significantly and rapidly increase the number of containers we collect for recycling – within two years Lithuania's system reached over 90% of bottles and cans being returned – and radically improve the quality of what's collected, as the glass, aluminium and plastic containers are separated at the point of collection. This creates a more efficient and cost-effective 'closed loop' system, where cans and bottles can easily be turned back into more cans and bottles without having to use so many virgin materials.

As the return rates demonstrate, a small deposit incentivises people to return their containers, or collect those that have been littered by other people. In all the countries and states that already have a deposit system, the growing popularity of the schemes has made the once ubiquitous sight of large, garish containers spoiling the view a thing of the past.

The retailers who host return points report that there are no adverse effects for them – if anything it can increase sales by increasing footfall, as people come to use the reverse vending machines used to collect the containers.

And the system will create jobs – a welcome benefit in any economy.

Despite these clear benefits, implementing a deposit system will be complex and there will need to be quite a lot of adjustment by several key sectors. One of those directly affected is local government, which currently collects bottles and cans by emptying street bins, litter picking or via kerbside collections.

Much of what's collected from bins or as litter is sent



either to landfill or incineration, meaning those valuable materials are lost forever. Plus, we're running out of landfill and anyone committed to resource efficiency knows that incineration should be the option of last resort. It's also a costly business, as in England we spend nearly £800 million every year on street cleansing alone.

In terms of kerbside recycling, legislation to encourage this has been introduced in a piecemeal way over the past 20 years and local councils have had to adapt as they go, meaning we have as many collection systems as we do local councils. The costs associated with delivering a kerbside service are high, but despite this investment, the quality of materials collected can be poor as they're often co-mingled with other packaging, resulting in contamination. Overall, the amount of packaging collected via the kerbside has slowed to a halt and there's a consensus that we need an updated approach that builds on people's willingness to 'do the right thing'.

Essentially the existing system can't stay exactly as it is now. Drinks containers are high in volume, taking up a lot of space and filling trucks more quickly than other types of packaging. By removing drinks containers from kerbside systems, local councils can reconfigure their service, making space to collect materials they're currently not able to and potentially reducing costs.

Research focusing on both English and Scottish kerbside systems has shown that, even though local councils will lose some revenue from the sale of the glass,

aluminium and plastic, the overall costs of managing their service will reduce. This research is borne out by 21 other independent studies from around the world, all of which had the same ultimate finding – a deposit return system will deliver cost savings for local councils.

With the Scottish Government having committed to a deposit system in September 2017, the push is now for a UK-wide system, with a deposit system running alongside a revamped kerbside system. To be an effective modern system, the deposit scheme will need to be designed with some key principles at its heart. It should cover all materials – glass, aluminium and plastic – and any new products should automatically be included. There should be the maximum number of retail-based return points, so it's easy for people to use. And it should be mandatory, as a voluntary scheme simply wouldn't work.

Ultimately, local councils will benefit hugely from a deposit return system, while our streets and countryside will be free of unsightly bottles and cans. ■

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Recycling: Lithuania deposit system exceeds all expectations

Lithuania exceeds container return rate expectations as TOMRA supports new state-of-the-art deposit system, as the firm's Lorraine Dundon, VP Head of Group Brand & Corporate Communications reveals

TOMRA supported Lithuania with the implementation of their new container deposit system, launched in February 2016 with a tight ramp-up timeframe. The roll-out represented the first time ever that TOMRA worked with a "throughput" model in Europe. The Lithuanian container deposit scheme has exceeded expectations, with 91.9% of all beverage containers returned for recycling by the end of 2017.

Container deposit system snapshot:

- Country population: 2.88 million;
- Container deposit: €0.10;
- Eligible containers: Glass and non-refillable plastic and metal beverage containers, 0.1-3 litres in size and;
- Container return rates: 34% (PET) prior to container deposit scheme, 74.3% at end of the first year, 91.9% at end of the second year.

Designing the deposit system

In February 2016, the government of Lithuania implemented a "deposit return system", to give consumers an incentive to return used beverage containers for recycling. To combat litter and increase collection and recycling rates, consumers would pay a deposit amount of €0.10 when purchasing eligible drink containers, to be refunded when the empty container is returned for recycling.

The Lithuanian Ministry of Environment initiated the deposit process in April 2013, passing amendments to the packaging law through parliament a year later. The legislation would apply to glass, non-refillable plastic and metal beverage containers, 0.1 to 3 litres in size.

In March 2015, the Ministry of Environment named non-profit Užstatas Sistemų Administratorius (USAD) as operator of the new deposit system. USAD was established by the Lithuanian Association of Brewers, Association of Lithuanian Trade Enterprises and Lithuanian Natural Mineral Water Manufacturers' Association, in a case of extended producer responsibility. The system operator is responsible for transparent data management, deposit clearing, reporting, logistics, marketing collected materials and educating stakeholders and consumers. Its sources of income include unredeemed deposits, revenue from the sale of collected materials and administration fees paid by beverage producers.

To guarantee convenient return possibilities for consumers, the government chose a "return-to-retail" collection model – meaning stores selling beverage containers must also receive used containers back for recycling. In Lithuania, this applied to stores larger than 300m² and all stores in rural areas, with optional participation from other

stores. Retailers were provided reverse vending machines (RVMs), either inside the store or as outdoor kiosk installations, depending on the retailers' size. Consumers are refunded their deposit as vouchers that can be redeemed in store as cash or credit toward their shopping bill, bringing additional foot traffic into stores.

"In February 2016, the government of Lithuania implemented a "deposit return system", to give consumers an incentive to return used beverage containers for recycling."

TOMRA supports roll-out in a tight timeframe by partnering with USAD

After a public tender process, USAD selected TOMRA to provide reverse vending solutions for the deposit system, to automate the return of containers and increase efficiency. TOMRA's international experience in other markets with successful deposit systems, the diversity of products for both industry and consumers and the need to roll out these solutions with a short deadline of 100 days enabled TOMRA to uniquely contribute to establishing a state-of-the-art deposit system.

What makes the cooperation between TOMRA and USAD unique is the financing model. In Lithuania, the investment in the RVM infrastructure was taken by TOMRA itself. Eligible stores receive an



Kęstutis Trečiokas, former Minister of the Environment of the Republic of Lithuania

RVM free of charge. USAD pays a handling fee per collected container to the store, to cover RVM-related costs like space, setup, maintenance, data exchange, etc¹. TOMRA recuperates its investment via a “throughput” fee USAD pays for each container collected through an RVM.

“By the end of 2016, 99.8% of the Lithuanian public were aware of the deposit system, with 89% having used it at least once. 58% of consumers reported recycling more and 78% believed the deposit system is good and necessary.”

The roll-out commenced in Lithuania in October 2015, just two and a half years after the government initiated the deposit process and one month after TOMRA was selected as the technology provider. TOMRA was tasked with providing 1000 RVMs, with a mix of low, medium and high-volume machines to suit different locations. TOMRA partnered with three Baltic construction companies to manufacture and deliver 350 RVM kiosks, which had to be warm, waterproof,

easily transportable and plug-and-play ready for electricity and internet connectivity.

Industry satisfaction, high return rates

Brewers and retail stakeholders have been pleased with the implementation of the Lithuanian container deposit scheme. One national supermarket chain installed approximately 200 TOMRA reverse vending machines across their stores and commented they think it's also quite good for business because people come back to the shop with their deposit and buy new products in-store. Laurynas Vilimas, Managing Director of the Lithuanian Retailers Association, said: “I can say with absolute confidence the deposit return scheme was the right thing to do.”

By the end of 2016, 99.8% of the Lithuanian public were aware of the deposit system, with 89% having used it at least once. 58% of consumers reported recycling more and 78% believed the deposit system is good and necessary. Prior to the scheme, only one-third of all beverage contain-

ers in Lithuania were returned. USAD had a goal of a 55% return rate in 2016 and far exceeded that mark with 74.3% of all beverage containers returned for recycling. The return rate reached a huge 91.9% by the end of 2017².

“We feel an obligation to take care of our country, society and nature. That is why we wanted to design a deposit return system that would work as well as possible for citizens, producers, importers and traders,” states Saulius Galadauskas, Head of the Lithuanian Brewers Association and Chairman of USAD. “We can be proud of our deposit return system, which brings us closer to the Lithuania we want to see – a cleaner, more beautiful and more modern country.”

TOMRA is proud to be chosen as the infrastructure partner of the Lithuanian Deposit System, in particular as the innovative throughput model significantly reduces the investment hurdle for important stakeholders like retail and therefore may ease the future implementation of CDSs in other countries / regions of the world.

¹ A lower handling fee is also paid to stores that do not have an RVM.

² Glass 83% / PET 92% / cans 93%.



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Deposit return and Scotland's circular economy

Iain Gulland, Chief Executive of Zero Waste Scotland shares his thoughts on Scotland's planned deposit return scheme for beverage containers and on the circular economy

The plastics agenda continues to gain momentum in Scotland – with fast-paced developments in recent weeks and months being met with a Scottish Government commitment to phase out non-recyclable plastics by 2030, in line with EU commitments.

Perhaps the most talked about initiative intended to change behaviours away from single-use items is Scotland's planned deposit return scheme for beverage containers – a measure that will target some of the most numerous and impactful materials that blight Scotland's landscape as well as improve our recycling rates.

Improving recycling performance

A recent Zero Waste Scotland report, *The Composition of Household Waste at the Kerbside*, showed that on average, 60% of what goes in the non-recyclable 'landfill' bin in Scottish homes could have been recycled instead using existing household recycling services. That's equivalent to more than 10 full wheelie bins per household per year.

That figure really serves to highlight the huge potential still to be realised in maximising recycling. It is despite positive progress – with the national average recycling rate having increased year-on-year to its current 45.5% and one local authority area now topping 60%.

Chinese import restrictions are bringing the importance of quality into a starker focus. Evidence shows that deposit return schemes overseas can reach a 90% recycling rate for targeted containers and material collected through deposit return systems, which is typically of high quality and thus higher value.

It's clear there is huge potential to capture recyclable materials with a value to the Scottish economy worth millions and accelerate Scotland's circular economy at the same time.



Iain Gulland, CEO, Zero Waste Scotland

Reducing litter

Scotland is recognised as a leading circular economy nation and yet, like many countries around the world, it continues to battle with items emblematic of our current throwaway culture. Around 250 million easily visible items of litter are dropped in Scotland each year.

That's why the Scottish Government, with support from Zero Waste Scotland, is working to shift the focus away from simply clearing up litter and fly-tipping – which costs more than a million pounds of public money a week in Scotland – and towards prevention.

Deposit return has its own part to play, with the potential to reduce litter by introducing a financial incentive for consumers to do the right thing. There is also an element of attitudinal change that's about perceived value – something you pay for as a consumer doesn't feel like a throwaway item, as demonstrated by the 80% drop in the distribution of single-use bags after the single-use carrier bag charge was introduced in Scotland in October 2014.

Next steps

Zero Waste Scotland is in the process of designing the best possible deposit return scheme for Scotland. We're building on our existing body of expert research and engaging with stakeholders to determine several key considerations, among them, the level of deposit, the types of container the deposit will apply to, the options for where containers are returned to and how the scheme will be managed and promoted.

A series of sector reference groups continue to help inform the process and will be followed by a public consultation period of three months later in 2018.

Once deposit return comes into effect there will then be a period of careful monitoring and evaluation to measure the impact of the scheme, as well as continuing communications with consumers and industry to ensure both remain fully engaged and help maximise the scheme's effectiveness.

Beyond deposit return

However, Scotland's commitment to a more circular economy goes beyond deposit return. It's a great start, but we're aware that to achieve a society in which products and materials are kept in use and waste is truly eliminated, we need to completely redesign the way we do things.

Extended producer responsibility is the name given to schemes where manufacturers and retailers are obligated to support the appropriate stewardship of products through their life to re-use, recycling or recovery. In Scotland, we currently have such schemes covering waste electricals, packaging, batteries and end-of-life vehicles.

The Scottish Government's circular economy strategy, [Making Things Last](#), marks out tyres, furniture and mattresses as waste types where a fresh approach could yield benefits – not just to the environment, but to the Scottish economy.

An approach in which things are designed to last, are easy to repair and ensures the manufacturer is responsible for the stewardship of the product, could shift the costs of managing waste and clearing up littered items from the public purse. More importantly, it could open up opportunities to create jobs and new economic value from things that would otherwise have been discarded.

Driving the circular economy

Scotland has a reputation as a leading circular economy nation, driving innovation and delivering disruptive new business models with the potential to change the way we do things for the better.

Deposit return represents a huge step forward for Scotland's circular economy vision – with the potential to transform how people think about products and materials for years to come, as well as benefits for recycling and litter. It's also a foundation on which to build, really transforming the way products and materials are designed, made and consumed.

These developments, deposit return among them, go entirely with the grain of Scotland being an innovative, creative and sustainable industrial nation. We are committed to action on single-use items that are emblematic of our throwaway society and proud to be pioneering measures that will make us fit for the future. ■

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Arctic science for the past, present and future

Cook, J., Dayal, A., Young, T. J., from the UK Polar Network (UKPN) Committee explore the wonders of Arctic science and how this applies to the past, present and future

Human activities are warming the planet, with the Arctic heating twice as fast as the global average¹. As well as posing an existential threat to Arctic ecosystems, environmental changes there have immediate effects at lower latitudes, including modifying weather, rising sea levels and changing the distributions of plant and animals.

Crucially, environmental change in the Arctic can have a multiplying effect on global temperature changes, making human-induced warming a self-accelerating process. Arctic ice is a cold-store for information about Earth's deep history – studying it allows us to learn from the past, be receptive to warning signs in the present and use this knowledge to predict Arctic change into the future.

The past

The Arctic ice is a vast frozen repository for information about the Earth's climate. The Greenland Ice Sheet is the largest continuous mass of ice in the Arctic and by far the thickest (up to 3 km at its thickest point). Vertical sections can be removed through various coring techniques, providing access to ice that formed hundreds of thousands of years ago. Like tree rings, layers in the ice are a proxy for age, with one layer representing one year's growth. Gases trapped in these layers help to determine what the temperature and atmospheric conditions were like when the ice formed.

The ice also contains particles that pin dates to particular ice layers, for example, dust from specific volcanic eruptions. The complete stack of layers then provides



Image: Alessio Romeo, courtesy of Mondler

The author and fellow scientist Francesco Sauro accessing ancient ice by abseiling into melt-chasms on the Greenland Ice Sheet



Image courtesy of Joseph Cook

Scientists at one of the crucial field sites in western Greenland

a continuous dataset of climatic changes stretching back many millennia, enabling scientists to determine, for example, temperatures during periods of high greenhouse gas emissions in the past as well as potential lags in the system, helping to predict the effects of human greenhouse gas emissions today. Ice sheets are unique and vital ice museums storing information that would otherwise be lost. The same is true for mountain glaciers and ice caps that may well disappear irretrievably in the next few decades. Reconstructing past climatic changes from ice sheets in the Arctic is therefore both urgent and important.

The present

We are living through a period of unprecedented anthropogenic climatic change. The Arctic is currently

warming at twice the rate of the global average, largely due to reflectivity feedbacks (melting ice becomes less reflective and absorbs the sun's energy with increasing efficiency, therefore melting faster in a self-accelerating feedback loop) and can be quantified by coupling measurements made by scientists on the ice with satellite data. On Greenland alone, an estimated 270 gigatons of ice melt each year. These feedbacks are operating now, and they can be quantified by coupling measurements made by scientists on the ice with satellite data.

A well-known maxim states that "what happens in the Arctic doesn't stay in the Arctic". Shrinking land and sea ice alter global atmospheric and oceanic circulation patterns and can affect the weather at lower latitudes². This has contributed to extreme weather in the United



The author sampling from a vertical section of ice accessed by abseiling into a melt-hole on the Greenland Ice Sheet. Similar samples can be obtained at much higher resolution by drilling long vertical cores from the surface, but at much greater expense

States and Northern Europe in recent years. To predict and manage floods, droughts, storms, heat waves and cold snaps in the world's most heavily populated cities, real-time monitoring is required which necessitates high-quality on-ice measurements and continued international engagement in satellite Earth observation.

Studying the Arctic now is necessary because present-day Arctic change is impacting human populations, infrastructure and economies in the present, and will continue to do so increasingly over time.


The future

Melting land-ice in the Arctic is increasingly adding to global sea level rise, raising water tables and accelerating coastal erosion. Combined with increased storminess, this will threaten even more communities and their infrastructures. The reflectivity feedback that enables Earth to absorb more solar energy is self-amplifying and will continue to exacerbate climate change. Robust connections between fluctuating Arctic ice cover and the shape of the jet stream may well promote more frequent and prolonged extreme weather at lower latitudes, endangering human lives and livelihoods directly and also placing increased strain on the Earth's resources and raising political and socio-economic

tensions. The warming Arctic also invites new plants, animals and diseases northwards, disturbing the fragile indigenous ecosystems. These are destabilising influences on the Earth system and human society that will exacerbate in the future.

“Arctic ice is a cold-store for information about Earth's deep history – studying it allows us to learn from the past, be receptive to warning signs in the present and use this knowledge to predict Arctic change into the future.”

Our ability to manage the future rests upon our ability to pre-empt it. Refining our predictions of future global climate change will rely heavily upon our ability to predict changes in the Earth's most sensitive region – the Arctic. Arctic science should, therefore, be a global priority. While aiming to protect humanity from the threat of climate change is justification enough for supporting Arctic science, there is also a significant economic opportunity space incorporating clean energy, eco-tourism, bioprospecting, conservation and geoengineering. Arctic scientists are therefore well positioned to guide the responsible leveraging of new opportunities arising as side effects of environmental change in the future.



A science camp on the surface of the Greenland Ice Sheet. This was part of the National Environmental Research Council's Black and Bloom Project

Outlook

The Arctic offers a unique opportunity for increasing collaborative links between scientists, science communicators, policymakers, diplomats and businesses. Innovative new technologies, international collaborations and interdisciplinary research can improve our ability to forecast and manage future climate and global ecological change with broad social, environmental and economic benefits. Equally, communicating established and cutting-edge Arctic science to the public is essential to raise environmental awareness and to ensure return-on-investment for taxpayer-funded science. Ultimately, the future of the Arctic depends upon our ability to learn from the past and act in the present. ■

UKPN is a UK-based early career polar scientist network, a national committee of the Association of Polar Early Career Scientists (APECS). Our aim is to educate, inspire and influence others in relation to polar science. For more information see polarnetwork.org.

