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HEALTH ANALYSIS

ADJACENT GOVERNMENT | September 2015

INNOVATIVE SOLUTIONS

Helping to tackle today's healthcare challenges

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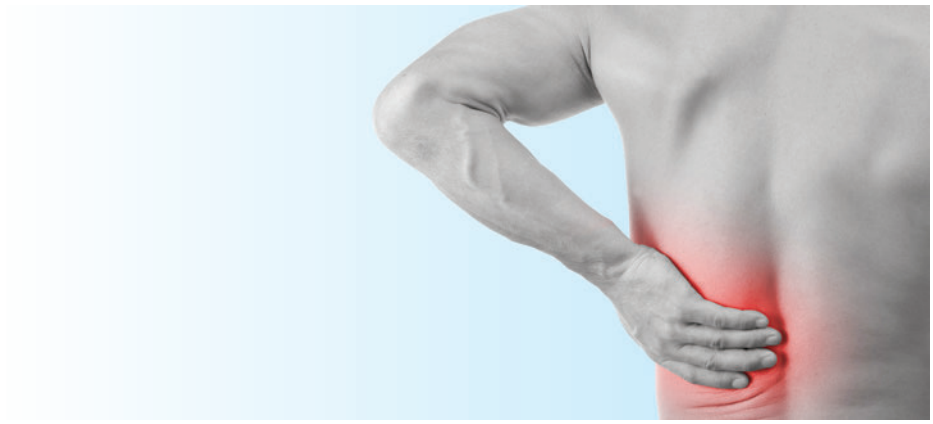

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The clinics expertise in nursing and its wide range of therapies are complemented by social and psychological support services, legal services, professional integration measures, trial accommodation opportunities and a number of other services.

The Balgrist

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Innovative solutions for healthcare challenges

European Commissioner for Health and Food Safety, Vytenis Andriukaitis spoke at eHealth week in Riga about how digital applications are integral to tackling today's health challenges in Europe...

When I started as a practising medical doctor, we kept hand written health records and had face to face consultations. There was no other way. But this has been changing ever since. Digital applications and digital solutions are part of our daily lives – including in the area of healthcare.

It is now common for health records to be kept electronically. Patients' health information can be shared between health professionals in no time regardless of geographic location.

Remote consultations with a doctor over the Internet facilitate access to care, save resources and pave the way for telemedicine and tele healthcare services across and within borders.

eHealth products and services are contributing to prevention, health risk management, and thus to more sustainable healthcare. It also generates income and jobs, while offering high-level technology solutions to healthy people, patients and doctors.

eHealth also creates many possibilities for overcoming today's challenges in Europe's healthcare sector.

First, there is an increase in health risk factors such as alcohol, smoking, malnutrition which are badly managed, thus causing chronic diseases and premature deaths due to the lack of prevention.

Second, the number of people with chronic diseases is predicted to continue to rise which will put even more pressure on healthcare services. Already today, the costs of chronic diseases account for 70-80% of total healthcare costs in the EU.

Third, another challenge is Europe's ageing population. The Europeans aged over 65 years already represent 17% of the total European population. This number will nearly double by 2060.

All of these challenges scream for innovative solutions – eHealth can offer them.

eHealth can empower people with risk factors and patients – we have to act in both cases.

"With the establishment of the eHealth Network, Member State authorities can take the lead in Europe's activities on eHealth. I have no doubt that the eHealth Network will continue fulfilling its mission to the maximum."

There is huge potential in using eHealth tools to help prevent diseases and to promote good health.

New solutions such as mobile health apps can enable people to actively engage in their own health management for instance by tracking their fitness or by monitoring their health status. Apps can invite people to take part in screening programmes or inform about promotion campaigns.

These solutions are already becoming increasingly popular and the market for them is growing rapidly.

Of course, this requires a shift how we organise healthcare systems, to focus more on prevention and promotion, rather than on cure.

And, it poses regulatory and other challenges. It is not easy to find the right balance between quality, safety and confidentiality issues and maintaining sufficiently low barriers for innovation. Indeed, this is a dynamic

Vytenis Andriukaitis, Commissioner for Health and Food Safety

market where we need to support European SMEs and start-ups.

In this context, the European Innovation Partnership on Active and Healthy Ageing plays a defining role in pushing for innovative solutions from idea to market, and to deployment across Europe.

The Partnership is bringing new solutions to practice, helping millions of EU citizens to continue to lead healthy, active and independent lives as they grow older.

The Partnership is also contributing to the sustainability of our health and social care systems. It is creating new opportunities for businesses in eHealth and the broader silver economy.

It is the right momentum and scale-up such innovative approaches to serve citizens in ever greater numbers.

To succeed we need to exploit and incorporate technological developments into our healthcare systems and improve their interoperability.

I am keen to ensure that the Commission is monitoring the functioning of health systems in the Member States including the implementation of eHealth applications. This will enable us to identify and – where appropriate – recommend actions.

I also believe that thanks to eHealth there is a scope to further integrate primary and secondary care in securing early diagnosis and timely treatment.

Health promotion through eHealth tools offers a cheaper solution to prevent or to manage chronic diseases.

Already, in many parts of Europe, diabetic patients are monitoring their blood sugar, transmitting the information electronically to their doctors. The care for their condition is ensured with less effort and at lower cost.

We at the Commission are convinced of the benefits of eHealth. We are already providing funding opportunities under Horizon 2020 to support research, innovation and cooperation. It also includes targeted measures to support innovative SMEs.

With the establishment of the eHealth Network, Member State authorities can take the lead in Europe's activities on eHealth. I have no doubt that the eHealth Network will continue fulfilling its mission to the maximum.

"New solutions such as mobile health apps can enable people to actively engage in their own health management for instance by tracking their fitness or by monitoring their health status. Apps can invite people to take part in screening programmes or inform about promotion campaigns."

It has already adopted the Patient Summary guidelines to provide continuity of care and patient safety across borders, and the Guidelines on ePrescription to facilitate the interoperability of electronic prescriptions between Member States.

This is a critical step forward – patients will benefit from an electronically processed prescription and get the medicine they need when travelling within the EU.

A new Joint Action on eHealth – funded by the EU Health Programme – will be launched to provide technical and scientific support to the eHealth Network.

Last but not least, the Commission has launched the new Digital Single Market Strategy.

This Strategy includes a set of key actions which will be taken at EU level in the coming years to complete the Digital Single Market.

Some of these actions, such as reinforcing trust and security in the handling of personal data; actions related to interoperability and standardisation; and supporting an inclusive eSociety, are of particular relevance for eHealth.

I am no techie but it is clear to me that we must seize the Digital Single market opportunities to fulfil a vision for healthcare in the 21st century – a vision of a single, universally accessible, sustainable and high quality, eHealth single market for the benefit of all European citizens and healthcare professionals.

By coming together and by sharing experiences in the Member States and at EU level, we will drive forward the case for eHealth. ■

This is a speech from eHealth week in May 2015, taken from European Commission website and republished with the permission of the Commission – http://ec.europa.eu/commission/2014-2019/andriukaitis/announcements/speech-ehealth-week-riga-2015-0_en .

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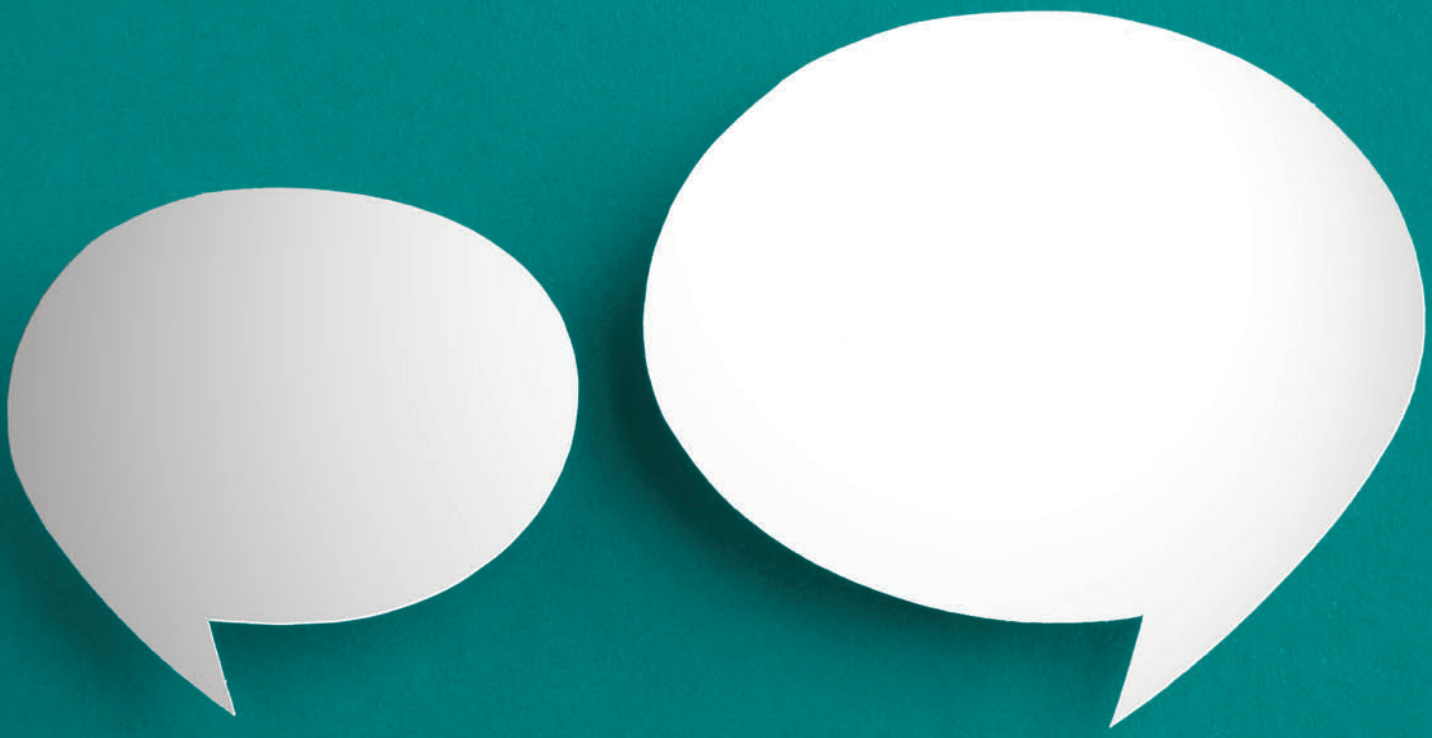
Commissioner for Health and Food Safety
European Commission
http://ec.europa.eu/commission/2014-2019/andriukaitis_en



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ADJACENT GOVERNMENT

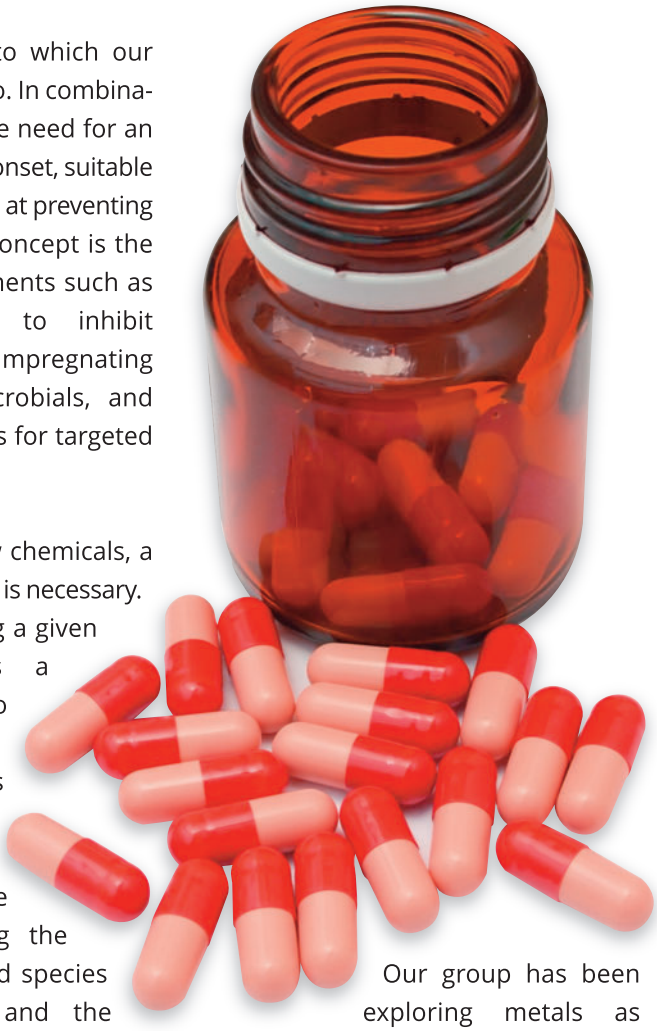
Challenge of antibiotic resistance and the promise of metals as antimicrobials

The decrease in availability of effective antibiotics is the result of the confluence of two world-wide issues; the continual increase of antibiotic resistance and the absence of new antibiotics being developed. The first is a natural process of evolution, yet has been exacerbated by their over use. The second has been driven by the economics of the pharmaceutical industry where it is not profitable to support research and development in this area.

There is now conscious thought towards a multi-pronged approach involved in handling the challenge of 'super-bugs' and antibiotic resistance. A fundamental step required for continuous usage of antibiotics focuses on stewardship for use, and of the unnecessary use, of antibiotics. This will require accurate education for the public and healthcare professionals. These efforts should be combined with further funding directed towards discovery-based research. This will result in new defences against the superbugs resistant to our antibiotic regimen presently available.

Currently, active research in academia is exploring a wide range of alternatives to traditional organic molecule antibiotics including: bacteriophages (viruses against bacteria); isolated bacteriocins and other components of natural bacterial warfare; competitive therapies in which 'good' bacteria are added; amphipathic cationic peptides; and metals, research to which our group has contributed to. In combination with recognising the need for an antibiotic post infection onset, suitable ideas have been directed at preventing the spread. One such concept is the use of antiseptic treatments such as engineering surfaces to inhibit biofilm formation, impregnating materials with antimicrobials, and use of nanotechnologies for targeted antimicrobial delivery.

Beyond developing new chemicals, a new structure of thinking is necessary. Rather than recognising a given bacterial species as a 'problem', we need to comprehend why such a bacterium proliferates well during infection. There has been relatively little focus in the area of understanding the relationships in a mixed species microbial ecosystem and the ramifications of an antibiotic on its efficacy and the microbial ecosystem balance. As we now appreciate the existence of the microbiome, the entire ecosystem of the animal must be considered for infectious treatments. For example a biofilm, which is composed of sessile bacteria attached to a surface, is found in a state surrounded by an extracellular matrix. It is this matrix, and additional changes in physiological state of the bacteria in the biofilm, that result in robust antimicrobial resistance.