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Protecting the Antarctic Ocean

Oceans campaigner at Greenpeace UK, Louisa Casson, explores the importance of protecting the Antarctic Ocean

This year, we can create the largest protected area anywhere on Earth. In October this year, governments from around the world will meet at the Antarctic Ocean Commission and decide whether to create an Antarctic Ocean Sanctuary. This would put 1.8 million square kilometres of pristine waters off-limits to industrial fishing vessels and create a haven five times the size of Germany for marine life to recover and build resilience to a changing ocean.

The Antarctic Ocean is one of the most important oceans around the world, driving ocean currents that affect our global climate, and providing the feeding grounds for whales that make mammoth migrations from tropical waters every year – including the blue whale, the biggest animal to have ever existed on this planet. Yet parts of the Antarctic are warming at a faster rate than anywhere on Earth as a result of climate change, while the carbon that the oceans absorb are creating a more acidic, hostile environment for the wildlife that calls these waters home.

Crucially, the Antarctic Ocean is one of the only areas of international waters which we can currently protect. Governments in the Antarctic Ocean Commission have a mandate to safeguard marine ecosystems in this ocean wilderness. This is practically unique: in most international waters companies are allowed to plunder the seas for profit because governments are unable to protect them. These vast blue expanses, outside the jurisdiction of any one state, cover about half of Earth's surface. They are home to some of the most biologically important and most critically threatened ecosystems in the world. Scientists recommend that to avoid the worst effects of climate change and protect biodiversity, we need to safeguard more than 30% of our oceans by 2030. Yet less than 1% of the high seas are currently protected.

But we can address this gap. This year, governments begin formal negotiations for a new global oceans treaty at the United Nations. It's a historic opportunity to set the global framework for establishing ocean



Image: © Paul Hilton Greenpeace

Half Moon Island in the Antarctic

sanctuaries in international waters. A strong agreement could supercharge ocean protection for generations to come.

But we know that we cannot leave negotiations over our global commons to stuffy conference rooms; that's why Greenpeace has launched our Protect the Antarctic campaign, calling on governments to demonstrate that international co-operation can protect our seas, and mobilising people around the world to hold their governments to account over the seas we all rely on.

The Antarctic is a special place, not just because of its colossal glaciers or its iconic penguin colonies – but because the region belongs to us all, as the preserve of peace and science. While the bottom of our planet certainly feels remote and difficult for many of us to impact, if we act together we can affect profound change for the common good.

In the 1980s, when oil and mining companies were eyeing up the landmass of Antarctica as a place of untapped deposits, a movement of millions convinced governments to put the entire continent off-limits to extractive industries. We've protected the Antarctic's land; now we need to protect its seas.

That's why a Greenpeace ship is currently on an 80-day expedition to the Antarctic Ocean, crossing some of the most treacherous waters on the planet to bear witness to the world's last wilderness and the threats it currently faces. Joined by scientists, researchers, journalists and even celebrities like Javier Bardem, we went down to a part of the Antarctic seabed never visited by humans

before, finding a seafloor carpeted with vulnerable life, from feather stars to sea squirts.

We have tracked industrial fishing vessels, sucking up the krill upon which all Antarctic life relies, in the very same waters that governments and scientists have earmarked for protection. And we have captured stunning aerial footage of the Weddell Sea, the coldest sea on the planet, which governments can protect this year.

Gathering scientific evidence bolsters our case for protection, a call now echoed by over a million people around the world who are backing the creation of an Antarctic Ocean Sanctuary.

Our oceans are facing mounting pressures, from overfishing, climate change and pollution. But collectively, we know what we need to do to protect them. Ocean sanctuaries work. Around the world, in waters that are protected, we see marine life that is more plentiful, bigger and more diverse. In combination with rapidly moving away from fossil fuels and tackling plastic pollution at source, we can turn the tide on the fate of our oceans by creating large-scale, fully protected, sanctuaries.

This won't be easy. But as the polar explorer Ernest Shackleton wrote in *Escape from the Antarctic*: "I have marvelled often at the line that divides success from failure and the sudden turn that leads from apparently certain disaster to comparative safety." Let's make that sudden turn this year, for the health of our oceans. ■

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The Antarctic notothenioid fishes: An especially interesting and unique marine species flock

Arthur L. DeVries, from the University of Illinois provides a comprehensive insight into a unique marine species flock, the Antarctic notothenioid fishes

At one time the Antarctic Ocean was home to a temperate fish fauna which included sharks, rays and bony fishes (teleosts). About 20 million years ago the Antarctic waters began to cool and all the temperate fishes died out, except for a bottom-dwelling fish that probably looked like a northern hemisphere sculpin. This hypothetical ancestor gave rise to a group of closely related fishes that survived the cooling waters, which today are known as the notothenioid fishes: (a sub order Notothenioidei nested within the modern bony fishes (Perciforms). Some of the shared features of this group are the lack of a swim bladder making them negatively buoyant in seawater, paired pelvic and pectoral fins positioned one above the other and just distal of the opercula and mostly benthic species.

This suborder includes eight families most of which are found in the Southern Ocean south of the Antarctic convergence. Members of five of the eight families are primarily confined to the narrow shelf region of the Antarctic continent. The families include the Nototheniidae, Channichthyidae, Bathydraconidae, Artedidraconidae and Harpagiferidae. They make up about 90% of the fish biomass of the shelf and the populations of some of the species are huge. The other three families (fig 1) are confined to the

waters of the sub-Antarctic islands and the Patagonian region of South America.

When the waters surrounding the Antarctic continent began freezing – a novel trait evolved in some of the progeny of the notothenioid ancestor – which permitted them to avoid freezing; this trait was a blood-born glycoprotein which had antifreeze properties. This antifreeze glycoprotein (AFGPs) lowered its blood freezing point a few tenths of a degree below the freezing point of seawater (-1.9°C). The antifreeze trait allowed them to survive and diversify into many species which filled the ecological niches vacated by the extinction of the temperate fish fauna. Presently, there are a variety of body morphs. Some of the nototheniids and harpagiferids resemble north temperate bottom dwelling thorny sculpins (Cottids).

Other species of the nototheniid family are like smelt and salmonids in body form with a fusiform shape. The nototheniid, *Trematomus borchgrevinki* inhabits the waters at the underside of the fast ice and finds refuge in the platelet layer and has a body form similar to a codfish. The two nototheniid fishes, *Pleuragramma antarctica* (Antarctic smelt) and giant Antarctic toothfish, *Dissostichus mawsoni* inhabit the water

column and are neutrally buoyant even though they lack a swim bladder. They have achieved neutral buoyancy by reducing mineralisation of their skeletons and scales and accumulating lipids which are less dense than seawater. The smelt accumulates sacs of clear lipid under its skin and between its dorsal vertebral spines. Neutral buoyancy adaptations allow these two species to cruise through the water column expending energy only for directional swimming rather than swimming to counteract sinking.

Channichthyids, often called crocodile fishes because of their large mouths as adults are sit and wait predators and can gulp and swallow a fish half their size. The most amazing trait found in this family is the lack of red blood cells and hence hemoglobin the oxygen transport pigment. Oxygen taken up at the gills is transported only as dissolved oxygen in their hemoglobinless blood.

However, they have evolved adaptations to partly overcome the lack of hemoglobin such as larger gills for a larger gas exchange surface to absorb oxygen, a larger blood volume with a larger heart and the absence of scales which allows some gas exchange through the thin skin. Despite these adaptations, they do not tolerate stress like their red-blooded relatives

Adaptive Radiation of Antarctic Notothenioid Fishes

➤ Major groups of fish taxa disappeared at ~40 mya.

➤ Rise of the notothenioid fishes :
➤ ~45% of all species in Southern Ocean;
90-95% of fish individuals on continental shelf.

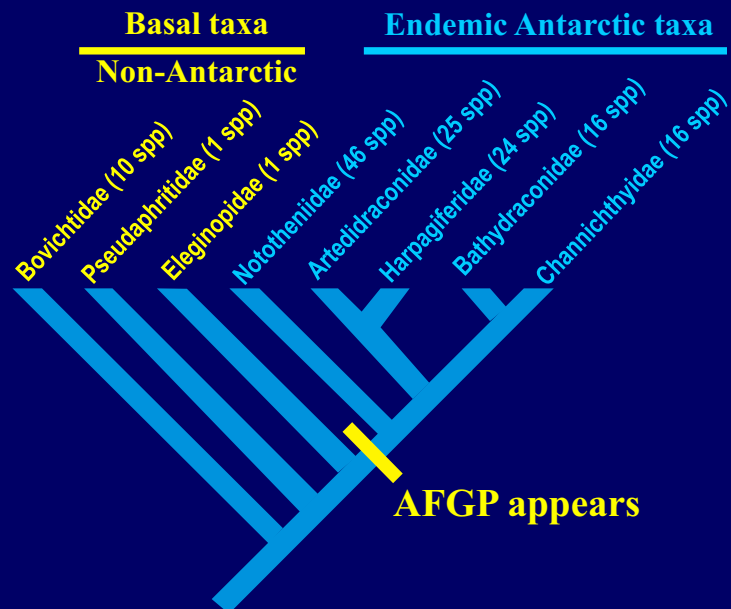


Figure 1. Cladogram of Antarctic fishes of the Suborder Notothenioidei and characteristics of the group

and are therefore at a physiological disadvantage relative to the other notothenioids.

However, they have been able to survive for millions of years because the cold Antarctic Ocean contains more oxygen than warm temperate waters because oxygen solubility is greater in cold water than warm water. The presence of one species of the channichthyid species in 12°C waters of Tierra del Fuego exemplifies the creativity of evolution as this one species can tolerate temperatures well above those ice fish species endemic to the Antarctic Ocean which fail to survive at temperatures higher than +6°C. Although this South American fish appears to exist near its physiological limit, it does attest to its evolutionary success despite having to compete with many coexisting red blooded species, such as salmonids and other non-Antarctic fish species.

The notothenioid group is an excellent example of a marine species flock. That is, a closely related clade of species that arose from a common ancestor and underwent an adaptive radiation that gave rise to a variety of species with unique morphological and physiological characteristics that allowed them to successfully invade and fill most of the underutilised ecological niches that were vacated by the extinct temperate fauna. Because they are closely related the similarities and differences in some of their biochemical, physiological and morphological traits can be more easily compared without having to deal with a phylogenetic signal that would be present if they originated from unrelated ancestors.

Thus, a clearer picture can be gleaned from comparative studies of their morphological, biochemical, physiological adaptations and the underlying

genomic changes that gave rise to them. This marine species flock is like the African Rift cichlids which also arose from a common ancestor and evolved into hundreds of species which exhibit morphological, behavioural and reproductive differences and utilise different ecological niches in the fresh water lakes.

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Protecting human health and the environment

The work of the U.S. Environmental Protection Agency and the Office of Environmental Information, to protect human health and the environment, is unveiled by Open Access Government

The United States Environmental Protection Agency (EPA) was formed on December 2nd, 1970 as an agency of the federal government of the U.S. During these 47 years, their concrete mission has remained the same – to protect human health and the environment. Headed as 14th administrator of the EPA, Scott Pruitt believes that promoting and protecting a strong and healthy environment is among the lifeblood priorities of the government and that the EPA is vital to that mission.

The mission itself is supported by the Office of Environmental Information (OEI), which manages the life cycle of information surrounding the EPA's mission. Stated clearly on its website, the OEI is proud to support the EPA, by identifying and implementing

innovative information technology and information management solutions that strengthen EPA's ability to achieve its goals. They ensure the quality of EPA's information and the efficiency and reliability of EPA's technology, data collection, exchange efforts and access services. The OEI also strives to provide technology services and manage EPA's IT investments.

Together, the EPA and the OEI act, by developing and enforcing regulations, giving grants, both teaching and studying environmental issues, sponsoring partnerships and publishing information to accomplish this important goal.

A recent illustration of some of these actions came about in January 2018, with the release of a report

outlining recommendations to promote agriculture, economic development, job growth, infrastructure improvements, technological innovation, energy security and the quality of life in rural America. As a member of the USDA Task Force on Agriculture and Rural Prosperity Release Recommendations to Revitalize Rural America, the Environmental Protection Agency (EPA) plays an important role in revitalising rural America. Pruitt confirmed his commitment to empowering rural America by stating that it will contribute to improving the [“environmental outcomes across the country”](#).

“Together, the EPA and the OEI act, by developing and enforcing regulations, giving grants, both teaching and studying environmental issues, sponsoring partnerships and publishing information to accomplish this important goal.”

In addition, EPA awards numerous grants to support state pesticide regulatory programmes ensuring these products are used properly, agricultural works are protected, and farmers can provide safe, healthy food for all Americans. More specifically, in May 2017 the EPA awarded \$574k to the Washington State Department of Agriculture to support state-wide pesticide programmes. [Administrator Pruitt states](#): “We are pleased to support the pesticide programs in ensuring that pesticides are used properly, agricultural workers are protected, and Washington’s diverse agricultural landscape can thrive and remain a provider of safe, healthy food.”

The U.S. agriculture sector itself is somewhat robust, producing nearly \$330 billion per year in agricultural commodities. The U.S. is also unsurprisingly currently the world’s leading exporter of agricultural products; the sector plays a critical role in the global economy. However, aspects of this are constantly under threat and with climate change becoming an ever-growing factor in the well-being of the agriculture sector, and as such, laws and regulations must be enforced to prevent lost capital.

On March 21, 2011, the EPA issued its final emission standards to reduce emissions of toxic air pollutants from industrial, commercial and institutional boilers located at area source facilities. [An area source facility](#) emits or has the potential to emit less than 10 tonnes per

year of any single air toxic or less than 25 tonnes per year of any combination of air toxics. This final rule covers boilers located at area source facilities that burn coal, oil, or biomass, but not boilers that burn only gaseous fuels or any solid waste.

An area under threat in today’s climate and toxic air pollution is forestry. While perhaps not the most obvious means of exportation, forests, in fact, provide several important goods and services, including timber, recreational opportunities, cultural resources and habitat for wildlife. They also create numerous opportunities to reduce future climate change by capturing and storing carbon by providing resources for bioenergy production.

Both agricultural and forestry production are sensitive to changes in climate, including changes in temperature and precipitation, more frequent and severe extreme weather events as well as increased stress from pests and diseases. However, certain adaptation measures, such as changes in crop selection, field and forest management operations and use of technological innovations, have the potential to delay and reduce some of the negative impacts of climate change and could create new opportunities that benefit the sector.

Clearly, both the EPA and the OEI take their roles very seriously as responsible for human health and the environment. A drastic change in the climate could not only be dangerous to both the environment and its inhabitants, but also drastically change the potential yields of agricultural and forestry products, shifting land allocation, crop mix and production practices throughout the U.S. It is, therefore, important to protect the environment through means such as grants and education to enable it to thrive, benefitting all. ■

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Greening the inner city: How do we choose the best trees?

Nina Bassuk from the Urban Horticulture Institute, School of Integrative Plant Science Cornell University shares her thoughts on the value of green spaces in inner cities and how we should choose the best trees for this purpose

The world's population is increasingly urban. In the United States alone, 85% of the population lives in urban areas and that trend is expected to continue. If we value the green spaces and trees in our cities and parks for all the benefits they give us, we need to choose the best trees that will thrive in challenging sites.

“By far, the most stressful urban condition for trees is the lack of accessible soil. This is caused by inadvertent and purposeful soil compaction. When any new road or building is built or demolished, the soil within the area inadvertently becomes compacted due to the use of heavy machinery and moving of earth.”

There are four basic principles of urban tree selection:

- Trees should be pest resistant and adapted to urban environmental conditions.
- Trees should be highly diverse, including native and non-native species, but avoiding invasive species.
- Trees should meet functional and design objectives.
- Trees should match management limitations.

When we investigate these principles, it is worthwhile to delve into specifics.



Tree roots escape a confined space by growing under a sidewalk into a neighbouring lawn

Pest resistant – adapted to environmental stress

Due to the inherently heterogeneous nature of the urban environment, tree planting sites are subject to microclimates caused by buildings and paved surfaces and the aftereffects of urban development written in the soil. On a warm sunny day when the air temperature is 24°C, the surface temperatures of pavement or building walls can reflect 40-52°C temperatures. Taken altogether, this increased heat gives rise to the urban heat island where inner cities are considerably warmer than surrounding rural areas. With increased air temperatures, trees lose water from their leaves more rapidly than a rural tree. Coupled with often-restricted planting spaces or soil

that is paved over, trees experience drought stress even during what would be considered normal summer temperatures and rainfall.

With the addition of climate change, cities experience longer periods without rain and then heavy downpours. The negative effects of too much water can also be stressful for trees when air-filled pores in the soil are filled with water depriving the tree roots of needed oxygen. Above ground, trees also have to compete with utility wires, streetlights, traffic and business signage. These cause conflicts if sight lines or electricity delivery is disrupted requiring drastic pruning to squeeze the tree's canopy into the allotted space.



Using air excavation tools we uncover roots

By far, the most stressful urban condition for trees is the lack of accessible soil. This is caused by inadvertent and purposeful soil compaction. When any new road or building is built or demolished, the soil within the area inadvertently becomes compacted due to the use of heavy machinery and moving of earth. Once compacted and crushed, it is difficult to bring back the soil so that it can support plant life. Moreover, when any pavement is laid, the soil beneath it must be purposefully compacted to bear the load of the new pavement to prevent subsiding or cracking.

Tree roots provide, water, nutrients and oxygen for healthy tree growth. When soil volume is restricted these

basic building blocks for tree growth can be severely restricted. Combined with reflected heat from building and pavement, poor water infiltration due to impervious surfaces, waterlogged soils that don't drain and often poor nutrient availability, it is no wonder that urban trees live a shortened life.

However, most people who enjoy a tree covered street would say that things cannot be that bad. After all many trees get big and provide many of the benefits we enjoy.

Where are the roots?

Whenever there is a large tree, there is a corresponding large, wide-spreading root system that supports that tree to supply water and nutrients.

With the use of air excavating tools, we have peeled back the soil to find where roots are growing. In many narrow, green, planting areas adjacent to roads, tree roots break out of the limited soil by exploiting the area of weakness at the interface between the sidewalk and underlying soil. When they do this, roots find accessible soil in someone's front or backyard or nearby vacant lot. Inevitably the roots of a large tree may not be where you think they are. When roots grow under pavement and increase in girth by radial growth, sidewalks may be raised causing tripping hazards, which set up a conflict between trees and municipalities.