Our group has been exploring metals as antimicrobial agents over the past decade in order to determine their efficacy at killing super-bugs and persister bacteria, and for the prevention or eradication of biofilms. Popular metals with antimicrobial activity include: silver, copper, zinc, and titanium. Essential metals such as zinc, calcium, nickel, copper and others have crucial roles in the biochemistry of living organisms. However in excess these metals are lethal, through various mechanisms, to all organisms. Other metals such as silver, mercury,

and tellurium, which are nonessential for life, demonstrate greater toxicity at lower concentrations than essential metals. The antimicrobial activity of both essential and non-essential metals has been exploited for several purposes, much longer than traditional microbe derived antibiotics.

"There is now conscious thought towards a multi-pronged approach involved in handling the challenge of 'super-bugs' and antibiotic resistance."

Presently, metallic antimicrobial compounds are consumed for a variety of applications in agriculture and medicine and are widely accessible as commercial products. Copper is used as an antimicrobial and antifungal agent in addition to an animal feed additive. Copper can also be found in consumer products such as bedding, for the control dust mites and for the treatment of athlete's foot by inclusion into socks. The EPA has already registered several copper-containing products as supplements to standard infection protocols in healthcare settings. Silver has certainly taken the stage seeing use as an antimicrobial topical agent in the treatment of burns. We also see silver impregnated into bandages, coated catheters and other medical devices as well as in bedding, towels, clothing, water filters, toothpaste, air purifiers, and homeopathic medicine. Additional examples include: zinc in toothpaste, shampoo and topical creams; tin in toothpaste; bismuth used to treat digestive issues and diarrhoea; and even mercury, which can be found as a preservative in eye drops.

Although metals are exceptionally effective antimicrobial agents, a fundamental concern is what happens to the metal after it has completed its role as an antimicrobial agent. As a result of metal persistence in the host (human or animal) or accumulation within the target bacteria, release into the environment upon death of the organism will eventually occur. When used in clothing or laundering, the washed out metals are transported through the drain and not cleared using current wastewater treatment processes. Furthermore, some water treatment facilities are now using copper and or silver. Such use leads to accumulation of metals in rivers and lakes. These examples, and others, might lead to ecological toxic disasters we now associate with industry drainage and mining.

The natural exposure of bacteria to metals is a process that has occurred for millennia and continues to occur. This exposure has driven the evolutionary capability of metal resistance in select micro-organisms to date. Some mechanisms include reduction in permeability or uptake, alteration of target sites, chemical modification, efflux of the metal ions, and detoxification – comparable to antibiotic resistance. The resistance of micro-organisms to metals might be regarded as of little importance due to their limited use in human and veterinary medicine to date, nonetheless their historical use in agriculture provides a reservoir of resistance.

The use of antimicrobials in both agriculture and medicine has contributed to the progression of microbial resistance. While we can continue to replace "mature" antimicrobials with novel agents, such as metals, understanding the mechanisms, transmission and development of multidrug resistance must be given more acknowledgment than that provided by any political '5-year action plan'. Postponing the emergence of metals as antimicrobials may lessen the development of resistance, however, the commercial widespread access of antimicrobial metals to the public has formally prevented this action. We must re-evaluate the use of metals for non-medical purposes before the presence of multidrug resistance outgrows this potential alternative.

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eHealth in health services and systems

Dr Joan Dzenowagis from the eHealth Unit at the World Health Organization (WHO) outlines how eHealth is making an impact in countries worldwide...

Ten years ago the World Health Organization's (WHO) governing body, the World Health Assembly, recognised that eHealth was transforming health services and systems around the world, and urged Member States to plan for appropriate eHealth services in their countries[1]. The digital economy was already a reality, and its continued growth over the past decade has further expanded the opportunities for health. On the broader development agenda eHealth is now seen as a driver, as well as a beneficiary of development, innovation and economic growth.

Today eHealth is making an impact in every country. From the local to the national level, information and communication technologies (ICT) in health, or eHealth, is changing how health care is delivered and how health systems are run. It supports critical functions by improving the ability to gather, analyse, manage and exchange information in all areas of health, from research on molecular genetics to large-scale humanitarian interventions. In health systems, ICTs are being used to improve the timeliness and accuracy of public health reporting and to facilitate disease monitoring and surveillance. They are fundamental in distance learning, and in enabling rapid response in emergencies. The strategic use of eHealth can support sector-wide planning as well as coordinating decentralised district health systems, and improving the ability to plan, budget and deliver services.

Since the first global survey on eHealth in 2005, WHO's Global Observatory for eHealth has documented the trends worldwide. Its adoption has continued to accelerate as stakeholders such as governments, industry, academia and others increasingly depend on it to conduct the daily business of health. More recently the rapid global uptake of mobile technologies has opened important opportunities in public health and clinical practice to reach patients, health professionals and the public when and where needed. As health systems face stringent economic challenges, greater demands for efficiencies and higher expectations from citizens there is a need to provide more care and better care to more people, especially those most in need. The use of eHealth is now understood to be central to this effort.

However, there are social, economic and other barriers that affect a country's ability to take advantage of digital opportunities. To make eHealth a reality, countries must tackle a number of challenges at the national level. These include planning for and building infrastructure, deploying services and applications, developing a capable health workforce, ensuring a sound legal and regulatory environment and improving governance, standardisation and interoperability. The days of pilot projects are waning as governments move towards strategic, integrated planning and sustainable financing mechanisms to enable solid foundations for investment and change.

WHO has long recognised the need for a systematic, practical approach that aligns the many stakeholders in eHealth around a national vision and strategy. Towards that end, sustained commitment, investment and political will are as important as ever. Legal and ethical issues must be addressed to ensure that everyone benefits. Leadership and engagement are critical, as well as a long-term view to develop the potential of eHealth in regards to a country's economic context and needs. Health systems will need to develop new ways to test and adopt innovations that create value for patients and society, but which may not match the short time horizons for return on investment that now characterise our approaches. Beyond the technical challenges of implementing

eHealth at the national level, it will be critical in the coming years to ensure that cross-border, regional and international efforts in eHealth work in harmony, and that all governments build their capacity to engage in this area.

"The adoption of eHealth has continued to accelerate as stakeholders such as governments, industry, academia and others increasingly depend on it to conduct the daily business of health."

WHO provides guidance to countries, to understand how ICT can support health goals and in defining a comprehensive strategy development process to go forward. Public policymakers often need a much better understanding of the main components of eHealth and how to plan for its adoption. The process of strategy development encourages the active participation of a wide range of stakeholders, public and private, towards achieving a shared goal of lasting progress in public and individual health.

The case for adopting information and communication technologies has been evident for over a decade. However, it has often taken a crisis in the health sector to move eHealth from the periphery to the centre of strategic health planning. Today, many countries are poised to take the next step: developing national eHealth strategies, building capacity, engaging in collaborations and striving to ensure public ownership, trust and confidence in eHealth for the years to come. ■

1 http://apps.who.int/iris/bitstream/10665/20398/1/A58_2005_REC1-en.pdf?ua=1

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Creating digital possibilities for healthcare

In an article, Federal Health Minister Hermann Gröhe, details the introduction of the electronic health card, the digital possibilities of telemedicine and the proposed e-health law...

On January 1, the electronic health card finally replaced the old insurance card. For now, it is like a sports car, which lurks in the garage on its use. We finally need information highways so that the electronic health card can show what it can do, as it is an important step towards the digital age of healthcare. It brings something forward, what we urgently need, but do not have much: networking! It is a paradox: Almost all surgeries and hospitals use digital data at a high level. But the transfer of this data is often still in the analogue age. Digitalisation must and will come. If we do not tackle it now, we will later run into problems after the development. Losing time now is a costly endeavour and harms everyone – in every respect.