"The one factor that no tree is adapted to is compacted soil. Compaction physically restricts root growth and prevents the acquisition of water, nutrients and oxygen. When this occurs, soil remediation must occur to engineer a more sustainable soil condition."

We can select trees that are adapted or tolerant of to:

- Small planting envelopes (above and below ground) by choosing small trees;
- Heat and cold temperatures;
- Dry and wet soils;
- Poor nutrient availability and salts and;
- Insect and diseases.

Each one of these conditions is a filter reducing the potential trees that may be chosen. It is notable that the more we can reduce the stress on trees, the greater the choices we can make will be.

The one factor that no tree is adapted to is compacted soil. Compaction physically restricts root growth and prevents the acquisition of water, nutrients and oxygen. When this occurs, soil remediation must occur to engineer a more sustainable soil condition.

“It is clear that the urban environment has been fundamentally altered by development and human habitation. The choices of trees must consider these environmental conditions and choose plants that are adapted to them.”

Highly diverse, non-invasive

I am often asked, “What is the best urban tree.” There are many common street trees that are preferentially grown in cities worldwide. In the eastern United States, maples (*Acer* spp.) make up about 40% of the urban tree population. In Scandinavia and other parts of Europe, lindens (*Tilia* spp.) make up a very large percent of the urban tree population. The problem with growing just a few tried and true species is that if they become susceptible to an insect or disease (and inevitably there is always some new insect or disease!) the demise of these trees causes an enormous negative effect on the urban landscape. We have the example of Dutch Elm Disease decimating elms, Emerald Ash Borers killing all the ash trees, Asian Long Horned Beetles destroying maples and a host of other species, as well as other examples. The only true defence against pests is to plant a very diverse urban forest.

Native or non-native?

It is clear that the urban environment has been fundamentally altered by development and human habitation. The choices of trees must consider these environmental conditions and choose plants that are adapted to them.

The popular ideology promoting native species only disregards the fact that urban conditions are nothing like native conditions where many trees evolved.

The best choice is to use both native and non-native trees when they are adapted to urban site conditions. A few species have become invasive, causing economic and environmental harm, as well as harm to human health. Identifying these trees varies on a local level and should be avoided.

Trees provide ecosystem and aesthetic benefits

Increasingly we are recognising and quantifying the benefits that trees provide in the urban environment including reducing storm water runoff and pollution, providing habitat for pollinators, sequestering carbon, reducing air pollution and providing significant energy conservation in summer and winter. Tree choice affects the accrual of benefits. Trees with large canopies provide the greatest amount of energy conservation, storm water runoff reduction and carbon sequestration. A diversity of trees that flower from spring through fall will provide the greatest benefit to pollinators and other urban fauna.

What about the cost of tree management?

Many cities have quantified the benefits they receive from healthy trees. In all cases, the cost of management (preparing sites, choosing good trees and providing reasonable aftercare) is far outweighed by the ecosystem benefits that are gained.

We take trees for granted. Only when many trees are removed do people realise the difference trees make in their lives. Continued research focusing on better tree selection for challenging urban sites will provide long-term benefits that we can all enjoy.

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Supporting the earth sciences in the United States

The Earth Sciences (EAR) Division of the National Science Foundation (NSF) is placed under the spotlight by Open Access Government

The National Science Foundation (NSF) is an independent federal agency in the United States that supports fundamental research and education across all disciplines of science and engineering. In fiscal year (FY) 2018, its budget is \$7.8 billion. NSF funds research throughout all 50 states to almost 2,000 colleges, universities and other institutions. Each year, NSF receives no less than 50,000 competitive proposals for funding and funds around 12,000 projects to keep the United States at the leading edge of discovery in areas from astronomy to geology to zoology.

The Division of Earth Sciences (EAR)

The Division of Earth Sciences (EAR), part of the NSF, gives unwavering support to proposals for research that intends to improve our understanding of the structure, composition and evolution of the earth itself, the life it supports and the processes that govern the formation and behaviour of the earth's materials.

The results of such research will clearly create a better understanding of the earth's changing environments, as well as the natural distribution of its mineral, biota, water and energy resources, not to mention providing methods for predicting and mitigating the effects of geologic hazards, such as volcanic eruptions, earthquakes, floods and landslides.

In a nutshell, we know that earth science is the study of the earth's structure, properties, processes and in the view of the NSF, it is also the study of four and a half billion years of biotic evolution. Certainly, understanding such phenomena is essential to the maintenance of life itself on the planet. The increasing world population demands more resources; heightens losses from natural hazards and creates more pollution.

The NSF website also points us to the way earth science

benefits society. We learn that the knowledge gained, as well as the work of earth scientists, help society cope with its environment in many ways. The knowledge of earth scientists concerns the structure, stratigraphy and chemical composition of the earth's crust and helps us locate resources that sustain and advance our quality of life. The NSF's website explains this point in more detail to us: "Understanding the forces in the crust and the natural processes on the surface allows us to anticipate natural disasters such as volcanoes and earthquakes and geologic environments, such as damaging mining practices or improper waste disposal, gives us information to correct such practices and design more benign procedures for the future."⁽¹⁾

"In a nutshell, we know that earth science is the study of the earth's structure, properties, processes and in the view of the NSF, it is also the study of four and a half billion years of biotic evolution. Certainly, understanding such phenomena is essential to the maintenance of life itself on the planet. The increasing world population demands more resources; heightens losses from natural hazards and creates more pollution."

Petrology and Geochemistry (CH) Division

Within the Division of Earth Sciences at the NSF, lies the Petrology and Geochemistry (CH) Division. Their work specifically involves the support of basic research concerning the formation of planet earth, including its early differentiation and subsequent petrologic and geochemical modification via igneous and metamorphic processes.

Proposals in this programme generally address the petrology and high-temperature geochemistry of igneous and metamorphic rocks (including mantle samples), volcanology, mineral physics and economic

geology. The Division's website explains that they focus on the development of analytical tools, theoretical and computational models and experimental techniques for applications by the igneous and metamorphic petrology, as well as geochronology communities and high- temperature geochemistry. ⁽²⁾

Examples of NSF-supported research on volcanology

An interesting example of how NSF supports and funds research into the earth sciences, for example, is around volcanology. In news from the field, the NSF website draws our attention to Frank Spear of Rensselaer Polytechnic Institute who thinks he's found the source of water that fuels earthquakes in volcanoes in subduction zones. This can be done by applying a new spectroscopy technique to garnet containing fragments of quartz, metamorphic petrologist, we are told. Spear's research is supported by a three-year \$419,247 grant from the NSF.

"The real culprit in powerful volcanoes and earthquakes is water, but scientists have been unable to determine where that water comes from," said Spear, a professor and head of the Rensselaer Department of Earth and Environmental Sciences. "Conventional thermodynamic equations predict that water is released at too shallow a depth to occur at the known locations of volcanoes and earthquakes. But when you factor in the overstepping we've discovered, the locations coincide. The idea of overstepping is an enormous paradigm shift" he explains. ⁽³⁾

In closing, it's worth noting another fascinating area of volcanology research supported by NSF, which can be found in detail about a study from New Zealand volcano by Brown University, which suggests that a volcanic system's response to tidal forces could provide a tool for predicting a certain type of eruption.

Prior to a surprise eruption of New Zealand's Ruapehu volcano in 2007, a seismic tremor near its crater became tightly correlated with twice-monthly changes in the strength of tidal forces, the new study reveals. The research suggests that signals associated with tidal cycles could provide advanced warning of kinds of

volcanic eruptions. This interesting point is explained further by Társilo Girona, the study's lead author.

"Looking at data for this volcano spanning about 12 years, we found that this correlation between the amplitude of seismic tremor and tidal cycles developed only in the three months before this eruption. What that suggests is that the tides could provide a probe for telling us whether or not a volcano has entered a critical state."

The research was funded by the National Science Foundation (1454821). Professor Christian Huber, also involved in this project said that they'd like to collect more data from other eruptions and other volcanos to see if this tidal signal shows up elsewhere "Then we can start to think about using it as a potential means of predicting future eruptions of this kind", he says. ⁽⁴⁾

Closing remarks

Such research is an excellent example of why NSF was created by Congress in 1950, one of the reasons of which was: "to promote the progress of science" and to fulfil the vital task of keeping the United States at the leading edge of discovery in numerous areas of exciting scientific discovery. ■

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Cities getting smarter by sharing

Anna Lisa Boni, secretary general, EUROCITIES, shares her thoughts on how Europe's cities are getting smarter by sharing

Europe's major cities are teaming up to make big savings. Through 'lighthouse' projects, such as Sharing Cities, cities can trial innovative technology and replicate results for other European cities to use.

The project, which is supported through EU funds via the Horizon 2020 programme, has created a knowledge network to enable exchange. Lighthouse cities Lisbon, London and Milan work alongside fellow cities Bordeaux, Burgas and Warsaw on digital, energy management and e-mobility solutions. Three years into the five-year project length, it is bringing results.

Lisbon, for example, has recently approved a PV installation in one of their historical buildings. Through Sharing Cities, Bordeaux, where 60% of buildings need retrofit – a measure that reduces inefficiencies in old structures, from installing solar panels and new heat systems to improving insulation – is now aiming to retrofit 9,000 dwellings per year for the next 40 years, making vast energy savings.

In Burgas, inspired by a project in Milan, 'smart lamp posts' use LED bulbs and a reactive dimming system to save over 50% of the energy used for street lighting. This means using less energy and allowing more money to be spent elsewhere. Sensors installed in the lamp posts also give the city information about noise levels and congestion patterns which can inform further urban developments. This is another idea that is spreading like wildfire across Europe, with the European Commission expecting to see 10 million of these lamp posts built by 2025.

In a similar vein, Warsaw has been inspired by examples from the Royal Borough of Greenwich in London, to launch a car sharing scheme this year, which will also add electric vehicles.



Anna Lisa Boni, Secretary General, EUROCITIES

Connecting smarter cities throughout Europe

Within the Sharing Cities project, EUROCITIES is leading on replication and knowledge sharing, and we bring solid experience to the table. As a network, EUROCITIES has been actively engaged in and leading smart city projects for several years. We bring together over 140 major European cities, more than 40 of which are directly involved in the lighthouse projects.

This year EUROCITIES is chairing the lighthouse projects task force, of which Sharing Cities is one of 12 projects. In this role, together with the EU Innovation

and Networks Executive Agency and the European Commission, EUROCITIES has been able to broaden the collaboration of the six cities of Sharing Cities and create meaningful exchanges with many other cities and stakeholders on how to replicate urban solutions.

Munich, for example, is piloting a 'virtual power plant', so that residents can store solar energy generated on their rooftops and use a mobile app to sell it back to the grid during peak demand. This technology is now being put in the hands of EU citizens in many European cities. Funding from the European Commission helps cities share these technologies and experiences so that they can learn from each other, replicate successful solutions, create new governance models and encourage behavioural shift throughout Europe.

"Lisbon...has recently approved a PV installation in one of their historical buildings. Through Sharing Cities, Bordeaux, where 60% of buildings need retrofit – a measure that reduces inefficiencies in old structures, from installing solar panels and new heat systems to improving insulation – is now aiming to retrofit 9,000 dwellings per year for the next 40 years, making vast energy savings."

Action for future results

Horizon 2020, the EU's research and innovation programme, has played a central role in creating space for cities to innovate and to make Europe more competitive. Ahead of the next seven-year cycle of the EU budget, it's important that the added value of EU research and innovation, and how it relates to cities, is well understood.

Demonstration projects, such as the lighthouse projects that aim to trigger further innovation, increasingly integrate ICT, energy, mobility, social or cultural aspects, reflecting the way many challenges come together in cities. Involving cities as partners in designing the priorities of the EU's next research and innovation programme is essential to reflect this, ensuring that future smart city, and other projects, are more effective.

Funding provided for the lighthouse projects has allowed the involvement of many more cities in research and innovation projects than previously. This

has a direct benefit to people's lives, and, through replication efforts, these benefits can reach cities and their citizens throughout Europe. The next EU budget should at least maintain the current level of investment in innovation through programmes like Horizon 2020, with a greater emphasis on capacity building in and between cities.

City governments facilitate local innovation eco-systems, by fostering collaboration between different stakeholders, institutions and users. Sharing Cities, for example, encourages collaboration with businesses and research institutes. Scaling up and replicating these efforts in future EU programmes will enhance the EU's collective innovation capacity.

At EUROCITIES we advocate for a city-led and citizen focussed approach towards resource efficiency and a high level of public services facilitated by digital solutions. Every day cities are bringing results that matter to people. With the right empowerment, cities can help Europe deliver a smarter future. ■

EUROCITIES is the political platform for major European cities. We network the local governments of over 140 of Europe's largest cities and more than 40 partner cities that between them govern some 130 million citizens across 39 countries.



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The role of planning in the deterioration of high-rise housing estates

Dr Gideon Bolt from the Faculty of Geosciences at Utrecht University shares his expert perspective on the role of planning in the deterioration of high-rise housing estates

According to Turkington et al. (2004, p. 265), the heydays of high-rise housing estates (the 1960s and early 1970s) produced the “most uniform and international European housing type” ever built.

All over Europe, housing estates emerged that were very similar in construction methods, location and urban design. Since then, large housing estates have experienced quite significant demographic changes in the course of years. Initially, many such estates were the places where young families started their housing career. For those who left inner-city slum areas, moving to a housing estate entailed a major improvement. Nevertheless, many housing estates ended up in a spiral of decline very soon after their completion. There are many different explanations for the deterioration and social degradation of large housing estates, but in this paper, I focus on the mistakes made in the phase of planning.

Bad physical quality

Many estates malfunctioned from the beginning due to physical shortcomings: elevators were too few and often not working, there were problems with waste disposal systems, with condensation and leaking and many high-rises had bad acoustics (Hall, 2014). Of course, not all high-rise housing estates had the same physical problems. There are differences in the quality of construction within

countries, between countries and between different time periods.

In Eastern Europe, the quality of design tends to be lower than in Western Europe, mainly for economic reasons (Monclús & Díez Medina (2016). Especially the five- or six-storey prefabricated buildings/houses built during the Khrushchev era in the 1960s, known as Khrushchyovka, were of a low-quality (Kährik & Tammaru, 2010). However, it is not necessarily the case that newer buildings are of better quality. For instance, in the Czech city Kladno, the urban design during the first two post-war decades was much better than in the 1970s and 1980s when, due to a lack of resources, the architectural design was weak, and facilities were lacking (Temelová et al., 2011).

Location

One of the planning flaws of many large housing estates was that they were located on the fringes of the cities, far away from any amenities and job opportunities. Functions like schooling, shopping and recreation were underdeveloped. In Southern European housing estates, the public transport connections to the rest of the city are often underdeveloped (Dekker & Van Kempen, 2004). The peripheral locations were chosen to reduce costs. For instance, Quarto Cagnino in Milan (1964-1973) was built as ‘marginal appendix to the city’, as the legal framework limited the development of public housing estates to

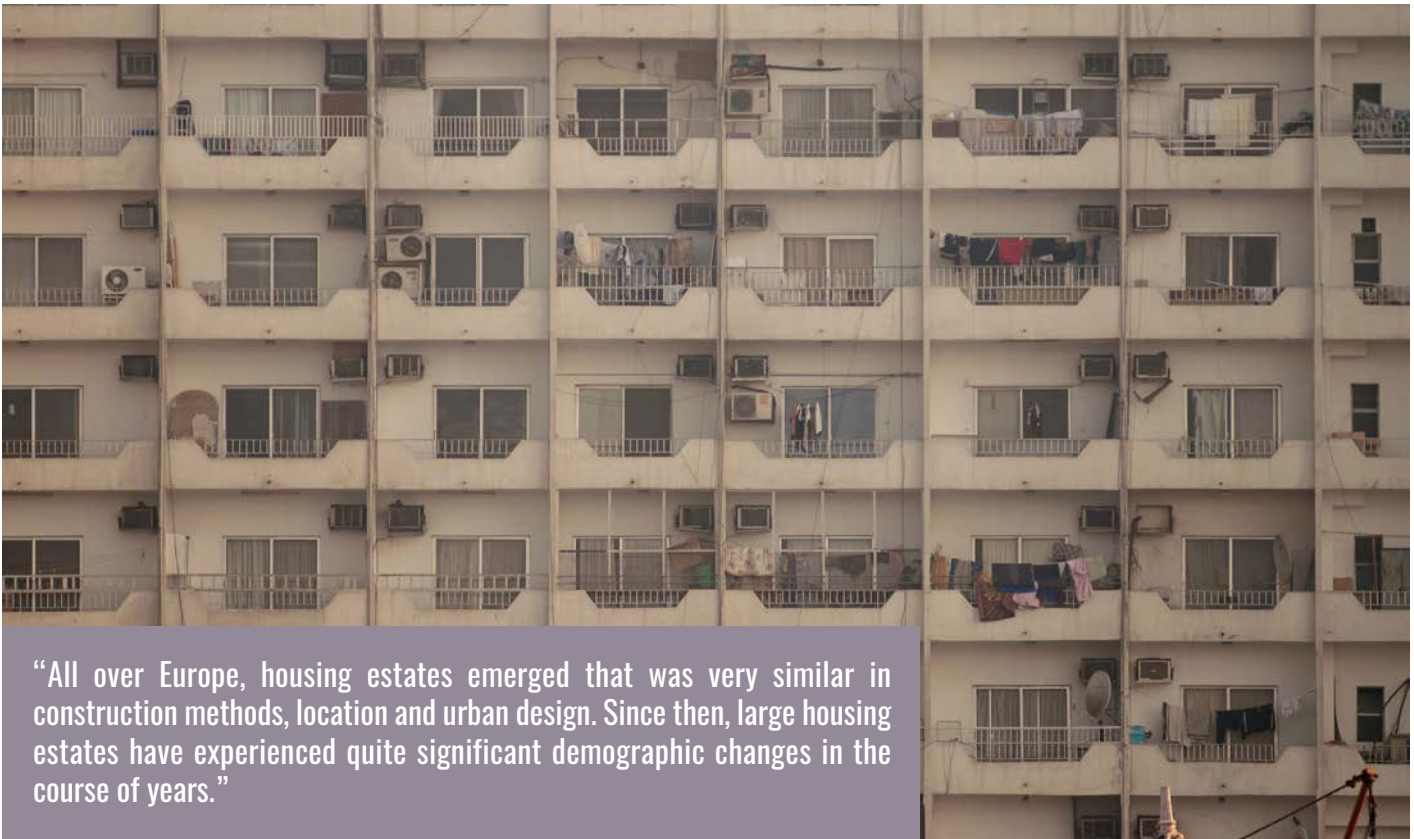
the availability of economic plots (Monclús & Díez Medina, 2016, p. 542).