Digital networking does not only mean faster communication and greater economic efficiency, for the most tech-savvy nerds or costs fixed manager, it's about tangible medical benefits. An example of the potential of the health card, which today lies idle but we finally want to open, with electronic, callable emergency data to the physician would provide important information in the future which is immediately available. This can save lives! We need more networking, but not just in emergencies. In Germany, unfortunately more people die by adverse drug reactions than on the road. A digital overview of the prescribed drugs can be a real step forward, especially for the elderly and people living alone.

We are just beginning to exploit the opportunities of the digital age in the health sector. However, I want more to happen quicker. For years, the electronic health card has been blocked and delayed by many sides. It makes no sense to stem the digitisation of healthcare. It is better to make this process constructively, and where necessary, also critically. I expect,

Hermann Gröhe, Federal Health Minister

doctors, hospitals, the entire self-government, and the industry to keep their promises and support the progress of the electronic health card with all their strength.

I do not understand that blockers appear on the scene again and try to stop the great progress into the digital age of health care with specious arguments. It is wrong, that it is not enough given privacy. The opposite is the case. The structure of the telematics infrastructure meets the highest safety standards: There is clear access rights, the access of doctors to data is logged, and health insurance companies are

obliged to provide information. Medical data is encrypted twice, the patient can also delete data – and unauthorised access leads to criminal prosecution. Above all, the relationship of trust between doctor and patient remains untouched. For me, the following applies: Effective data protection and health care in the digital age is of paramount importance.

Digital networking is a driver of medical progress. It is fascinating to see what is possible through telemedicine. For example, if someone has a stroke an expert is already available in the emergency room via video-conference for the treatment, and is placed directly above played computed tomography images of the patient within a few seconds. This ensures that the expert can help the patient quickly and efficiently along with the doctor. It overcomes telemedicine spatial barriers, especially for rural areas that will be in the future of the utmost importance.

Networking, telemedicine, new therapies and privacy protection – this is the digital revolution in the healthcare sector. Whoever denies this step out of selfishness, harms the interest of the public. This is why the "e-health law" that we now bring, has a simple principle: Who blocks, pays. The central actors of self-government – in particular the accredited physicians' associations and the central association of statutory health insurance – get periods to which they must achieve specified results. Cannot be sent, they have to take financial cuts in purchasing. Only then can we take pace. Nevertheless, it is not about what is technically feasible. But, it is important that we use all technical possibilities to ensure that the medical progress all patients really benefit. ■

This is an article that was used from permission of the Minister's office. It was first published in the Frankfurter Allgemeine Zeitung of 13/01/2015.

Hermann Gröhe
Federal Health Minister
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www.bundesgesundheitsministerium.de

Transnational leadership programme between Germany and Canada

Increasing Innovation through Leadership in public funded Expert-Organisations – Finding a road to resilience...

Background

The many challenges in health care today create a special need for advanced effective leadership strategies (Stoller 307 -28; 876-78). Leadership development in healthcare includes principles of competency-based development, interdisciplinary, team learning and continuous assessment (Leatt and Porter 14-31). Progressive health systems that invest in leadership development for the entire senior management team will have the more significant return on investment in terms of organisational effectiveness (Leatt and Porter 14-31).

There have been a range of networks and programmes develop related to education involving specific aspects of healthcare such as technology assessment (Kristensen et al. 107-16) and interprofessional education (Liaskos et al. S43-S47), as well medical practice (Williams, Blomkalns, and Gibler 203-09;Wilkerson and Irby 387-96;Schwartz and Pogge 187-92;Poorman and Mastorovich 142-43;Kristensen et al. 107-16). Additionally, a range of pedagogical strategies have been proposed (Wilkerson and Irby 387-96;Kumm and Fletcher 82-89;Jones and Sackett 204-08;Grossman 72-75;Copp 236-41; Burdick et al. 414-21). One of the most innovative to date has been the AFWI[1], which is provided a contemporary approach to the translation and mobilisation of scientific knowledge into practice an the Transnational leadership Programme (TNLP) (Bomke 66-69).

Method

Once established, the international relationship initiated a three-year programme implementation phase. This phase required identification of participants, definition of roles, curriculum outline, timelines, processes, objectives and goals. In situ across the programme a continuous reflective process was enacted for the purpose of feedback and goal correction at each step. The implementation process involved three international excursions and a summative symposia.

Results

The programme was well accepted within the health service networks of both countries. Participants were able to use the programme to enhance local projects designed to innovate and improve service delivery, which were component prerequisites and goals of their roles in the leadership programme. Furthermore, the international context was identified as a highly useful and novel learning space. While all aspects of the project were conducted in English, the fact that English was not the first language for half the group resulted in the simplification of concepts and principles that were to be communicated within and between groups and within and between the different professions of the participants.

Last but not least, the programme is the base of the ongoing prevention-initiative in the palatine region, called “Die Pfalz

macht sich/Dich stark – Wege zur Resilienz" (The Palatinate region braces itself/you – building a road to resilience). Resilience is not only a matter of each individual it must be realized on all social levels (Bomke, Kendall-Taylor and Cawthorpe 2014; Bomke and Kendall-Taylor 2014). Enterprises, schools and communities should also promote mental health as a preventive measure and network their activities. So the group around the Pfalzklinkum uses a socio-ecological and multi-agencey approach. Together with experts from medicine, health, work and social policy the initiative looking for ways to promote a sustainable change towards prevention in the health system in the Palatinate and are cooperating closely with international initiatives, such as the Centre for Early Child Development, Blackpool and the think tank Framework Institute, Washington, D.C. The vision is to build a resilient Palatinate until 2025 where mental health will be high on the citizens', enterprises' and politicians' agenda.

Conclusions

1 The requirement to simplify language in the international context was directly related to the ability to simplify language and concepts in the communication of innovation within the responsible organisation.

2 The international context also highlighted leadership is a learning process related to both others and the self.

3 The international context provided an atmosphere that was directly related to the ability of participants to identify foci for innovation, strengths and weaknesses within their own organisations.

4 The long-term nature of the programme was a cornerstone of its success in relationship to participants' realising their organisational goals and objectives and to improve the social skills of the participants.

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[1] Alberta Family Wellness Initiative; http://www.albertafamilywellness.org/

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Ireland's health priorities for 2015

Kate O'Flaherty, Director of the Health and Wellbeing Programme at the Department of Health – Ireland outlines the health priorities for 2015 and the Healthy Ireland Framework...

Earlier this year, the Minister for Health Leo Varadkar set out 5 priority areas for his Department and a number of priority deliverables over the period 2015-2017. The Irish health and social care system is undergoing a significant reform programme, with a focus on modernising the health infrastructure including the development of a new national children's hospital; progressing universal healthcare with the introduction of GP services without fees to the under-6s and the over 70s; developing new strategies for maternity care and cancer, pursuing innovative funding models, and a range of reforms to improve patient outcomes and patient safety.

Driving the Healthy Ireland agenda is one of the 5 priority areas. This agenda is focussed on implementation of the government-led, multifaceted framework to improve the health and wellbeing of the population published in 2013. Drawing on international policy approaches such as World Health Organization (WHO) Europe's Health 2020, Healthy Ireland seeks to more effectively address the key lifestyle behaviour issues which result in ill health and chronic disease as well as the social and environmental determinants of health and wellbeing, through a 'whole of government' and 'whole of society' approach.