Monotony

Another shortcoming of the modernist housing estates is that their monotony does not facilitate its appropriation by the new inhabitants. The standardisation tends to be the most problematic in the largest housing estates. The ‘drab monotony’ is in Eastern Europe even more extreme than in Western Europe (Monclús & Díez Medina, 2016). Apart from the larger scale of the projects in Eastern Europe and the higher lack of resources, the monotony also fitted in the communist idea that uniformity was a sign of equality among residents. This idea is also in line with the conviction that Le Corbusier developed in the course of his career that a city without classes should be created (Fishman, 1982).

Urban design and social life

Modernist housing estates are also criticised for the negative impacts of the built environment on social life. Oscar Newman (1972) uses the term indefensible space to describe the discouraging effect of the physical design of these estates on collective community actions, which makes these neighbourhoods susceptible to crime. He concluded: “For low-income families with children (...) the high-rise apartment building is to be strictly avoided. Instead, these families should be housed in walk-up buildings no higher than three stories.” (Newman 1972: 193).



“All over Europe, housing estates emerged that was very similar in construction methods, location and urban design. Since then, large housing estates have experienced quite significant demographic changes in the course of years.”

Hall (2014) argues that Le Corbusier (the most famous pioneer of modern urban design), as well as his followers, had no real feeling for the way-of-life of working-class families. The famous estate Unité in Marseille, designed by Le Corbusier himself, is a completely different world compared to the British council tower blocks or the French grand ensembles. That is not so much due to the quality of the design, which in Hall's view makes the complex resemble 'a medium-quality hotel', but due to the fact that it is occupied by middle-class professionals. According to Ward (1976, p. 51), these kinds of residents are much more out of the house than working-class families, because they can afford to be: “Mum isn't isolated at home with the babies, she is out shopping at Harrods. The children, when small, are taken to Kensington Gardens by Nannie. At the age of eight, they go to a preparatory school and at thirteen to a public school, both of them residential. (...) At any rate, they are not

hanging around on the landing or playing with the dustbin lids.”

Epilogue

It should be acknowledged that not all housing estates are problematic or have become problematic during their existence. Next, to that, exogenous factors, like the construction of new neighbourhoods and economic restructuring often play a more dominant role in the deterioration than internal (planning factors). In the next issue of Open Access Government, I will dwell upon these exogenous factors.

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The City of Varberg:

The City of Varberg profile their attractive and exceptional city based in the south-west coast region of Sweden

Varberg is an attractive community, based in the south-west coast region of Sweden, with a long history of growth. In fact, 2017 marked the year where the municipality experienced 60 years of continuous population growth, which is quite unique in a Swedish context. Only 14 municipalities in Sweden have achieved this.

The city of Varberg is ideally located in the historic city centre, right next to the coastline and boasts a rich and diverse countryside. Our location is exceptional - right in between two of Sweden's fastest-growing regions, The Greater Gothenburg region and the Greater Copenhagen region. The Swedish Government is investing heavily in the west

coast railway to increase the capacity for commuting and to connect cities and regions along the way. In Varberg, this means our section of the railway will be in a tunnel under the city centre. To make the most of this, we will move parts of our harbour and have already begun planning for a new waterfront area that connects the city centre with the coastline, which will remove any industrial barriers.

In the 1950s, Varberg was "discovered" by people in Sweden's bigger and more industrial cities. This, of course, coincided with the larger availability of cars to a greater number of people. Before that, the towns along the south-west coast of Sweden were mostly dependent on the fishing and farming industries, but suddenly the tourist sector exploded when the demand for city people to take a summer holiday on the coast increased. Varberg is one of the cities that has really flourished because of this development, whereas others flourished for a while and then slowly went into a quiet slumber.

Come to Varberg. Share our vision.



A hidden gem in Sweden

That Varberg is different from other communities is obvious in so many ways. It can largely be attributed because there is a high level of entrepreneurship here, indeed there is a very diverse business sector in the municipality. This ranges from the large-scale industrial production of timber, pulp and energy, to countless hotels and restaurants that serve Varberg as one of Sweden's most popular spa and coast resorts – all year round. Varberg is in many ways a hidden gem, but more and more people discover the city as a place to settle down. It's less than an hour away by car or train to Sweden's second largest city (Gothenburg) and the airport of Landvetter, Varberg is well connected.

Varberg is really making the best of its fortuitous position today. The building boom in Sweden is also apparent here, indeed new residential areas are the results of wise planning for developing former industrial properties and using fill in sites to make the city more interesting for everyday life.

Although most of the development for housing is focused on the city, we strive to involve residents living in our more rural communities too. We engage people in the decisions that have the greatest effect on their everyday life. Through dialogue and local action plans, we work together to see where public and commercial service, infrastructure and housing will come to best use. It is also a way for our citizens to meet with local politicians and decision-makers and share their thoughts about how the municipality can be made even more attractive.

A sustainable society needs to be based on people empowerment and the foundations of democracy. New forms of meetings are important for reinventing the community. Our aim is clear, and we are acting on it. We are building a community converging around means of public transportation and a sustainable lifestyle. ●

Come to Varberg. Be inspired.

New-build market in the UK to benefit from genuine competition for water connections

John Marsh, Water Director at GTC shares his views on how the new-build market in the UK is to benefit from genuine competition for water connections

From April 2018, measures introduced by Ofwat, the UK water regulator, sweep away barriers to competition and, for the first time, give housebuilders and developers in England and Wales a real choice of providers for new water and wastewater connections. This opening up of the water market is expected to bring developers in both the private and public sectors significant benefits, including the opportunity for developments of all sizes to adopt a truly multi-utility approach, sourcing all of a site's utilities through a single network provider.

Until now, there have been very limited opportunities for developers to source their water networks from anyone other than their local water company. In England and Wales, water companies supply domestic water and wastewater services on a monopoly basis within their specific geographical areas. It has always been an option for new developments to choose a competing water company, but under the previous rules, it was only financially viable for competing companies to become involved on the largest projects.

Water competition – the changes

These competing water companies are referred to as NAVs – 'New Appointment and Variation' – and are



licensed by the regulator on a per-site basis. NAVs own and manage the site network providing billing, maintenance and customer services. They either install the network themselves or adopt networks installed on a developer's behalf by Self-Lay Providers (SLPs).

Following an investigation into how the water market was operating, Ofwat identified several significant barriers to competition. These involved the way in which tariffs for bulk water supply and income offset were calculated. The changes being introduced will make it easier for developers and competing water companies to establish what an incumbent water company will charge to connect a new development to their existing

water network. The charges will also be fairer, with new connections being the same irrespective of who the final network owner will be. In addition, Ofwat has undertaken to streamline the lengthy licensing process required to appoint alternative network providers, such as GTC.

Bringing water into line with the markets for gas and electricity

Housebuilders and developers are used to the freedom to choose their network providers for gas and electricity connections and indeed most of new electricity and gas connections are undertaken by independent network providers. The gas and electricity markets in the UK were liberalised twenty years ago and the opening up of those markets has delivered increased competition on price, higher service standards and more innovation and development. The same benefits will now be available in the water and wastewater markets. The Home Builders Federation (HBF), the representative body for the home building industry in England and Wales regards these developments as so significant that it has established a committee to focus on how these major changes will impact its members.

GTC, as the UK's largest independent utility network provider to the new-build market, has welcomed the



opening up of the water market and has been working with Ofwat and Water UK, which represents the water industry, to help make these changes happen. GTC has considerable experience of being a NAV licence holder and is already responsible for more than 8000 live water and wastewater new connections, with contracts to build out tens of thousands of further connections on sites from Newcastle in the north to Weston-Super-Mare in the southwest. GTC is looking forward to being able to offer the whole housebuilding sector the opportunity to benefit from its different approach to network provision across all the utilities.

The future is.... multi-utility

With the arrival of genuine competition in the water market, adopting a multi-utility approach is now a realistic option for housebuilders and developers working on sites of all sizes. Now all a development's utilities – water, wastewater, electricity, gas,

ultrafast FTTH (Fibre-to-the-Home) and in some case district energy – can be sourced from a single independent provider. Utility procurement can be simplified with only one set of tenders, one company to deal with and a single project manager who oversees the installation of all the utilities with all the time and cost-savings, that would deliver.

GTC and its sister company Metropolitan, has worked in just this way on several flagship projects such as King's Cross and Greenwich Millennium Village in London and has direct experience of the benefits that co-ordinated utility installation and combined network management can bring. Those benefits will now be available to much smaller developments, even those of as few as 50 houses.

Developers need to act now

The new measures come into force in April and every housebuilder and developer needs to consider how

these changes will affect their utility procurement. Provided an order has not yet been placed, it is still possible to review options.

Robust competition across all the utilities for new-build developments can only be a good thing. It is now up to housebuilders to take full advantage of these new opportunities.



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UK government introduces new legislation to cap poor value energy tariffs in time for next winter

New legislation to cap poor value energy tariffs and save UK consumers money was recently introduced to Parliament, as this article from the Department for Business, Energy & Industrial Strategy reveals

New legislation to cap poor value energy tariffs and save consumers money was introduced to Parliament on 26th February 2018. In summary, it will achieve the following:

- New price cap power introduced to Parliament following BEIS Select Committee endorsement;
- Move will guarantee protection for the 11 million households currently on the highest energy tariffs – in addition to 5 million vulnerable households already protected by Ofgem’s safeguard cap and;
- New temporary cap is one of a number of measures from government designed to save people money on their bills including smart meters and faster switching.

The Domestic Gas and Electricity (Tariff Cap) Bill will put in place a requirement on the independent regulator, Ofgem, to cap energy tariffs until 2020. It will mean an absolute cap can be set on poor value tariffs, protecting the 11 million households in England, Wales and Scotland who are currently on a standard variable or other default energy tariff and who are not protected by existing price caps.

Currently some consumers are paying up to £300 more than they need to – this cap will help bring this overcharging under control.

The Bill is part of a package of measures being introduced by government to increase competition in the retail energy market and lower prices for consumers, including the rollout of smart meters in every household and initiatives to promote smarter and faster switching.

The government intends that Ofgem implements the cap as soon as possible so that customers get the protection they need by winter 2019.

UK Prime Minister Theresa May says: “It’s often older people or those on low incomes who are stuck on rip-off energy tariffs, so...we are introducing legislation to force energy companies to change their ways. Our energy price cap will cut bills for millions of families. This is another step we are taking to help people make ends meet as we build a country that works for everyone.”

Business and Energy Secretary Greg Clark comments: “Energy prices for millions of households on default tariffs are still too high. Our new price cap will guarantee that consumers are protected from poor value tariffs and further bring down the £1.4 billion a year consumers have been overpaying.”

Energy and Clean Growth Minister Claire Perry says: “We are working hard to deliver an energy supply that is clean, affordable and innovative and an energy market that delivers the best possible value and service for energy customers. This new legislation is a big step forward toward that goal.”

The introduction of the Domestic Gas and Electricity (Tariff Cap) Bill comes after the Business, Energy and Industrial Strategy Select Committee scrutinised the draft Bill as part of the government’s work to build consensus for the cap. The Committee backed an absolute cap and made a number of other recommendations about the Bill in its report, which the government has accepted in full.

In setting the cap, Ofgem will also take into account the need to create incentives for suppliers to improve efficiency, the need to set the cap at a level that enables suppliers to compete effectively for supply contracts, the need to maintain incentives for customers to switch and the need to ensure that efficient suppliers are able to finance their supply activities. This will make sure the cap reflects the interests of both consumers and suppliers.

It will be in place until 2020 when Ofgem will recommend to government whether it should be extended on an annual basis up to 2023. In line with the Committee's recommendation, the government will ensure Ofgem reviews the level the cap is set at every six months while it is in place.

We have also taken account of the Select Committee's recommendation to add in safeguards for the exemption of green tariffs from the cap so that where consumers make an active choice to opt for a green tariff it is only exempted where Ofgem is satisfied that the tariff supports the production of renewable energy.

The Competition and Markets Authority 2016 review of the retail energy market found that customers of the Big Six suppliers faced a £1.4 billion a year detriment.

The latest league table from Ofgem comparing the default or standard variable tariffs of the 10 largest energy suppliers shows that those households who are prepared to shop around can, on average, save around £300 from switching to the cheapest tariffs on the market. The government is determined to tackle this detriment, by encouraging consumers to switch suppliers and tariffs. The introduction of smart meters will enable consumers to see the cost of their energy usage and more easily find the best tariff for them.

Earlier in February 2018, one million more vulnerable consumers who receive the Warm Home Discount were protected from higher bills with the extension of Ofgem's safeguard tariff cap, introduced in 2017. There are now five million households protected by this cap. Government also announced a new consultation to give Ofgem and DWP new powers to make it easier for vulnerable consumers to be protected from unfair energy bills.



Energy and Clean Growth Minister, Claire Perry

The cap is part of a package of measures designed to deliver the UK government's objective of clean, affordable and innovative energy as part of the Industrial Strategy. ■

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The latest league table from Ofgem comparing the default or standard variable tariffs of the 10 largest energy suppliers shows that these tariffs are still around £300 more expensive than the cheapest deals on the market. Ofgem's league table and other reports can be found [here](#).

Explainer about Ofgem's existing safeguard tariff cap can be found [here](#).

Announcement on consultation on better data sharing between DWP and Ofgem can be found [here](#).

The Industrial Strategy sets out a long-term plan to boost the productivity and earning power of people throughout the UK. It sets out how we are building a Britain fit for the future – how we will help businesses create better, higher-paying jobs in every part of the UK with investment in skills, industries and infrastructure.

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UK heat pump market is growing again

Senior Market Intelligence Analyst at BSRIA's World Market Intelligence Division, Socrates Christidis looks at the current growth of the UK heat pump market

The latest BSRIA research indicates that around 22,000 heat pumps were installed in the UK in 2017, which represents an increase of 18% in volume compared to the previous year.

This increase comes after five years of almost continuous market decline that has been caused by the economic slump, the low price of oil, the uncertainty around the Renewable Heat Incentive (RHI) programme, the Brexit outcome and the concerns around the pound to Euro exchange rate.

In 2017 the overall market background changed, with oil prices at the highest level for the last three years and the RHI programme lifetime extended to 2021, offering significantly increased tariff rates for heat pumps. Some heat demand limits have been introduced later in the year giving a boost to the market of high heat demand projects from the middle of the year.

Product awareness is also definitely up, owing to TV programmes and to advertising.

Market progress is definitely good news for the industry and for the environment, however, it is important to note that the number of units sold is nowhere near where they were expected to be 10 years ago – of at least 100,000 units needed for the market to sustain itself without the help of subsidies. The main barriers have persistently been the cost of investment and the disruptive installation in case of the system refurbishment.

The government has for too long seen heat pumps as an important technology in its carbon reduction policies. But an air-source heat pump investment cost is on average twice as much as for a condensing boiler and a ground-source heat pump costs twice as much as an air-source one.



Socrates Christidis, Senior Market Intelligence Analyst

RHI was introduced by the government in November 2011 (for non-domestic units) and in April 2014 (for domestic ones) to support households, businesses, public bodies and charities in transitioning from conventional forms of heating to renewable alternatives, including heat pumps. While it has arguably had a positive impact on the industry, the sales suggest that it is still far from delivering a real change.

RHI pays the investment back over several years – but nothing upfront – thus constraining its availability to the relatively wealthy minority. Moreover, it requires that installation is carried out by an MCS registered installer, a registration process described as “expensive and laborious”. MCS certification of contractors and products is crucial for the quality of the installation, but the route towards obtaining it should be more streamlined. Last, but not least, some upfront payment would also be crucial to offset the initial capital cost required.

Third-party ownership of RHI, such as the recently announced Assignment of Rights, may help but only under certain conditions that encourage investors but not quick profit organisations. Shared ground-loop systems can qualify for non-domestic RHI and ECO programmes making them more affordable.

RHI needs to become more end-user friendly: easier to implement and simpler to understand; a mix of incentives may be worth considering as well. The current idea of receiving a return on investment over seven years (domestic RHI) is not appealing to everyone. The younger, more environmentally aware generation, is the one more likely to move to a new house more often. For them, a different incentive, such as reduction in council tax, or a low-interest loan may be more important.

The next iteration of the ECO scheme, which will run from 2018-2022, may include, besides insulation, new innovative measures, such as the obligation to include ground-source or air-source heat pumps in the technologies to install, with the option for large utilities to get involved.

A consistency of approach would also be helpful – RHI requirements could, for example, be in alignment with building regulations – more towards the Scottish model – which would make life easier for suppliers of heat pumps in the UK.

Looking into the future, the government must decide if RHI has a future after 2021. Uncertainty similar to the one experienced between 2013 and 2017 will for sure result in a lower level of investment.

It is understood that the government's solutions to meet UK heat demand and achieve its legally binding climate change targets, are:

- A commitment to building and extending heat networks in urban areas.
- Development of "green gas", hydrogen or biomethane, that will replace natural gas in the existing grid, assuming that this low-carbon gas can be deployed at scale.
- Shift away from conventional oil-fired heating to heat pumps in the off-gas areas.

Around 3.6 million homes in England and Wales are currently off the mains gas grid. Of those, around 2 million use electric heating (mostly old-fashioned electric storage heaters) and 1 million use oil heating – of which half are non-condensing. The vast majority of those dwellings can be targeted for the installation of heat pump-based heating.

On the other side, there are currently around 900,000 homes in the UK with solar PV panels installed. PV and heat pumps can be seen as complementary technologies hence they, as well, represent a significant potential for heat pumps.

Nevertheless, undeniably, considerable government support is needed to off-set the heat pumps' high up-front costs. And, furthermore, with the number of MCS accredited installers falling, some government support and possibly a different approach to incentivise installers' training is needed, which is now left to the manufacturers.