Under the Healthy Ireland agenda, a number of significant policies and strategies are being developed and are due for publication over the coming months. These include a first National Physical Activity Plan jointly developed with the Department of Tourism, Transport and Sport; a new Obesity Policy and Action Plan; a Sexual Health Strategy and a significant legislative agenda including public health legislation on alcohol and tobacco.

Healthy Ireland Framework and implementation

The Framework's vision is an Ireland where everyone can enjoy physical and mental health and wellbeing to their full potential, where wellbeing is valued and supported at every level of society and is everyone's responsibility. It emphasises the international evidence that a whole-system approach, involving government and society, is required to effect sustainable improvements in health and wellbeing.

The Framework has 4 main goals:

- Increase the proportion of people who are healthy at all stages of life;
- Reduce health inequalities;
- Protect the public from threats to health and wellbeing;
- Create an environment where every individual and sector of society can play their part in achieving a healthy Ireland.

It sets out a range of action areas under themes which include partnerships and cross-sectoral working, empowering people and communities, reform of the health service to ensure a renewed focus on prevention, and building capacity around research, monitoring and evaluation.

The implementation of the framework is overseen by the Cabinet Committee on Social Policy and Public Sector Reform which is chaired by the Taoiseach (Prime Minister). A Cross-Sectoral Group comprising senior officials from other government departments, as well a range of national agencies relevant to health,

Minister for Health Leo Varadkar

research, environmental protection and local authorities supports the cross-sectoral implementation.

In addition, a Healthy Ireland Council, consisting of stakeholders from a wide range of sectors and chaired by businessman and former Irish rugby captain Keith Wood, has been established to champion the 'whole of society' engagement. It will also act as a platform to connect and mobilise communities, families and individuals into a national movement with one aim: to support everyone to enjoy the best possible health and wellbeing. The first meeting of the Council in June 2014 was addressed by WHO DG Dr Margaret Chan, who complimented the Framework, saying that it was " ... a carefully orchestrated and united fight in a whole-of-government and whole-of-society approach. Engagement goes from the national level to the local, from the heights of academic research to the grass-roots voices of civil society organisations, who are extremely important, right down to communities and families which is where action will happen".

The Council has published an action plan for 2015, and established a number of subgroups to focus on key areas including communications and health inequalities. We are currently developing a communications strategy for the Council to support their role in engaging with their stakeholder networks and the wider public around the key deliverables such as the forthcoming National Physical Activity Plan.

Health challenges in Ireland

Ireland's health challenges are not dissimilar from those of other countries across Europe. While our population is living longer, people are unfortunately not necessarily leading healthier lives. Ireland consistently records high rates of self-evaluated good health, but as set out in the Healthy Ireland framework, the picture in relation to chronic disease related to poor diet, smoking, alcohol misuse and physical inactivity presents a real clinical, social and financial challenge. For example, over 60% of Irish adults, and 25% of 3-year olds are overweight or obese, and the

prevalence of chronic conditions and accompanying lifestyle behaviours are strongly influenced by socio-economic status.

A new Healthy Ireland Survey which will report later in 2015 will give us an up-to-date picture of the health and wellbeing of the population for the first time since the last similar study in 2007.

Meeting the Challenges

The Healthy Ireland Framework provides the context for addressing not only the lifestyle behaviour issues which adversely affect health and wellbeing, but also the social determinants and predictors of health and wellbeing. Many of these fall outside the health sector, e.g. housing, transportation, education, workplaces and environment along with an individual's socio-economic status.

In addition, the broad and complex nature of the Framework and the massive change agenda associated with its implementation requires that a critical focus remains on the wider enablers of implementation, such as stakeholder consultation, building a supportive culture, communication and leadership.

The initial phase of implementation (2013/14) focussed on:

- establishing the underpinning architecture and accountability structures and mechanisms;
- building the capacity of the new Programme set up in the Department to coordinate implementation, and embedding its work in the Department's overall responsibilities and work;
- establishing and supporting the Health Service Executive (HSE) capacity around health and wellbeing through a new Health and Wellbeing Division;
- identifying and building key strategic relationships and partnerships across a range of cross-sectoral partners.

The successful delivery of the priority projects set out for 2015, in addition to driving a number of cross-sectoral projects in partnership with other government departments and stakeholders, is the agenda over the next phase of implementation. These include ensuring close alignment with the new national policy framework for children and young people; integrating health and wellbeing into the educational agenda across primary, post-primary, higher and further education; embedding health and wellbeing into new structures and arrangements in local government; and, developing a national 'Healthy Workplaces' initiative across public and private sectors. In addition, the HSE recently published its implementation plan for Healthy Ireland in the Health Services for 2015-2017 which will be the main driver of that strand of implementation.

The implementation of Healthy Ireland, as well as the other significant reforms of our health system, is critical to the future health and wellbeing of our population, which in turn is central to our social and economic recovery and progress.

The enormity of the challenge is clear but by taking a collective and collaborative approach across government and society we aim to achieve the critical mass that can generate fundamental changes and make lasting positive impacts on Irish society. ■

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Depression in adolescence

Dr Rhys Bevan Jones, Clinical Research Fellow at the Institute of Psychological Medicine & Clinical Neurosciences, MRC Centre for Neuropsychiatric Genetics & Genomics at Cardiff University details how depression can affect adolescents...

Depression is common in young people, with around 1 in 20 of those in adolescence affected. This leads not only to distress for the individual and their family and carers, but also social and educational impairments. Depression is also a major risk factor for self-harm and suicide, and there is an association with poor physical health, including increased rates of smoking and substance misuse, and obesity. There is a high recurrence rates in adulthood – young people who experience depression are more likely to experience an episode in adult life, compared to young people who do not. Adolescent depression is therefore a major clinical problem but there are treatments available.

Everyone's experience of depression is different. However, there are common symptoms listed in the diagnostic criteria, such as those of the International Classification of Diseases (ICD-10), published by the World Health Organisation (WHO). The criteria for a diagnosis of depression in young people are similar to those in adults, with the core symptoms being depressed mood most of the day and almost every day, loss of interest or decreased energy. Irritability is also a core symptom in adolescence in the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), published by the American Psychiatric Association.

Other possible symptoms include: loss of confidence, unreasonable or excessive feelings of guilt, change in activity levels (agitated or 'slowed down'), concentration and sleeping difficulties, appetite loss/gain and a corresponding change in weight, and self-harm or suicidal thoughts/behaviour.

However, the diagnosis is more often missed in adolescents than in adults. This might be because the presentation can be different in young people, for example because of the presence of irritability and fluctuating symptoms. The primary presenting problem may not be specific to depression, for example physical symptoms such as pain (especially in younger adolescents), a decline in academic performance or social withdrawal. Many young people with depression have at least one other mental health difficulty, which can also complicate the assessment and management.

There is a range of risk factors for depression in adolescence – including individual, family and social issues. The strongest risk factors are a family history of depression and exposure to psychosocial stress, such as bullying. Offspring of parents with depression show 3-4 times increased rates of depression compared with offspring of non-depressed parents, although many children of depressed parents do not experience difficulties. Usually there is a complex interaction of the factors above, although there may not be an obvious reason.

The treatment of depression is targeted at the reduction of early and later adversities, modification of ways of thinking and feeling (such as cognitive behaviour therapy and other psychotherapies), and antidepressant medication in more severe episodes. Prevention strategies focus in particular on a combination of education and psychological approaches. There has also been increasing interest in resilience, which could be defined as better than expected functioning across psychosocial outcomes over time, in the context of a known risk factor (such as a family history of depression). Protective or resilience factors can inform prevention and management approaches.