The government needs to make many of its key decisions to actively promote the decarbonisation of UK's buildings over the next two years. Its Clean Growth Strategy is not clear yet in terms of details but is viewed as a positive signal of intent that could see a significant uptake of heat pumps in the UK. Still, a lot more reassurance is needed on how this programme is going to be implemented. ■

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The importance of world food production systems: Healthy food for all people

The importance of reviewing world food production systems for mankind is examined by Horticulturist at the Swedish University of Agriculture, Håkan Sandin in terms of the need for humanity to eat more healthy food and to produce it in a way that does not harm nature

Our world food production systems need to be reviewed from several perspectives, the two most important ones being obvious as follows:

- Firstly, humanity must learn to eat more healthy food, not to overload the healthcare system.
- Secondly, we must learn to produce food that does not harm nature.

These two aspects meet in a complete harmony and are neither costly nor difficult to achieve for mankind.

Healthy food

There is no doubt that today we know how to consume and what is useful for man to eat. It is useful and environmentally friendly and sustainable to eat in terms of:

- Fish;
- Vegetables and;
- Legumes.

Nevertheless, we strive to eat more of what we know is useless to us. This can be expressed very easily in two sentences:

- It is unhealthy to eat too much and;

- We should not eat a lot of carbohydrates.

The reason why we eat too much is not easily explained. One explanation, however, is that there was a huge lack of food in the world some decades ago. The easiest way to deal with this was to cultivate large areas of arable land to produce what we call staple crops, on a large scale, using machines. These staple crops contain very large amounts of carbohydrates and can quickly satisfy a growing population of people in the world and can also be used for animal feed to produce meat and milk. By that time, this strategy solved a threatening hunger catastrophe. These crops are corn, rice, wheat, starch banana, cassava, sweet potatoes and others. These crops are also easy to store and distribute worldwide.

Today, the world is not threatened by a worldwide hunger catastrophe and a decreasing number of people suffer from starvation. Therefore, we must ask ourselves the question. **We can change people's way of eating and their views on what to eat?**

Energy

To produce food, we must use large quantities of energy, in addition, on an ever-increasing scale. The reason that the need for energy is increasing is that more and more people move to

the city and that the population is growing. Today, more than 50% of the world's population lives in cities.

The world's production system is changing at a furious pace and more and more energy-consuming means of production, such as fertilisers and pesticides are used.

Since we still use the same areas to produce our food, like when we lived in rural areas ourselves, it requires many, long and costly methods of transport to the city to be consumed.

Our consumption patterns are also changing. We prefer to buy our food in food bags distributed to our homes. As a result, the transport in our cities has increased further and dramatically.

The conclusion of this reasoning is that transport on our roads and in our cities is increasing ever more. The question we must ask ourselves is then: **Can we save energy when producing food?**

Environment

The large-scale machine-based agriculture is harmful to both our nature and humanity. It is simply not sustainable. It can be simply expressed in the following five points:

- We over fertilise our nature with phosphorus and nitrogen and other nutrients;



500 ha tomatoes, cucumber, letuces and herbs. Consumption by today 2018.

In Sweden 500 hectares are enough to be self-sufficient for vegetables in greenhouses

500 hectares illuminated year-round production costs around SEK 10 billion in total investments and we have full environmental control

- We consume finite resources, such as phosphorus and oil, at a furious rate;
- We irreversibly poison our ecosystems;
- We reduce the diversity of plants and animals in nature and;
- We overconsume land resources.

We must, therefore, ask ourselves the question: **Can we save the environment when producing food?**

Intensive, circular and symbiotic food production

The answer is both simple as obvious. We must close the systems and make them completely circular and symbiotic. To understand this reasoning and the continued articles in this series, there is some statement that we all need to analyse and relate to. Over time we can do the following:

- We can change people's eating habits!
- We dramatically reduce the need for arable land to produce food!
- We can reduce transports and start to produce food locally!

- We can develop intensive, symbiotic, fully closed production systems which are more environmentally friendly than large-scale production in arable land!
- We can produce renewable fuels and lubricants using ecologically sustainable renewable materials!
- We can develop ecologically sustainable fertilisers and sustainable systems for the nutritional supply of food crops!

- We can develop ecologically sustainable plant protection agents and systems for the protection of food crops against diseases and pests!

- And so, on

I mean, that this can be done using the full capacity of nature and the innovative ability of humanity itself. The challenge, however, is to do this without destroying our living space on the planet earth.

Food production in houses where people live

Producing our food in-house, where people live, is undoubtedly part of the solution by doing the following:

- Producing fish and vegetables in-house, so that we provide humanity with the food that is useful to us and best for nature. I realise that many will protest, based on wanting to eat bread and meat, but it's about how we must change our habits over time so that we do not destroy our living space here on planet earth.
- By producing food in-house, we can place them exactly where we wish and where we have full control over all flows, giving us possibilities to develop circular and symbiotic production systems.
- Place them in urban areas where people live today, we reduce the need for transportation and can also benefit from surplus heat, electricity, organic materials, leftovers and other unused resources. Then we can also more easily employ people who have no work.
- By producing in-house, we are open to endless innovation possibilities by using high technology and ingenious solutions that the world has not seen.

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The priorities of the U.S. Energy Department

Open Access Government charts the history of the U.S. Energy Department and some of its present-day priorities, including clean energy and solar manufacturing

The mission of the U.S. Energy Department, according to their website, is: “To ensure America’s security and prosperity by addressing its energy, environmental and nuclear challenges through transformative science and technology solutions.” ⁽¹⁾ This article will look at the background to the Department’s work, including some of its present-day work, including driving energy-efficient technologies and promoting clean energy, as well as solar manufacturing.

By way of background, the U.S. Energy Department is said to have one of the most diverse histories in the U.S. Federal Government. While it began its life in 1977, the U.S. Energy Department’s lineage can be traced back to the Manhattan Project effort to develop the atomic bomb during World War II and to other energy-related programmes that were covered by several federal agencies.

During its long history, the U.S. Energy Department has shifted its emphasis and focus in accordance with the changing needs of the nation. In the late 1970s, the emphasis was very much on energy development and regulation. During the 1980s, the priorities changed towards nuclear weapons research, development and production. Following the end of The Cold War, the focus turned to the environmental clean-up of the nuclear weapons complex and the non-proliferation and stewardship of the nuclear stockpile.

After the millennium, the U.S. Energy Department’s objective has been to ensure the nation’s prosperity and security. This is achieved by addressing its energy, environmental and nuclear challenges by means of innovative science and technology solutions. The U.S. Energy Department seeks to transform the U.S.’s energy system and secure leadership in clean energy technologies, pursue world-class science and engineering and enhance nuclear security through defence, non-proliferation and environmental efforts.

Driving energy productivity improvements and efficient technologies

A more recent example of the U.S. Energy Department’s work is evidenced in an announcement on 10th April 2018 about their partnership with the National Association of Manufacturers (NAM). This intends to help U.S. manufacturers drive energy productivity improvements and accelerate the adoption of energy-efficient technologies.

“Working alongside our private sector partners, we are driving cost savings and a stronger, more secure U.S. industrial base,” says Secretary of Energy in the U.S., Rick Perry. “The Department’s partnership with the National Association of Manufacturers will further spotlight industrial leadership and boost awareness of the resources across the DOE enterprise to boost manufacturing competitiveness through energy savings.”

NAM President and CEO Jay Timmons adds: “Manufacturers accept the responsibility to better the future of our communities, our environment and our children, which is why over the past decade, we have reduced emissions by 10% even as our value to the economy has increased 19%. This initiative is another example of the Trump Administration’s true partnership with manufacturers in America and it will take our sustainability efforts to a new level of progress.” ⁽²⁾

Clean energy policy and solar manufacturing

Today, a clean energy revolution is said to be taking place across America, underlined by a steady expansion of the U.S. renewable energy sector. The clean energy industry is predicted to continue the trend of rapid growth in the future. There is a marvellous economic opportunity ahead for the countries that invent, manufacture and export clean energy technologies, we are told.



The responsible development of all of America's rich energy resources – including geothermal, bioenergy, solar, wind, water, & nuclear – will help ensure America's continued leadership in the field of clean energy. Moving forward, the U.S. Energy Department aims to drive strategic investments in the transition to a cleaner, domestic and more secure energy future.

In January 2018, the U.S. Energy Department announced a \$3 million prize competition to revitalise innovation in U.S. solar manufacturing. The aim of this is to incentivise the nation's entrepreneurs to develop new products and processes that will reassert American leadership in the solar marketplace. U.S. Secretary of Energy Rick Perry explains more about this, in his own words.

"The United States possesses the talent, expertise and vision to surpass the rest of the world in solar technologies and forge a new solar energy landscape around the globe. The American Made Solar Prize will galvanise our country's entrepreneurs, allow them to utilise technologies and innovations developed through DOE's early-stage research and development and, ultimately, bring new American-made products to market."

In addition, this solar prize brings together the country's research base with its entrepreneurial support system which is made up of energy incubators, universities and the U.S. Energy Department's 17 national

laboratories, who together can create a sweeping portfolio of innovations primed for private investment and commercial scale up. ⁽³⁾

Reducing the costs of solar energy

The U.S. Department of Energy has a Solar Energy Technologies Office, who support early-stage research and development to improve the affordability, performance and reliability of solar energy technologies on the grid. This includes investment in innovative research aimed at securely integrating more solar

energy into the grid, enhancing the use and storage of solar energy and to lower the costs of solar electricity.

To end this article on a positive note, we know that with the dramatic reduction in the cost of solar, installations in the U.S. have risen dramatically. This encouraging development, of course, creates fresh challenges for the country's ageing electricity grid. To cater for these changing needs, the office announced in September 2017 a continued focus on solar energy research and development efforts that aid the country's critical energy challenges, which are: grid reliability, resilience and affordability. ■

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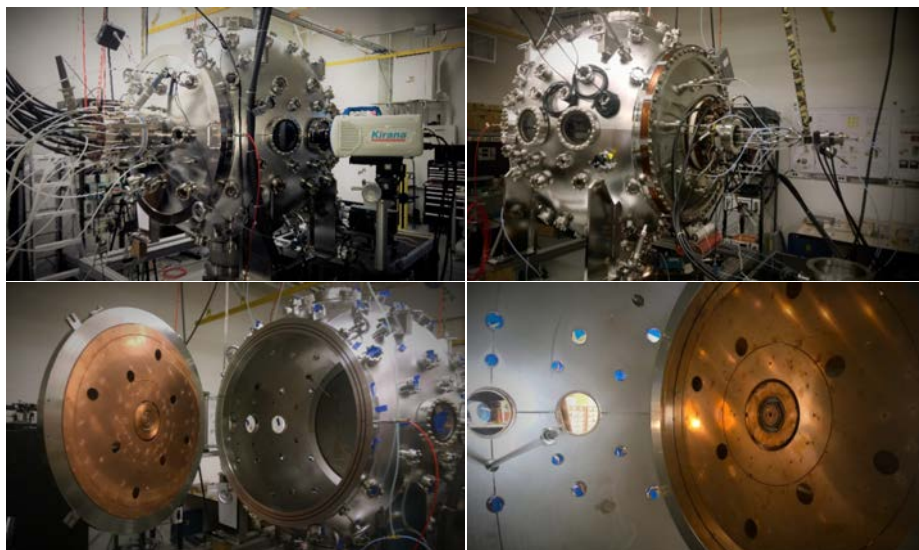
Research on self-organisation in plasmas

Setthivoine You from the Department of Aeronautics & Astronautics at the University of Washington shares his insights into the intriguing world of self-organisation in plasmas

Research into plasma self-organisation lies at the intersection of fusion energy, astrophysics and space propulsion. The aim is to understand the ability of plasmas to spontaneously re-arrange themselves into different shapes. Harnessing this remarkable property can make fusion power plants more compact, therefore more economical and lead to fusion rocket engines. Fusion energy is a breakthrough technology for producing limitless clean energy on Earth and for colonising the Solar System.

Plasmas are ionized gases, heated to temperatures beyond 11,000°C. Above these temperatures, the gas particles are broken into ions and electrons that interact with electric and magnetic fields. We can, therefore, keep the plasma away from cold walls or accelerate it to provide thrust with suitable arrangements of electric and magnetic fields.

This is how conventional concepts for fusion energy or plasma rocket engines operate. For example, the world's largest fusion energy experiment, ITER in the south of France, uses doughnut-shape magnetic fields arranged in a special configuration called a tokamak to confine the plasma. Then, just like a microwave oven, radio-frequency electromagnetic waves then heat the plasma to more than 150 million degrees, whereupon deuterium and tritium particles fuse to create helium and release neutrons.

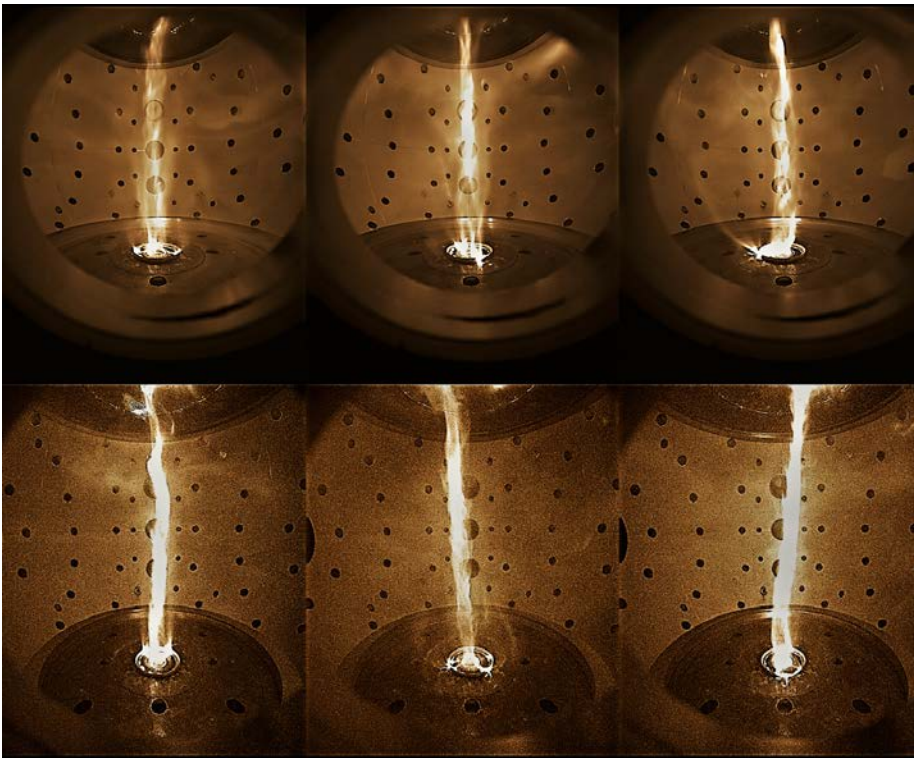


The neutrons are captured to heat steam, turn turbines and generate electricity. The experiment, currently under construction, aims to demonstrate 500 MW of fusion power from 50 MW of heating with a gigantic 16,000 m³ apparatus that weighs 23,000 tonnes and holds an 840 m³ burning plasma.

Plasma rocket engines use electricity to accelerate the plasma and generate thrust for spacecraft propulsion. Examples include ion thrusters used on the soon-to-launched Bepi-Colombo mission to Mercury or Hall thrusters used in the Deep Space 1 spacecraft. The primary benefit of using plasmas for in-space rocket engines is that the propellant can be ejected at velocities much greater than is possible with chemicals, so less propellant is needed to fly faster.

These engines are limited by the available electricity, so solar electric propulsion is limited by the size and mass of solar panels compounded by the decreasing amount of sunlight available farther out of the Solar System.

How do we make power plants smaller and how do we break the solar power limit? One possibility is to exploit the spontaneous interaction between plasmas and magnetic fields to generate large flows or magnetic structures. With the right conditions, plasmas suddenly form flows in the magnetic doughnut that doubled the plasma confinement time. This fortuitous discovery in the 1980s made fusion reactors smaller than would otherwise have been the case and forms the basis of operation of the ITER tokamak.

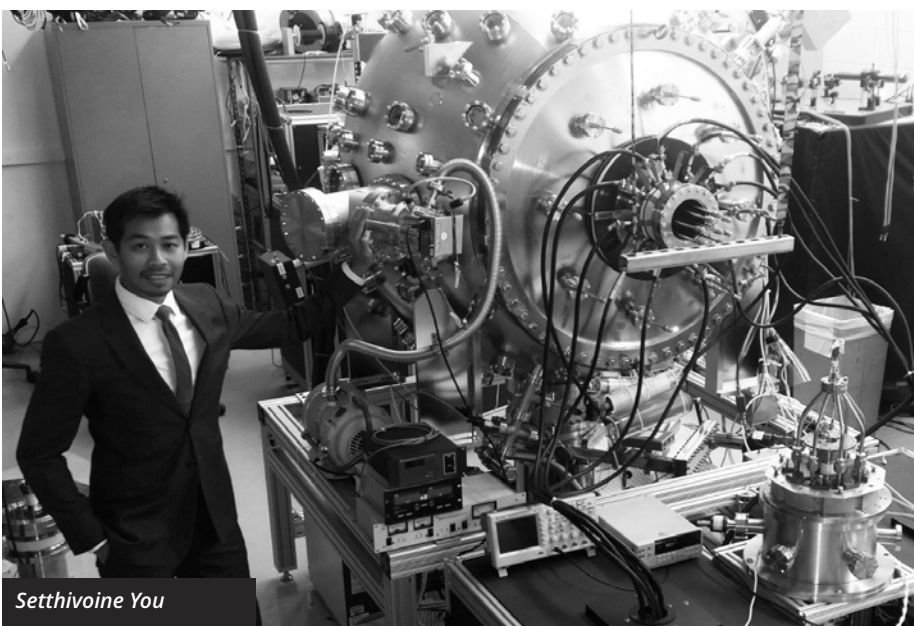


Another discovery shows that with the right conditions, the plasma can form a different kind of magnetic doughnut that can also confine the plasma. These other doughnuts are variously called spheromaks, or field-reversed configurations and are smaller than the equivalent tokamak. Merging two of these configurations generates

strong flows and converts magnetic field energy into heat. This could be exploited to heat plasma to fusion temperatures without using microwaves nor compression. The spontaneous conversion of magnetic fields to flows or vice-versa while generating heat or new magnetic configurations is a signature of plasma self-organisation.