There have been government calls for an emphasis on prevention and early intervention of depression, and centres such as the Child and Adolescent Psychiatry Section at Cardiff University have led studies in this area. For example over recent years, the 'Early Prediction of Adolescent Depression' (EPAD) study aimed to understand the links between parent and child depression. The study has also looked at protective and resilience factors in relation to adolescent depression. The translational aims of EPAD included increasing awareness, and improving assessment, prediction and monitoring of depression in children and adults.

Further to this study, a group within the department is developing an online multimedia package and accompanying 'app' to help young people with (or at high risk of) depression and their families. This is funded by the National Institute for Health Research (NIHR), and is consistent with the National Institute for Health and Care Excellence (NICE) guidelines for 'Depression in children and young people (Identification and management in primary, community and secondary care'), which were updated earlier in 2015. These stress the need for good information for the young person, family and carer and the use of psychosocial interventions which are evidence-based in the initial management.

Engaging young people in prevention and early intervention programmes is a major challenge for health and other services, as is improving the identification of depression and its management in this age group. ■

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For more information please visit:
Young minds – www.youngminds.org.uk

National Centre for Mental Health – www.ncmh.info

Royal College of Psychiatrists – www.rcpsych.ac.uk

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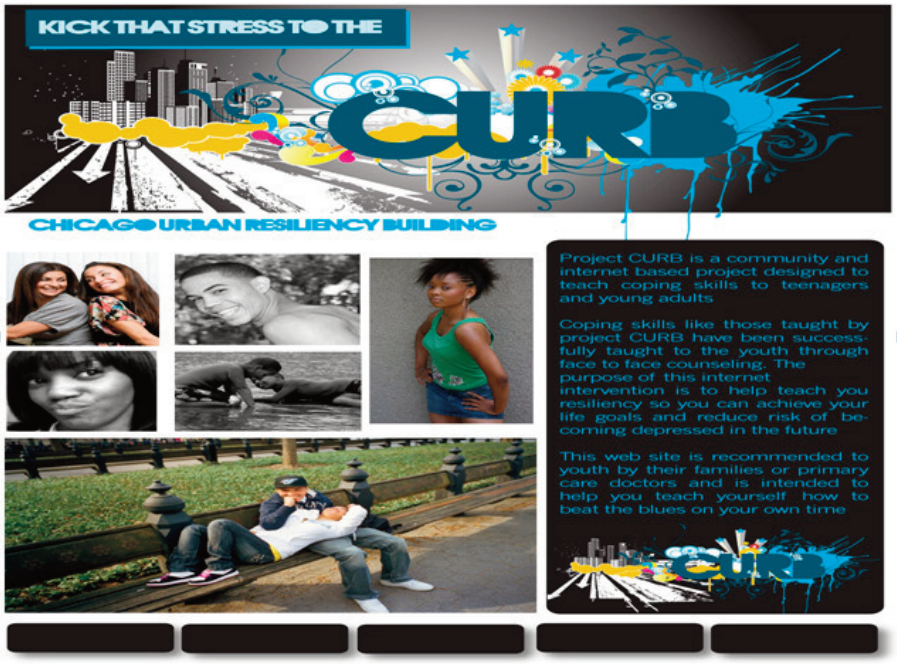
Addressing Population Health – One Teen at a Time

Answering the National Call for Better Mental Health Care...

In response to the call from the Institute of Medicine and as a key priority for the National Institute for Mental Health (NIMH) to prevent mental illness in adolescents, Benjamin Van Voorhees, MD, MPH and colleague Tracy Gladstone, PhD have developed a primary care/Internet based depression prevention intervention called CATCH-IT (Competent Adulthood Transition with Cognitive Behavioral Humanistic and Interpersonal Training). Currently CATCH-IT is in the third phase of randomised clinical trials, funded by the NIMH. With each phase they have refined their approach to addressing the pressing need for catching depression before it begins. They developed the primary care/Internet based depression prevention intervention (CATCH-IT) and are currently, in this phase comparing this intervention to a control intervention consisting of general health information (Health Education, HE). CATCH-IT is being fielded in a multi-site trial within six major primary care health (and over 30 primary care clinics) systems in Boston and Chicago. They have been able to demonstrate the feasibility of implementing this model in multiple health systems and have to date screened over 4,000 teens from primary care offices.

The design of this intervention, that targets adolescents with beginning signs of depression, works within the framework of the recently established United States' Affordable Care Act.



The goal is to create a widely available public health strategy to reduce illness and death associated with depression, which is a lifelong illness. This strategy is intended to meet the NIMH call for developing "new and better interventions" for "diverse needs and circumstances" to "...preempt the occurrence of disease." These interventions must:

- Have broad "reach" into at-risk populations;
- Work outside of traditional mental health systems;
- Use new technologies;
- Build on previous clinical trials;
- Reduce identified disorders/enhance functional outcomes;
- Include families; and
- Be personalised.

While such approaches widely desired, few if any have been successfully implemented at scale in diverse population within actual primary care sites and little is known about whether benefits of such interventions may be sustained or which aspects of these complex interventions are most associated with favorable outcomes.

Innovation of the Trial Design

The innovation of this work lies in its novel approach to addressing population needs. Population based prevention of major, common mental disorders has not been previously been attempted at scale within multiple, complex health systems and

Dr. Benjamin Van Voorhees

diverse populations. Face-to-face interventions have shown to be effective, however the CATCH-IT intervention represents a paradigm shift. The key innovations of this study include:

- It is the first of its kind, a public health adolescent depression prevention strategy (low cost, easily disseminated, acceptable and feasible primary care/Internet model),
- It combines a brief primary care-based motivational program with an Internet-based self-directed Cognitive Behavioral (CBT) and Interpersonal Psychotherapy (IPT) approach to address the key barrier of engagement/adherence;
- It targets both adolescent and parent vulnerability and protective factors in separate interventions, using an ecological model;
- It is personalised to the presence of parental depression and ethnicity/culture, key moderators in prior studies; and
- It uses media based learning strategies including music, videos, and stories to convey learning.

"The goal is to create a widely available public health strategy to reduce illness and death associated with depression, which is a life-long illness."

Relational Intensity Necessary to Address Barriers to Implementation

Fielding a trial of this nature is not without its difficulties – but the study staff has adapted to both internal and external barriers presented by this trial. The internal barriers are identified as organisational and behavioral, and the external behaviors as political, economic, and regulatory complexities. These factors work against the implementation process and consequently affect the potential public health benefit to the proportion of adolescents at risk for major depression identified through screening in primary care.

During the initial run in phase of the clinical trial, the team examined the nature of how they confront barriers to implementation of the study. The themes reflect the considerable, and largely relational intensity of their work, rather than purely traditional practice education and implementation guidance to the primary care sites. This relational intensity was found to be necessary on the part of study staff members to effectively implement the study. Critical factors of implementation have emerged around the need to deepen and broaden relational engagement with the practices so that they would create an environment in which screening could take place of adolescents. The team has considered the impact of the nature of the study – mental health – on the willingness of the practice sites to carry out the study. Because of the less discussed nature of mental illness in society in general, the team works to reflect back to the sites the recognition that the topic of mental illness may be difficult; but the effect of addressing it with teens before it is severe is a great service to individuals and the population at large.

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Cancer research – 50 years and counting

Christopher P. Wild, Director at the International Agency for Research on Cancer (IARC) outlines how 50 years on, prevention still remains key to cancer research...

"Have you found a cure yet?" Which cancer researcher upon revealing their profession has not faced this question? One can respond confidently with examples of major improvements in survival: childhood leukaemia, testicular and breast cancers being notable. One can point to remarkable insights into the previously hidden biology of cancer, with drugs now tailored to exploit the molecular Achilles heel of an individual tumour. These triumphs of scientific creativity and endeavour merit the telling. Yet the disturbing, deeper truth is we cannot treat our way out of the cancer problem.