In nature, this property is observed over a wide range of scales. Reconnection of magnetic fields and re-arrangement of magnetic tubes are at the heart of solar prominences, the mystery of solar coronal heating and the origin of magnetic fields around planets and stars throughout the Universe. Astrophysical jets are manifestations of matter rotating around stars linked by magnetic fields.

The Mochi.LabJet experiment is thus designed to observe the self-organisation of plasmas in a simple experiment designed to mimic an astrophysical jet. Using technology derived from fusion and plasma space propulsion experiments, nested electrodes with magnetic fields produce long stable jets of plasma that travel at 80 km/s. The experiment demonstrates how astrophysical jets can be remarkably stable, collimated and straight.



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The rise of Britain's sustainable homes: Building eco-friendly on a budget

The drive to cut carbon emissions means sustainable homes are growing in popularity. Johnathan Bulmer, managing director of shipping container experts Cleveland Containers, discusses this rising trend and how to build an eco-friendly property on a budget

Some 12% of the UK's carbon emissions come from domestic buildings. The government has declared that by 2020, all homes must be zero carbon. That only gives the country two years to reach this target.

Sustainable homes are on the rise

A sustainable house is defined as one that makes effective use of all natural resources available to it.

There are many benefits to sustainable houses, with a crucial one being the reduction of energy bills. The amount saved depends on the reliance of renewable sources like wind and solar power, yet the average eco-home cuts energy bills by 30%.

It's even been reported that eco-friendly homes can make money, with one property in Wales pocketing its owners £700 a year due to renewable energy grants.

The popularity of eco-properties is growing around the globe, with the Shanghai Tower in China cited as being one of the greenest – and tallest – skyscrapers in the world.

However, it's the UK that's home to the world's first emission-free building. [The Beacon](#) boasts 17 storeys of luxury flats, drawing much of its energy from the sun with embedded PV panels. Additional warmth is provided from underground heat pumps and rain is collected and reused for laundry purposes. As such, residents don't pay any energy bills, and the building 100% sustainable.

This eco-friendly thinking extends to other parts of life, with bikes and an electric pay-as-you-go car scheme available to residents.



Image: © Steve Morgan

Johnathan Bulmer, managing director

Building eco-friendly properties on a budget

Many property developers are turning to eco-friendly options when building new homes; as are many families, who are opting for self-builds.

With the help of a talented architect, self-builds can look very stylish and work out as very cost-effective. One home in Cornwall only cost £82,000 to build and is now valued at £500,000.

When it comes to building eco-homes on a budget, there are several things to consider, with one of the



most important aspects being insulation. Ultimately, the more eco-friendly you can make the property, the more cost-effective it will be in the long term.

Triple-glazed windows will help to keep warm air trapped, and aren't as expensive as you might think. Opt for glazing with a lower U-value, as that represents a better thermal performance.

You should also look to seal any drafts where air could escape, and insulate the attic so air that has risen remains trapped in the house.

Natural light is another thing to consider. A house with natural light will use less artificial lighting, reducing energy bills over time.

Alternative housing options

Instead of traditional bricks and mortar, builders are turning to other materials that are more eco-friendly.

Earthbags – where bags filled with earthen materials are stacked together to create a house – logs, stone and recycled shipping containers are all rising in popularity to create eco-friendly homes across the world.

Some builders are even incorporating natural materials like bamboo and straw into their new builds, showing that the variety of materials is ever-expanding in a conscious quest to be sustainable.

There's no denying that eco-homes have grown in popularity over the years, and this shows no signs of slowing down. Environmentally friendly and money-saving are a winning combination and it turns out that eco-builds aren't as expensive as you'd think.

Nevertheless, the UK has a long way to go to reach the ambitious zero carbon proposal by 2020. But if builders continue to create eco-friendly homes then steps are being made in the right direction. ■

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An almost zero energy building in Denmark

Peder Vejsig Pedersen & Miriam Sanchez Mayoral from Kuben Management profile an exciting project at Copenhagen International School (CIS) in Denmark that concerns an almost zero energy building – the largest BIPV (building integrated photovoltaic) installation in Europe

Copenhagen International School (CIS) is a private school owned by the ECIS foundation, which managed to get funding from several large funds in Denmark for the realisation of the school, where all education is in English.

Location

Northern Harbour in Copenhagen, Denmark

Project type

New build

Use

Private school of 25,550m²

Client

ECIS, The foundation of CIS

Design

C.F. Møller Architects

Year

2017

Based on this, there was an interest to make a payback to the society by establishing the largest BIPV (building integrated photovoltaic) installation in Europe at CIS, with approximately 6000m² equal to 720kWp photovoltaic (PV) in total.

Due to this, it has been agreed that the project at CIS should be introduced into the Danish ForskVE/ EUDP project, "LowCost Active House BIPV"



and in connection to this should have made a full Active House labelling by Cenergia, now part of Kuben Management.

Comfort

The CO₂ concentration level at CIS has been calculated at 350ppm above outdoor CO₂ concentration, which is equal to level 1 of the Active House radar (which is the best) and concerning the maximum temperature level, this is calculated to level 2 in the Active House radar which means it is in the range between 21°C and 26°C during the year. These good results are based on using decentralised ventilation systems, which provide a high air exchange.

The lighting quality is also good based

on a combination of LED lighting and access to daylight. The windows area has an average ratio of around 20% of windows area over the floor area, which is expected to ensure a good level of daylight inside the rooms.

There are also no emissions from heating and cooling systems because district heating and district cooling are used for the school.

Energy

The Danish Be15 calculation shows an overall final energy use of 15 kWh/m² per year at CIS, which is better than low energy class 2020 in Denmark, which demands a maximum level of 25kWh/m² a year for a school.

For ventilation, an electricity use (SEL



value) of 1.3 kJ/m^3 is calculated and boasts a heat recovery efficiency of 82% as an average.

The actual heating use at CIS is 10.4 kWh/m^2 and 6.3 kWh/m^2 for room heating and domestic hot water (DWH), also based on a very good insulation of the building envelope with values of 0.74; 0.1; 0.11 and $0.12 \text{ W/m}^2 \text{ }^\circ\text{C}$, for the windows, external walls, roof and ground floor respectively.

The PV modules were produced by SolarLab from Denmark as 60 W green chromatic coated hardened glass panels of $700 \times 716 \text{ mm}$, with 16 monocrystalline PV cells (6 inches) and a bypass diode, where eight panels are coupled to a micro inverter which is easily accessible from the loft.

The panels were wind tunnel tested prior to use to avoid noise. Furthermore, the panels have different tilts with a 4° inclination randomly chosen.

The contribution from 720kWp PV panels on all facades (approximately 6000 m^2) is 10.7 kWh/m^2 , which can be compared to the annual amount of electricity used for operation: lighting, fans, pumps and cooling of 7.0; 5.3; 0.2 and 0.9 respectively.

It is important to point out, that approximately 58% of the central district heating/cooling in Copenhagen is produced by green energy sources. Moreover, renewable resources produce also 50% of the Danish grid electricity. In total, taking in consideration the renewable aspect of electricity and district heating from the grid, 69% of the energy demand is supplied by renewable energy sources, resulting in a final energy consumption in the building of only 6.7 kWh/m^2 , equal to a level 2 in the Active House radar.

Sustainability

CIS is a good example of the Prosumer

building of the future – with BIPV on all facades and with a good architecture due to the special PV panels and architectural design.

And with about 39% of the total electricity use covered by the PV modules, it is a good example of an almost zero energy building, which also has a good score in the Active House labelling.

Input from: Peder Vejsig Pedersen & Miriam Sanchez Mayoral.

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MANAGEMENT

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Miriam Sanchez Mayoral

Kuben Management
<https://kubenman.dk/>



Creating a smarter smart meter

Most smart meters tell households how much energy they've used but do nothing to help them actually reduce that use. A new project led by Professor David Coley of the University of Bath aims to make smart meters smarter by providing practical advice on cutting consumption

The official UK smart meter network was switched on in November 2016 and since then smart meter devices have been installed in millions of homes across the UK. The government wants one in every household by 2020, which will cost several billion pounds to achieve. The question is, are they using the right technology or something way out of date?

A typical smart meter isn't so smart; it simply shows the amount of energy you are currently using and how much you have used over the past week. This will be presented in energy and money units. And that's about it. The device will not tell you what this energy is being used for or what actions you might take to reduce it. One thing is certainly doesn't try and do is make you understand your energy consumption.

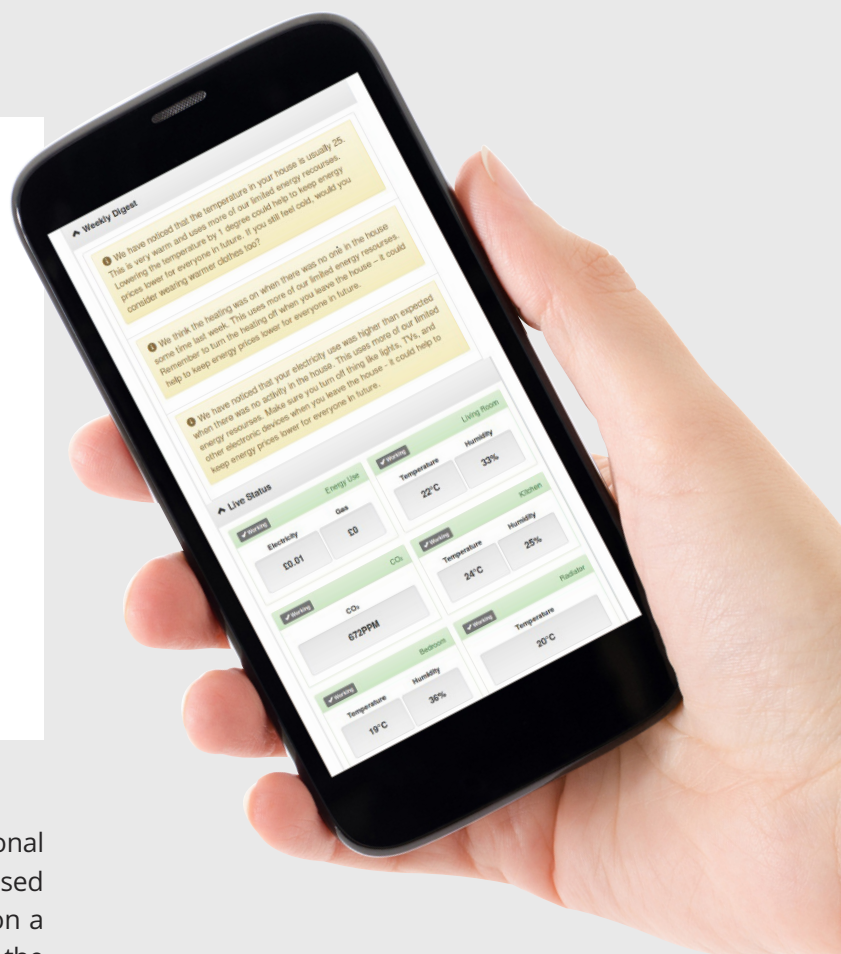
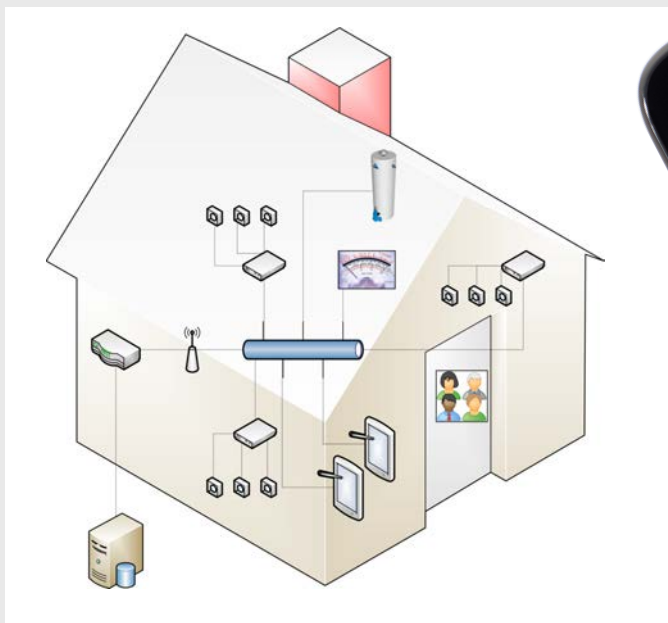
A team of engineers and psychologists led by Professor David Coley at the University of Bath, in partnership

with Exeter City Council, has spent the last three years designing a meter to do just that.

"...a survey showed the occupants became better consumers of energy by being more educated about where energy was being wasted in their homes."

The device, named ibert, monitors your gas and electricity consumption and the temperature in your home then offers advice in plain English sentences sent to your phone. Some of these are simple statements of fact, much like a normal smart meter; others go far deeper. For example: "I notice that your heating system turns off at 10am each morning, yet the house would seem to be unoccupied from 8am. Resetting the time clock might save you £89 per annum".

The first sentence in this example is potentially useful, but might well not engender change. The second sen-



tence is the clever bit, in that it gives a direct personal message. The message really is personal; it is not based on typical rates of heat loss from UK homes but on a mathematical model of the house in question, which the device generates for itself – including a prediction of what the home is made of. This model is very similar to the thermal model used by engineers when designing a large commercial building, except rather than the engineer entering the dimensions and constructions of the building, the device uses the data from its sensors and a lot of mathematics to reverse engineer the model.

The team tested the device in 47 homes and achieved an unprecedented 22% saving in gas consumption. In addition, a survey showed the occupants became better consumers of energy by being more educated about where energy was being wasted in their homes. It can even spot if windows have been left open far beyond that needed to provide good air quality, and tell you how much it is costing you to leave them open.

The researchers concluded that the whole smart metering project needs to be changed and technologies introduced that work with consumers, use up-to-date technology and a dash of psychology.

The findings of this study have been published in *Building & Environment* and was part of the ENLITEN project,

funded by the Engineering & Physical Sciences Research Council (EPSRC). The team's most recent paper from the work 'How smart do smart meters need to be?' can be accessed at <http://www.sciencedirect.com/science/article/pii/S0360132317304225> ■



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Using smart technologies to create more sustainable cities

Head of Smart Cities at the Environmental Industries Commission (EIC), Sam Ibbott, explains the use of smart technologies to create cleaner, greener and more sustainable cities

Cities around the globe exist in a state of perpetual flux, constantly evolving and growing exponentially. It's a well-worn fact that over 50% of the world's population now lives in cities (75% within the EU), with the newer category of 'megacity' being created for the world's largest urban metropolises.

But despite this constant change, the basic needs of a city and the underlying environmental challenges faced by city governments, remain constant: the need to efficiently move goods and people; tackle air pollution; manage energy demand; abate carbon emissions; collect and recycle waste; and to provide clean, accessible water. These are stubborn issues – and ones which only become more acute as populations and densities increase.

Hope, however, lies in technological innovation – that is unlocking new approaches and new solutions; ultimately improving our quality of life in ways not previously thought possible. At the Environmental

Industries Commission (EIC) – a trade association for the environmental technologies and services sector – we have been looking at this very issue. Can the latest smart technologies, the use of real-time remote sensing, the analysis of newly-available big data and the rollout of the 'Internet of Things' open up new, more efficient and more (cost) effective solutions?

Our research suggests so, but despite the potential of the nascent market which supports this innovation to unlock transformative change, it is not a market that is growing without challenge. One of the more major barriers our work has highlighted – is the lack of hard evidence that these smart solutions can work at a major scale – we hear lots of 'coulds' and 'shoulds', but fewer 'hads' and 'wills'. Just because an innovative technology works in laboratory conditions, it does not mean automatically that it will work across an entire city with a vastly increased number of variables – and this is a problem.



Sam Ibbott
Head of Smart Cities at the
Environmental Industries
Commission (EIC)

Cities, particularly in the UK, remain in a period of relative austerity. Money is scarce, and it is a gamble to invest potentially significant sums in untested technologies which may or may not work. This leads to a chicken and egg situation: with city authorities hesitant to unlock investment without any hard evidence, but with hard evidence not being created until a technology has been tested at scale.

EIC has established a taskforce to look at how this problem could be solved in a pragmatic way, drawing on the full spectrum of required stakeholders, including senior representatives from city and central governments, technology manufacturers, engineering consultants, universities, NGOs and others. The taskforce agreed that a central industry repository to promote case studies, share currently disparate best practice and help better match the cities facing these environmental challenges with cost-effective smart solutions would be beneficial for both local authorities and industry – and so this is what we have done.

Last year, we launched www.SustainableSmartCities.org. This free-to-access website is an industry-led resource to bring together and provide a central focal point for, all stakeholders involved in the use of smart technologies to create cleaner, greener and more sustainable city environments.

The site is used as a foundation from which to promote the accelerated growth of this industry through a series of targeted activities, including:

The provision of a platform for sharing international case studies and best practice – helping both industry and city leaders learn more quickly what works (and what doesn't) to underpin investment decision making.

Connecting people and encouraging collaboration, by acting as a neutral broker between parties – through

networking events, roundtables and seminars; and operating as the nexus between technology, cities, policymakers and academia.

Providing thought leadership, market intelligence and investment insight – including in-depth policy reports, briefings and blog posts by leading industry practitioners.

Pro-actively lobbying governments and policymakers – at both city and national levels – for a regulatory framework which supports and encourages innovation and its implementation.

In this way, we can learn how to better capture and use data about cities to improve the quality of life of their citizens – which should always be the purpose, after all.

To ensure our outputs continue to meet a self-defined industry need, we would welcome your engagement in this work. We have a series of outputs already planned for this year, including a seminar being organised in conjunction with the Association for Directors of Environment, Economy, Planning & Transport (ADEPT) on how smart tech can be used to save money; some thought leadership work on smart procurement; an innovation summit co-organised with InnovateUK; and a conference aimed at connecting CIO across from across the infrastructure sector. ■

If you would like to be more involved I would be delighted to hear from you at sam.ibbott@eic-uk.co.uk to discuss further how we can help.

Sam Ibbott is Head of Smart Cities at the Environmental Industries Commission, a UK-based trade association representing the environmental technologies and services sector.

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Milestone: The first all-electric refuse collection vehicles

New Geesinknorba RCVs totally powered by batteries to save money, save the planet and save lives

When health experts warn of the number of lives being cut short every year because of emissions from diesel engines, the pressure to find an alternative is intense. Enter lithium-ion battery power.