As people live longer and populations increase, the number of new cancers each year is projected to rise sharply. In 2035, just 20 years from now, there will be an estimated 10 million more people every year facing a cancer diagnosis. Increases are greatest in the developing countries where there is least capacity to treat and care for patients. The spread of risk factors linked to western patterns of individual behaviour and societal structure will exacerbate the problem. Even for the world's richest countries the spiralling cost of cancer means improved treatment alone is an inadequate response. For the world's poorest, the out-of-pocket expenses of treatment for one individual can be financially catastrophic for an extended family. The pain of cancer is far reaching. How did we end up here and what might be done better?

Fifty years ago, when the International Agency for Research on Cancer (IARC) was established, IARC scientists considered the striking global variations in cancer patterns and decided to study the causes of this heterogeneity as an avenue to prevention. Over the last 5 decades IARC played its part, with many others, in discovering human carcinogens. Tobacco remains the pre-eminent culprit. Chronic infections account for 16% of all cancers, one in 4 in the most populous nation, China. Alcohol, radiation including excess sunlight, unhealthy diets, environmental contaminants and occupational exposures all contribute. Imbalances in calorie intake and expenditure are adding to the problem; many people are no longer moving enough to justify the amount they eat and drink.

"The benefits of prevention can take many years to manifest. This is incompatible with the duration of a political mandate (at least in most democracies) but also with the immediacy of people's personal experience, where what is sought is a cure."

Estimates vary but one can safely conjecture that some 40-50% of cancers could be prevented by translating this accumulated knowledge into interventions. Further inroads are made by detection of early-stage cancers or pre-cancerous conditions, combined with more effective treatment e.g. for cervical, breast, colorectal and oral cancers. Furthermore, prevention and early detection demonstrably work. Major declines in lung cancer following reduced tobacco consumption are remarkable as are the falls in cervical cancer following introduction of screening. Improved protection against work place carcinogens form part of the successes. Vaccination against hepatitis B virus and human papilloma viruses will in time yield their fruits. Many interventions have added value through reducing other illnesses of aging such as cardiovascular disease and diabetes.

Despite proof and promise, prevention is too often neglected. Commonly less than 5% of cancer research funding goes to prevention, a proportion dwarfed by the investment in basic science and clinical translational research. In addition, the science that is performed

too often remains at the stage of proof-of-principle, with a failure to implement. This under-investment in research and in implementation is costly and while the underlying drivers are complex, they merit exploration.

Part of the problem may be time. The benefits of prevention can take many years to manifest. This is incompatible with the duration of a political mandate (at least in most democracies) but also with the immediacy of people's personal experience, where what is sought is a cure. Economics is important, because while new therapeutics offer opportunities for private sector investment and growth, public health interventions are perceived as cost pressures. Complexity is a further element. Prevention requires a multi-sectoral cooperation across health, transport, environment, etc., to address the "causes of the causes". Responsibility has been too often placed solely on the shoulders of the individual whereas tobacco control has shown how appropriate legislation has been key to success.

Nevertheless, this is an exciting time for cancer prevention. Advances in cancer biology offer fresh impetus to studies of causes, early detection and prevention. Implementation research, close to policy, can better indicate factors which help or hinder the translation of promising interventions into effective national programmes. Thorough analyses of the economic benefits of prevention may yet reduce the unpopularity of the Minister of Health among government colleagues. Prevention, applied at the population level, offers a sustainable approach contributing in turn to reduced inequalities in society.

From a global perspective the necessity of prevention is blindingly obvious. IARC enters its second 50 years with a renewed mandate to conduct cancer research for cancer prevention. As there is an undeniable responsibility to offer the very best in treatments for the patients of today, there is also an undeniable responsibility to prevent the suffering from cancer for the populations of tomorrow. Perhaps eventually, on revealing one's identity as a cancer researcher to a new generation, the question may just occasionally be: "Can you prevent it yet?" ■

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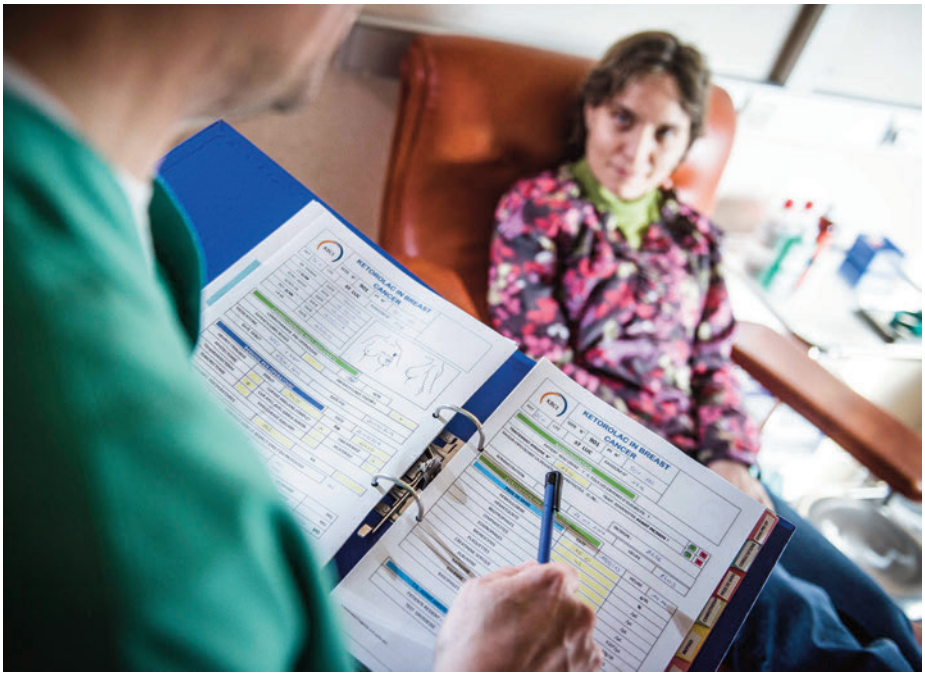
The Anticancer Fund

Emerging from the Swiss-based organisation Reliable Cancer Therapies, founded in 2009 by Belgian entrepreneur Luc Verelst, the Brussels-based Anticancer Fund (ACF) is a private not-for-profit foundation dedicated to expanding the range of treatment options available to patients. It is this central focus on patients which is the common theme that runs through the diverse activities of the ACF – both in terms of its approach to scientific and clinical research and also in its day-to-day work. While the ACF is a relatively small organisation, employing mainly scientists and medical staff, it has an international reach which extends well beyond the borders of Belgium. This manifests itself both in terms of supporting projects worldwide and in making available comprehensive scientific information to the public in multiple languages. These twin tracks of scientific and public engagement are apparent in the range of ACF projects and activities.



Public Engagement

The most visible form of public engagement is in the provision of scientifically accurate information to the public via the ACF website (www.anticancerfund.org). Here patients can find information on current cancer treatments, a gateway to search for clinical trials and information on non-mainstream treatments – including dietary and lifestyle interventions. Also of importance is information on some of the 'alternative' and complementary therapies that cancer patients may come across.

The ACF takes seriously the task of 'quack busting', and has been active in exposing the activities of fraudsters who seek to exploit vulnerable cancer patients seeking 'miracle cures'. For example there is a very active group of people in Europe selling a fake cure called GcMAF. The ACF has been active in informing the authorities about the fraudsters, publishing factual information about GcMAF, and ensuring retraction of a number of fraudulent scientific articles. The ACF is seeking recommendations at the European level on how we can act against fraudsters operating in different countries.