Mick Hill, UK Business Director of refuse collection vehicle (RCV) manufacturer Geesinknorba, explains: "The whole industry is looking for alternatives and battery-powered vehicles are the solution most manufacturers are after, but Geesinknorba is well ahead of the field."

"While the weight and space of batteries are significant, battery-powered vehicles do not need heavy diesel engines, AdBlue tanks, fuel tanks or the weight of liquids they contain. Our GPMIV body was also designed with energy efficiency in mind, making it as light as possible without compromising strength or durability. All these contribute to making the vehicle totally viable in urban environments."

The company makes a range of RCV bodies in different sizes and configurations that can be mounted on to chassis of any other manufacturer. They also make the lifts required to empty wheelie bins into an RCV's hopper. But since 2006, it has been producing electric-powered vehicles – at first, hybrids – where just the bodies and lifts were battery-powered.

"As battery technology developed, we introduced much more efficient lithium-ion batteries – our 'Li-On Power' – in 2015," says Mick Hill.

"It has been tried, tested and proven in efficiently powering the lifting, compacting and tipping mechanisms of our hybrid vehicles. But now, we have developed the next stage – the 'Li-On Power Pro' – in which lithium-ion batteries mounted on the chassis power the whole RCV with no diesel engine required. It's a huge milestone, a world's first. And it's ready to go."

Geesinknorba estimates that a typical, conventionally powered RCV will consume around 70 litres of diesel a day, leading to the annual emission of 52 tonnes of CO₂, 160kg of CO and 380kg of NO_x gases. In comparison, the all-electric vehicle produces zero emissions. Instead, its batteries are charged by electricity which operators could take from entirely renewable sources.

This leaves the running costs at around a tenth of a traditional diesel vehicle. In addition, electric vehicles hardly produce any noise, making them very useful for operators collecting early in the morning or later at night.

"The main selling points of all-electric vehicles are their green credentials and the low operational costs," explains Mick Hill.

Image: © John Morley



Mick Hill

"Zero emissions and much-reduced noise speak for themselves. But, in terms of costs, not only does this vehicle offer massive fuel savings, but also fewer parts to go wrong, introducing the potential for further savings in maintenance and repairs.

"We've tested a vehicle in collaboration with a chassis partner in Spain with great success. It's due to be delivered to a UK customer this spring. And a second vehicle will soon be delivered to another UK customer after collaboration with a different chassis partner."

The all-electric RCV has been designed for urban environments which characteristically have short journeys between collections and shorter overall routes. An increasing number of towns and cities in the UK are introducing low emission zones to which the vehicle is consequently well suited.



And their very quiet operation introduces the possibility of another benefit as extending the working hours of vehicles in urban areas can also reduce fleet size and capital expenditure.

“The main selling points of all-electric vehicles are their green credentials and the low operational costs.”

“How a vehicle is used will determine precisely how long it can run between recharges, but it has enough battery power to cover a typical day’s urban collections on a single charge,” says Mick Hill.

“While the weight and space of batteries are significant, battery-powered vehicles do not need heavy diesel engines, AdBlue tanks, fuel tanks or the weight of liquids they contain. Our GPMIV body was also designed with energy efficiency in mind, making it as

light as possible without compromising strength or durability. All these contribute to making the vehicle totally viable in urban environments.”

Of course, the limiting factor for electric vehicles has always been the range, so what of longer, non-urban rounds?

“Over longer routes, they still need recharging which makes them less practical, so, for now, our hybrid vehicles offer a better solution in longer, rural rounds, powering the body and lifts with lithium-ion batteries to reduce emissions and cut operational costs,” says Mick Hill.

“But there is a huge amount of R&D going into battery technology and efficiency will improve to the point where all-electric RCVs will be able to operate all day over the longest routes – without stopping for a recharge.

“The whole waste and recycling industry is confident of that because the incentives could not be clearer.”



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Sustainable aviation fuels, the next frontier for air transport

Michael Gill, IATA Director Aviation Environment imparts his expertise on sustainable aviation fuels and why he believes these are the next frontier for today's air transport

Air transport is going through an astonishing period of growth. Ten years ago, there were 2.5 billion passengers' journeys a year. In 2017, there were more than 4 billion. In 20 years' time, we anticipate the number will have almost doubled, to 7.8 billion. Each new journey offers opportunities to open up new business markets, generate social and educational possibilities, bring far-flung families and friends together and provide a chance for people to explore and understand our wonderful, diverse world.

But such growth in air transport brings a huge environmental challenge – one that the industry is aware of and planning for. A decade ago, the aviation industry set out clear goals for carbon emissions, including carbon-neutral growth from 2020 and to cut CO₂ emissions in half by 2050, compared to 2005 levels. Behind these goals lies a comprehensive four-pillar strategy, encompassing new technology and operations, better infrastructure and a global carbon offset and reduction scheme (called CORSIA), which is scheduled to come into effect in 2021.

One of the key components of the technology pillar is sustainable aviation fuels (SAF). These offer an exciting path to carbon reduction, potentially cutting emissions by 80% over the carbon lifecycle compared to conventional jet fuel. Progress on using SAF has already moved faster than many predicted. In the 2000s, when the aviation and carbon debate began in earnest, many experts felt that SAF flights wouldn't happen before the mid-2010s. In fact, the first SAF flight occurred in February 2008, when a Virgin Atlantic 747 flew a test flight from London to Amsterdam.

In the decade since, a number of airlines have conducted test flights that have ensured several different

types of SAF – everything from algae to jatropha plants, to municipal waste – can now be turned into certified aviation fuel. In recent years, sufficient amounts of SAF have become available that some airports, notably in Norway and Australia and several airlines, such as Cathay Pacific, United and KLM, have been able to secure a continuous supply, albeit for the time being in limited quantities.

The result of all this work has been that the number of flights using a SAF-JetA1 blend has moved from 1 in 2008, to 100,000 in 2017 and we hope to reach 1 million flights in 2020. But this is just the start. The next step is to move into large-scale production in order to create a lasting and increasing reduction in aviation's carbon emissions.

This is where public policy becomes crucial. Biofuels for the automotive sector have long received encouragement or even outright subsidy from the public sector to incentivise production. It is now high time that SAF is put on the same pedestal. This is all the more crucial as aviation, unlike automotive, has no alternative to liquid-energy fuels in the short-medium term. Hitherto, fuel refiners have not had sufficient incentive to generate aviation fuels at price levels the industry could afford.

Why should they, when the policies encouraged them to go for automotive biofuels? Slowly, this is changing. In the United States, policies exist to ensure that a proportion of alternative fuels refined must be for aviation use. And in Europe, the Renewable Energy Directive is being revised. Already the European Parliament has indicated that aviation biofuels should be encouraged. Now we're urging the European Commission and the European Council to agree to this enhancement.

In addition, globally we are calling for measures including:

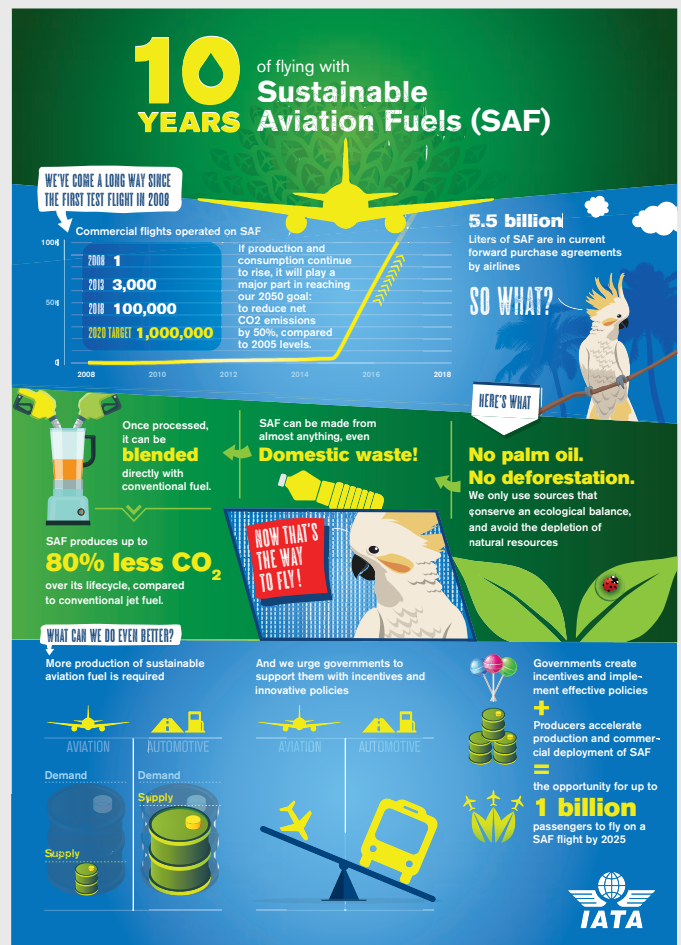
- Implementing the policy to de-risk investments into SAF production plants, including loan guarantees and capital grants for production facilities;
- Support for brokering aviation off-take agreements;
- Support for SAF demonstration plants and supply chain research and development;
- Tax incentives for public-private partnerships for early-stage plant development and;
- Developing a harmonised transport and energy policy including inter-department coordination, such as agriculture, transport, energy and military.

We recognise that in the past, the biofuel sector has not been without controversy. First generation automotive and biomass fuels were criticised for encouraging deforestation or promoting agri-monoculture. Fortunately, lessons have been learned. Most aviation biofuels are certified by the Roundtable on Sustainable Biomaterials.

“In the United States, policies exist to ensure that a proportion of alternative fuels refined must be for aviation use. And in Europe, the Renewable Energy Directive is being revised. Already the European Parliament has indicated that aviation biofuels should be encouraged. Now we’re urging the European Commission and the European Council to agree to this enhancement.”

Even more importantly, following unanimous adoption of a resolution at the 2017 IATA AGM, the aviation industry is, in the words of our Director General and CEO Alexandre de Juniac: “Clear, united and adamant that we will never use a sustainable fuel that upsets the ecological balance of the planet or depletes its natural resources.” We are in a process of defining new sustainability criteria for SAF to understand how it might play a role in the CORSIA scheme, which would be a big fillip for SAF take-up if it were approved.

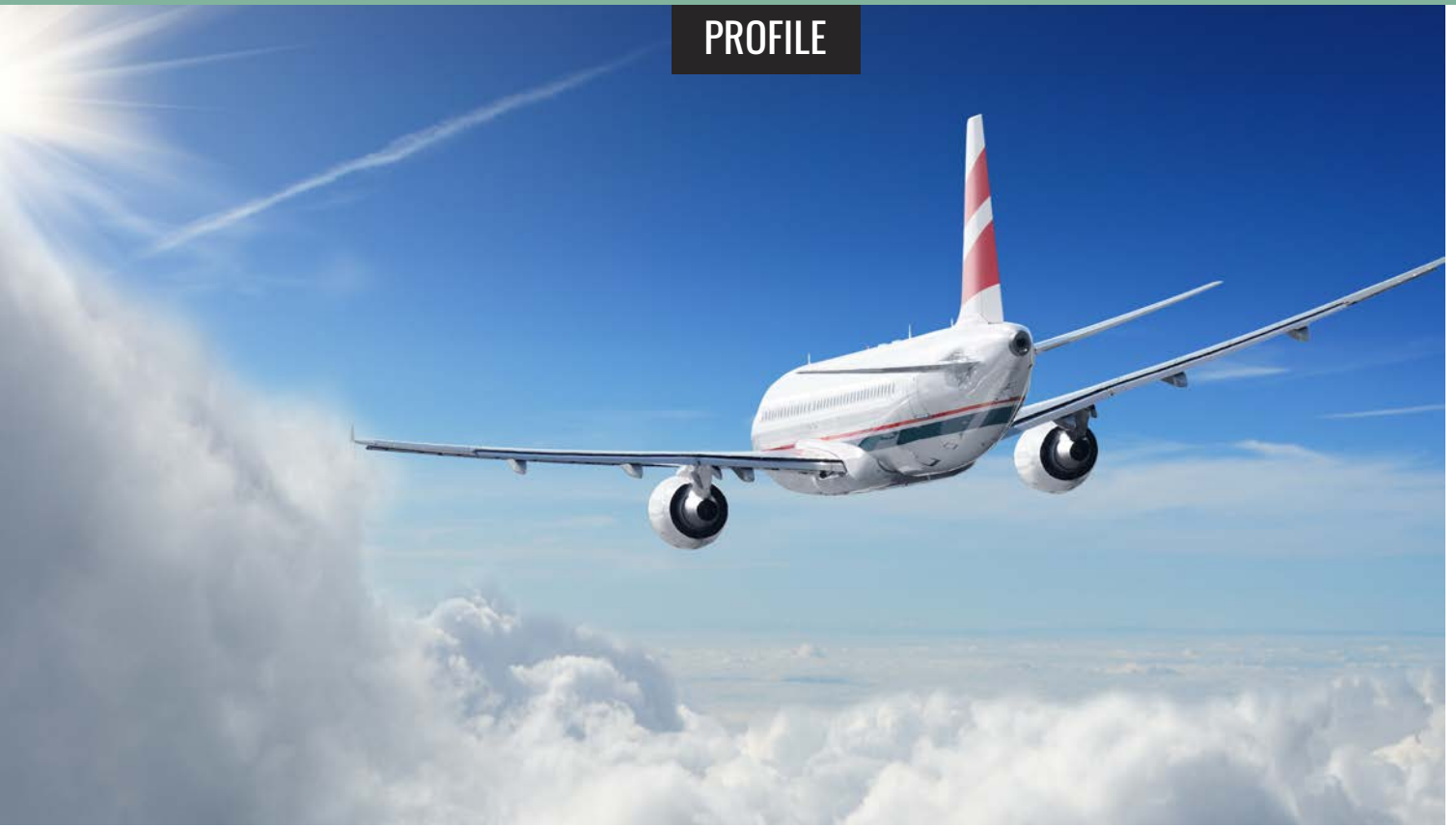
If policies can be aligned to ensure aviation biofuels get a fair chance, then we believe it is possible that 1 billion



people would have the opportunity to fly on a plane powered by a mix of traditional jet fuel and SAF by 2025. That is a fabulous prize to aim for.

Sustainability is the next great frontier for the industry. But aviation has a history of taming frontiers – and for providing opportunities for people to explore their own personal frontier, whether for work or pleasure. We are confident that with the correct policy support, we can continue that great tradition. We all owe it to future generations, who expect to fly and expect to do so with minimal impact on the planet. ■

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Technologies for future aircraft designs

University of Bristol's Jonathan Cooper describes a range of technologies that could be used in future aircraft designs, to enable optimum performance and reduce the impact on the environment

Aircraft are currently designed for one type of mission, for example, short or long range and are, therefore, sub-optimal when used for different route lengths by the airlines.

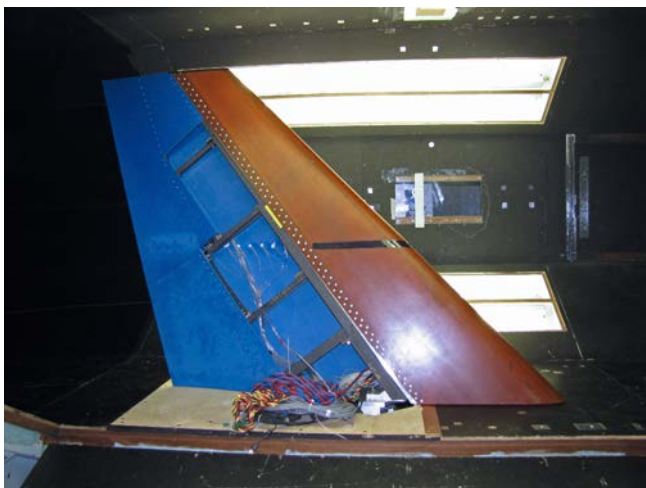
When the Wright Brothers became the first people to achieve controlled powered flight in 1903, their aircraft were steered by "warping" the wings, that is changing the twist along their length, by using a mechanism with which the pilot, who was lying down, commanded by moving his body to one side or the other. The control of the aircraft using a slow rolling motion – one wing up and the other down – was the key to the success of the Wright's aircraft.

Other developers of early aircraft were forced to find a different way of controlling aeroplanes and consequently, the technology moved towards the use of control surfaces (the movable parts that can be seen on the rear parts of wings and tail structures) that are used on today's aircraft.

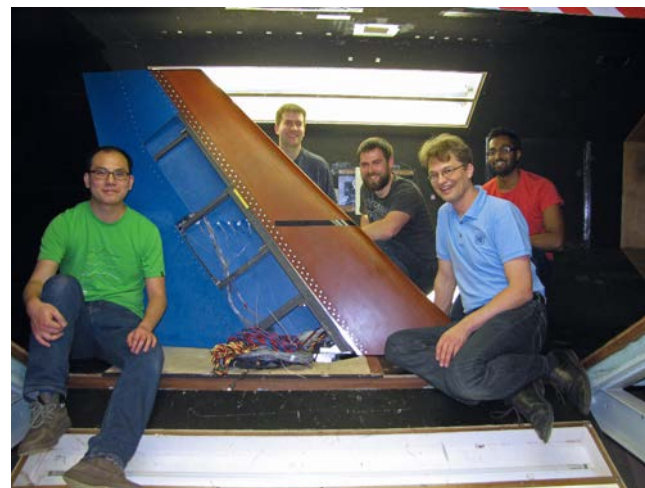
All commercial jet aircraft are currently designed so that they have the optimal fuel burn for the mission that they are designed for, primarily considering how many passengers they will carry over what distance. If aircraft are used in a different way, for example, by carrying less passengers over a shorter distance – then they are not going to be as environmentally friendly.

Over the past 30 years, a range of technologies have been developed that can enable aircraft to attain the optimal wing shape, or even change shape, for the least possible fuel burn throughout the entire duration of each flight. This technology is often referred to as "morphing"¹ and it can be categorised into two main types:

Planform morphing – where the entire shape of the wing (as seen looking down on the whole aircraft) can change in flight, which is useful when the role that the aircraft is performing is changed. An example of this is the Tornado military aircraft where the wings are kept almost straight for speeds below the speed of sound,



Wind Tunnel Model with a Morphing Leading Edge



Researchers from University of Bristol UK and DLR Germany pictured with the Wind Tunnel Model

whereas when a supersonic flight is required, the wings are swept backwards to reduce the drag that slows that aircraft down.

A further example is the use of telescopic wings, for example, for a search and rescue drone because it is beneficial to keep the wing span (i.e. their length) as long as possible so that the fuel burn is kept to a minimum, whereas if wreckage was spotted in the sea, the drone would need to become more manoeuvrable and this could be achieved by reducing the wing span. NextGen Aeronautics have developed and demonstrated several designs that enable total planform morphing, including span, chord and sweep².

Performance morphing – where the chordwise (i.e. in the direction of the airflow) wing twist and camber are changed so that the aircraft performance is optimised in flight to reduce the fuel burn. This approach is particularly effective for aircraft which are being used for missions, which are not the same as for which they are designed, for example, by flying from London Heathrow to Brussels which is a very short flight. Recent examples of research in this area include the development of morphing leading edges³ (the front of the wing) and morphing

wing tips⁴ (the end of the wings) whose shape can be adjusted to ensure optimum aerodynamic flow over the wing at all points during a flight.

“Over the past 30 years, a range of technologies have been developed that can enable aircraft to attain the optimal wing shape, or even change shape, for the least possible fuel burn throughout the entire duration of each flight.”

Most of the above morphing designs can be achieved without the need for exotic new materials and devices. The one area that still needs to be completely solved is the development of a morphing skin capable of large changes in size – whilst still being able to carry loads in all directions. The space, weight and power requirements for the morphing mechanisms need to be far less than the aerodynamic benefits that they bring and there are the safety considerations that must be contemplated for all new technologies used for aerospace structures. Due to the above issues, it is likely to be many years before morphing become commonplace on the aircraft that we fly in on a regular basis, but we are likely to see their use on much smaller aerostructures in the near future.

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Upgrading the UK's railway infrastructure

The role of Network Rail in upgrading the UK's railway infrastructure in England, Wales and Scotland is detailed here by Open Access Government

Network Rail operate and own the UK's railway infrastructure in England, Wales and Scotland. In total, that's an astonishing 20,000 miles of track, 40,000 bridges and viaducts and thousands of signals, tunnels, level crossings and points. They also manage rail timetabling and 19 of the largest stations in England, Scotland and Wales. Network Rail work tirelessly to ensure a safe and reliable experience for the users of the railway.

When it comes to improving the UK's railway infrastructure, Network Rail is spending £130 million every single week on improvements for passengers through the [Railway Upgrade Plan](#), including maintaining and renewing Britain's 20,000 miles of track. Due to this, there will be an additional 170,000 passenger seats into major UK cities throughout the country daily by 2019, a clear sign that the country's railways are on the up. This encouraging development will ensure the provision of 6,400 extra train services and 5,500 new carriages, both of which are said to represent a 30% increase in capacity.

According to Network Rail, journeys will be quicker, trains will run more frequently, and things will be more comfortable for passengers. This ambitious plan to upgrade the UK's railway infrastructure is said to be the biggest programme of rail modernisation since the Victorian era. It's therefore not surprising that the next five-year funding period, 2019-2024, Control Period 6 (CP6), represents a significant infrastructure investment programme by Network Rail.

In March this year, Network Rail issued a Prior Information Notice (PIN) via The Official Journal of the European Union (OJEU) process for a tender exercise concerning the next generation of track works contracts, valued at up to £5 billion over a period of 10 years,

commencing, of course, in 2019. These contracts are expected to cover the design, development and delivery of plain line and switches & crossings, plus associated infrastructure works.

Owing to the long-term and large-scale character of the contracts, it will be crucial for potential bidders to demonstrate their commitment to delivering value through the relentless pursuit of highly innovative approaches and excellence in their work, not to mention a demonstrable track record of success in collaborative environments.

Commenting on these recent developments, Network Rail's director for track, Steve Featherstone, says: "This tender represents a major milestone in the development of our strategy for our track infrastructure investment programme. It also represents a significant commitment by Network Rail to the rail industry and we are expecting high levels of interest in these contracts from the supply chain. In return, we will be looking for clear and firm commitments from the supply chain to deliver value for Network Rail." ⁽¹⁾

As part of Network Rail's strong commitment to improving rail infrastructure in the UK, we find out in early April about the 400 railway projects completed successfully during the Easter 2018 weekend, thanks to a 15,000-strong workforce. One of the projects concerns Manchester Victoria being closed so that the old track is replaced, and to lower the track under Cheetham Hill Road bridge, as part of Manchester to Stalybridge line speed improvement upgrade.

Another, involves the continuing works on the Preston to Blackpool North line, an upgrade that involves rebuilding 11 bridges, remodelling 11 station platforms, replacing 11km of track, plus installing 84 new signals



and upgrading drainage. Also, the South East route had improvements to the Sevenoaks tunnel in Kent made, bringing new signalling equipment into use through Mitcham and Sutton, as well as laying down the new track between New Cross and Norwood Junction. ⁽²⁾

Bringing these exciting infrastructure developments up-to-date, we know that a 32,100-strong workforce will be working hard over the two 2018 May bank holiday weekends, to help deliver a more reliable rail infrastructure, not to mention improved services and facilities for passengers. As such, Network Rail is reminding passengers to bear this in mind, as 822 projects are delivered as part of the ambitious Railway Upgrade Plan.

Mark Carne, chief executive at Network Rail comments on these planned improvements: "This huge investment programme will provide faster, better services and help relieve over-crowding to respond to the huge growth on Britain's railways. While most of the network is open for business as usual, some routes are heavily affected and so we strongly advise passengers to plan ahead this May." ⁽³⁾

The future for rail infrastructure is, therefore, an optimistic one, as these recent efforts of Network Rail

illustrate, in that they most certainly: "Work round-the-clock to provide a safe, reliable experience for the millions using Europe's fastest-growing railway each... day." Added to this, they are: "Delivering the biggest and most ambitious upgrade our network's seen in over 150 years." ⁽⁴⁾ ■

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Asset management in rail: Making the right decision

Marcel van Velthoven from ZNAPZ and Frans van Helden of ORTEC explain how to optimise business results for the rail industry by means of asset management to make the right decision

Asset management is optimising the performance of your assets against business objectives, over the lifetime of the assets, while minimising cost and risk. This requires that management must make thousands of decisions, all the time, quite a challenge a) to make the right decision and b) to prove to the stakeholders that the right decisions have been taken. Fortunately, modern IT does offer good support for this day to day challenge.

Asset investment optimisation

Decisions are often taken based on a single business case, does this solve a problem and is there a positive ROI. However, companies and in particular rail companies have complex structures and many decisions to take.

Decisions with many variables that are not able to be caught in a single business case. How can management take the right decisions? This can only be done with the right algorithms in place and based on the right set of data. How this works is described in the following paragraphs.

The value framework

The first step in asset management is aligning your assets with the strategic business plan. What are the objectives of the organisation? How many passengers will we transport, how much cargo, what are the main lines and what are secondary lines? What is the punctuality target and what is an acceptable travel time? Just a few of



the objectives a rail organisation have. Of course, legislation, health, safety and environment targets have always to be met. These should be the basis of the value framework the rail organisation should define and manage its performance. When the value framework is defined, the organisation needs to look at its assets.

Rail assets

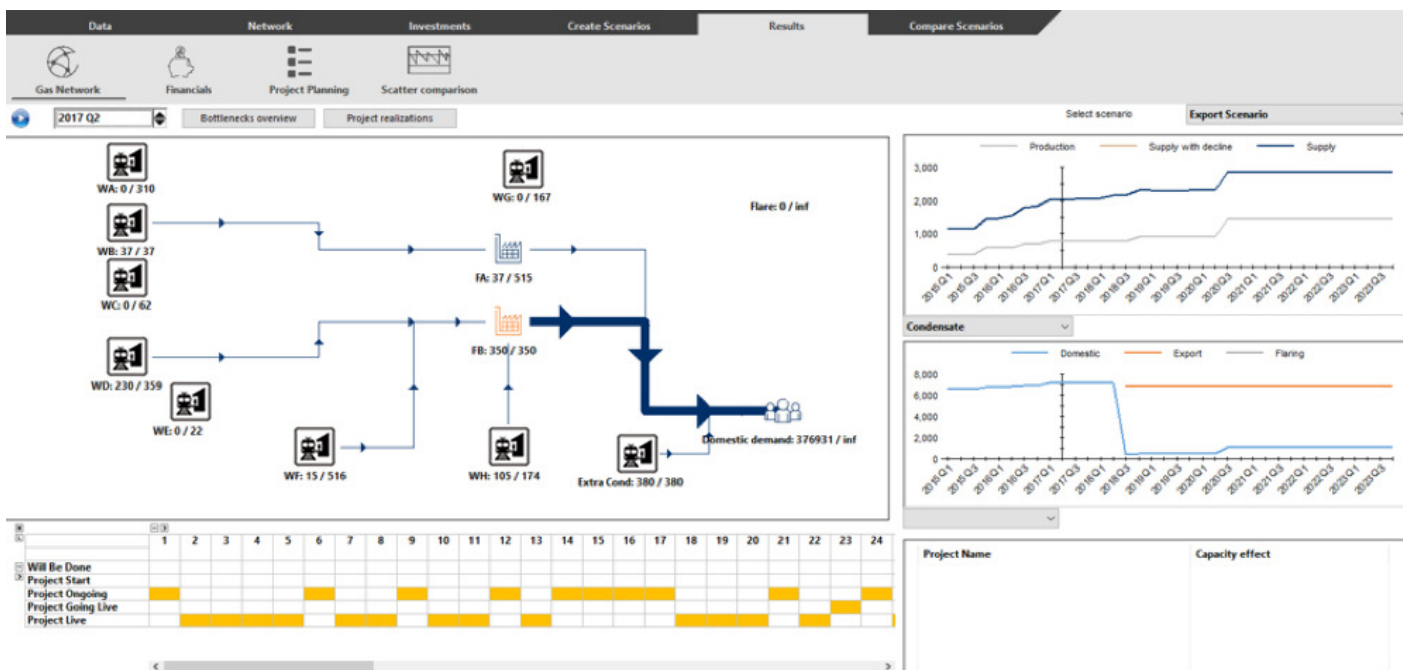
One of the characteristics of a rail organisation, which makes it different from other organisations is the obligation to deliver. A second one, the ageing of the assets. Often the decision to build or maintain a railway between two places is taken a long time ago and difficult to alter even when the demography has changed significantly. When a line is installed, it becomes part of the status quo and the rail infrastructure organisation must maintain the line to operate it safely. At the same time, railways

have long-lasting assets, not only the track, but also bridges, tunnels, etc.

On top of this, there are switches, power lines and signalling systems. What is the status of these assets and what maintenance is required and when should those assets be made available and reliable? Adding to these questions is often the lack of data available to assess the actual asset health and with this, the risk of asset performance. Asset investment optimisation is strongly dependent on the right data. Building up a reliable asset register, an overview of all rail assets is a significant task and should be started as soon as an organisation decides to adopt asset management.

Rail data

When the asset register is built, and processes have been implemented to maintain, the asset register the second



step in the maturity programme can be taken. This is: define, gather and maintain rail data. The rail data will tell the organisation about the asset health, based on rail usage and other variables. With this information, a better assessment can be made of the risks of the asset, another important element of asset management today. Many if not all rail organisations, have not yet defined a reliable data set to fully assess the asset health. The coordination of this could, therefore, help all rail organisations to have a much better insight.

Rail maintenance

With the asset register and asset data becoming more or less accurate, the organisation can then start to define what maintenance is required of its rail network. Now the optimisation question comes into place. What are the variables, timing, alternative assets, etc.? How the best decision be made with the available resources? Where are the resources: the available budget, the people to execute the job and the availability of the network during a given period and of course the materials? If this is not complex enough, changes in the network,

removing switches, adding new lines and other investment requirements makes this decision a challenge, indeed not many asset managers are able to make these without proper tools. Also, the risk appetite and available budget are key elements that affect the decision.

The RAIO tool

The solution is the Rail Asset Investment Optimisation tool. ZNAPZ and ORTEC, both IBM business partners have based on their individual strengths, developed over the last two years a specific and unique optimisation tool that takes in account the asset risks of a rail network, supports linear assets, network planning and enables a rail organisation to perform their asset investment optimisation.

ORTEC is one of the largest optimisation companies in the world, with proven asset optimisation projects, e.g. in the oil & gas industry, but also optimisation of passenger schedules in the rail world with ProRail. ZNAPZ is IBM's specialised ISO 55000 partner with in-depth knowledge of the rail industry and rail customers around the world for both infra and rolling stock.

The unique parameters of the tool are the integrated solution to make a decision on the real asset health, taking into account both asset risk and performance. It enables rail organisations to analyse against unlimited risk patterns and budgets. Of course, simulation is supported and full visibility of the consequences of each of the selected scenario's. The tool is being developed supported by several rail organisations and with an interest from rail organisations in Europe and the Middle East.



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Are electric luxury vehicles on the brink of technological evolution?

Automakers focus on sophisticated tech integration to create superior in-car luxury experiences and deeper customer engagement, argues Research Associate from Frost & Sullivan, Pooja Bethi

Autonomous, Connected, Electric and Shared (ACES) is the new mantra transforming the mobility industry. Taking up the chant, premium automakers are focusing more than ever on electric vehicles (EVs) to combat rising pollution levels and stringent emission norms.

The EV luxury space is on turbo-charge and rapidly outpacing its internal combustion engine (ICE)-powered counterpart owing to the transformative impact of the ACES trend. Premium brands such as JLR, Volvo, BMW, Mercedes, the VW Group and Cadillac are introducing various plug-in hybrid EVs (PHEVs) and battery EVs (BEVs) in their lineup.

By 2025, about 50 PHEVs and 25 BEVs will be introduced by luxury or premium car manufacturers. Frost & Sullivan analysis projects that the luxury EV market will experience a compound annual growth rate (CAGR) of 28.3% in the time frame of 2017 to 2025 and realise sales of about 1.8 million units by 2025 in Europe and North America alone.

So how will the ACES trend shape the future of the luxury EV industry? What will be its impacts and implications?

Autonomous technologies will be highly compatible with EVs, with the high power required by autonomous technologies being supplemented with bigger battery packs. Moreover, flat-battery packs, like those of Tesla's, will be an added advantage in achieving higher levels of autonomy as they open up cabin space, enabling improved in-car experiences and superior driving dynamics and performance. Lightweight seats that can rotate 180°, retractable steering wheels, panoramic views, moving control panels that adjust to the passenger's position, wrap-around displays, bigger screens and

premium eco-friendly interior materials will change the dynamics of a traditional car experience.

Wireless charging is another hot trend with a slew of luxury car manufacturers including Mercedes, BMW and Audi planning on featuring static wireless charging on their upcoming PHEV models. Dynamic wireless charging is expected to revolutionise autonomous luxury EVs by enabling a seamless journey without having to stop for a charging station. The challenge here will be to promote the large-scale deployment of charging station infrastructure and ensure that charging occurs optimally during transmission.

With electric drivetrain becoming increasingly standardised, human-machine interface (HMI) will emerge as a key differentiating factor in the strategic arsenal of luxury EV car manufacturers. The EV cockpit is expected to undergo massive changes over the next five years: AI-based applications, telematics, the Internet of Things (IoT) and vehicle-to-everything (V2X) communication will be crucial elements on which consumer decisions will pivot.

Augmented head-up display (HUD) with interactive EV display elements such as dynamic maps of charging stations, virtual information on battery charge and range, EV-specific eco route and free EV parking zones will become the norm. Leveraging AI and predictive analytics will improve overall range through the optimisation of battery use. Clutter-free, simple, highly energy efficient and lightweight user interfaces (UIs) will be designed exclusively for EVs.

Another trend that will transform the luxury EV market is the changing perspective on vehicle ownership. Newer business models are expanding beyond the

traditional product-centric approach to focus on the overall customer experience. Subscription-based models are being touted as the next big thing where customers can opt for different EV models – long-range EVs for long distance travel and smart cars for intercity commuting – based on their needs. Such flexibility will be attractive for future luxury EV customers.

“By 2025, about 50 PHEVs and 25 BEVs will be introduced by luxury or premium car manufacturers. Frost & Sullivan analysis projects that the luxury EV market will experience a compound annual growth rate (CAGR) of 28.3% in the time frame of 2017 to 2025 and realise sales of about 1.8 million units by 2025 in Europe and North America alone.”

The automotive industry is in the midst of another tectonic shift: from a narrowly defined, product-centric approach to the concept of mobility-as-a-service. The BMW-Daimler collaboration for car sharing, ride-hailing, parking locator and EV charging services is indicative of this trend. The objective here has been to create a unified digital ecosystem that accelerates the transition from private car ownership toward multimodal mobility use. This move not only ensures that these two mobility powerhouses complement each other in the creation of this future mobility ecosystem for their combined consumer group but also shows that conventional notions of vehicle ownership are becoming obsolete.

Impact of ACES on luxury retail strategies

Unlike a conventional car purchase, EV consumers need to be educated about an array of related issues ranging from the technology that underpins an EV to the dynamics of battery charging. Vehicle manufacturers, therefore, need to reinvent their retail strategy to accommodate newer business models and develop favourable consumer experiences around a luxury EV. They need to enhance the customer purchase journey through a targeted strategy that integrates retail paradigms with the relevant technical support. For instance, digital stores and retail formats such as pop-up stores that leverage virtual reality and augmented reality technologies will improve consumer understanding of EVs and facilitate the purchase experience.

Importantly, vehicle manufacturers also need to create an ecosystem that supports an EV-centric consumer lifestyle. This would mean not only providing the physical product, but also diversifying into complementary premium products and services in collaboration with third-party vendors from different verticals. In other words, it will become essential to look beyond solely the product to develop a high-quality customer experience that promotes a sustainable transition to luxury EVs and drives competitive differentiation.

For example, Tesla has not only disrupted the luxury EV industry but owns all the aspects of the ecosystem, from in-car software systems, batteries and other components, to charging infrastructure (home and destination), utilities, pre-owned car services and autonomous tech software. This ensures that they can provide a 360° holistic solution, while others depend on external suppliers for end-to-end solutions.

Overall, evolving dynamics will push OEMs to innovatively integrate services and experiences to transform the entire luxury EV ecosystem. ■

For a more in-depth analysis on the future of luxury electric vehicle market, please see our recent research on [Future Trends in the Luxury Electric Vehicle Market in North America and Europe, 2016–2025](#).

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