However, the ACFs engagement with the public goes beyond publishing information and extends to direct support for individual patients seeking new options. Since 2010 over 500 patients, primarily from France, Belgium and the Netherlands have used this service.

Finally, there is another form of public engagement in which the ACF is becoming increasingly involved and that is public policy intervention – most notably this arises from the ACF research agenda.

Scientific Research

The ACF believes that as a society we need to ensure that no treatment option is left untapped. To this end there are three major strands of research, focused primarily on non-mainstream treatments: drug repurposing, non-commercial immunotherapies

and non-pharmaceutical interventions. The objective is to bring these non-mainstream treatments into mainstream clinical practice.

The Repurposing Drugs in Oncology (ReDO) project is a collaboration with the US not-for-profit organisation Global Cures. The aim of the project is straightforward – to identify a range of existing non-cancer drugs which show strong evidence of anti-cancer activity and which have the potential for clinical use. There is a broad spectrum of drugs that the project has identified, many of them available as cheap generics, including antibiotics, antifungals and antiparasitics. Taking evidence from a variety of sources, the ReDO project has reviewed, summarised and published the results in peer-reviewed journals.

The ACF also aims to confirm this promising data in well-designed clinical trials. Examples include a pioneering trial of ketorolac in women undergoing breast cancer surgery, and the use of celecoxib and fluvastatin in paediatric optic nerve gliomas. The ultimate goal is to persuade other foundations, European and national governmental organisations to start mining this relatively unexplored field of affordable, non-toxic and potentially breakthrough opportunities that could benefit patients.

Another key area is non-pharmaceutical interventions, which covers nutritional, lifestyle and other non-drug approaches to cancer. While these interventions are gaining more and more public attention there are important issues to tackle in order to allow proper evaluation of these as additions to current standard of care treatments or, as claimed by some proponents, as alternatives to standard of care therapies. Quality of supplements and plant extracts need to be guaranteed, mind body interventions standardized and clinical trial guidelines adapted. In terms of non-pharmaceutical interventions the ACF supports a UK trial exploring dietary changes in advanced breast cancer; another is investigating mindfulness meditation in young adults during and after their cancer treatment.

Finally, the ACF is also active in the field of immunotherapy – with an emphasis on commercially neglected areas, such as non-patentable, cellular immunotherapy or combinations of the latest generation of highly expensive immunomodulating drugs with low-cost interventions.

The patient focus of ACF is also reflected in the support of clinical trials in patient populations with high unmet needs – particularly rare, refractory or metastatic cancers. For these indications repurposed drugs are the logical choice. An example is a multicentre trial in France with four repurposed drugs in advanced pre-treated osteosarcoma. This is a start but ideally this type of trial should be organised at a European level to minimise problems of slow patient accrual.

Another instance of the ACF commitment to public engagement is to look at the institutional and regulatory obstacles to these non-mainstream treatments. These treatments need to be compared to standard of care, but this is not always a simple task. For example, trials using herbal extracts or nutraceuticals as a monotherapy are problematic due to current European clinical trial directives. There is also a lack of standardised extracts or GMP manufacturing of agents – and manufacturers are unwilling to invest to gain accreditation.

Trials in drug repurposing are easier to initiate, but there are obstacles to the adoption when positive results are reported. For example there have been a number of instances where repurposed drugs have shown evidence of efficacy but which have not then been licensed for cancer nor been adopted clinically. Changing practice is hard and the ACF believes it needs the involvement of regulators, insurers, clinicians, patients and other stakeholders to make it happen.

If we are to deliver on the potential benefits of these commercially neglected non-mainstream therapies, particularly in an era with globally rocketing health-system costs, these non-scientific barriers must also be overcome.

Anticancer Fund

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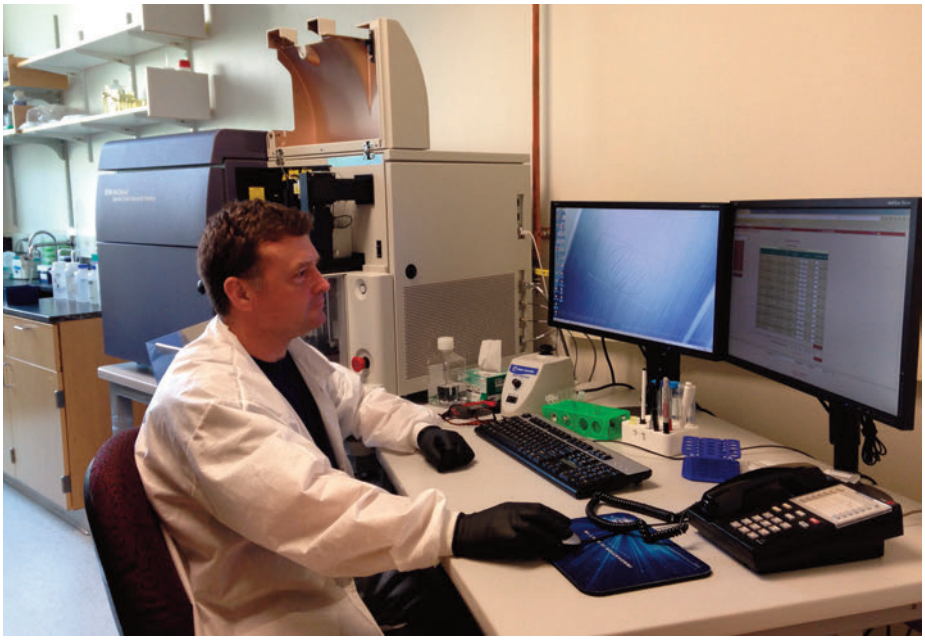
Vitamin D & Analogues in Cancer Prevention & Therapy Research

It is well-recognised that cancer is a major public health problem worldwide. In fact, it also constitutes an enormous economic burden on society. The increasing burden is anticipated because cancer will surpass heart diseases as the leading cause of death in the US in the next few years. This is also likely in other parts of the world as well, in part, due to the growth and aging of the population. Therefore, effective and low cost cancer prevention and therapeutic regimens are urgently needed.



Vitamin D was discovered almost a century ago as an antirachitic agent. Its role in maintaining healthy bones is well-established. There are two major forms of vitamin D, vitamin D_2 and vitamin D_3. They are derived from two different, but closely related precursors, 7-dehydroergosterol (provitamin D_2) and 7-dehydrocholesterol (provitamin D_3) by the same photosynthetic mechanism. In humans, vitamin D_3 is the endogenous form and can be photosynthesised in the skin from provitamin D_3, which is present in the epidermis of human skin, after sunlight exposure. However, vitamin D (D_2 or D_3) itself is inert and must be activated before it can exert its biological effects on bone.

The activation of vitamin D involves two successive hydroxylation steps catalysed by cytochrome P450 enzymes. The first hydroxylation occurs in the liver at the carbon-25 of vitamin D molecule, mainly by CYP2R1, to form 25-hydroxyvitamin D [25(OH)D], the major circulating form of vitamin D. The subsequent hydroxylation of 25(OH)D is carried out by 1α-hydroxylase or CYP27B1 to produce 1α, 25-dihydroxyvitamin D [1α,25$(OH)_2$D], the active form of vitamin D. CYP24A1 is another one involved in vitamin D metabolism and actions. This enzyme is responsible for the degradation of 25$(OH)D_3$ and 1α,25$(OH)_2D_3$ and, therefore, terminating the vitamin D actions.

The dependence of vitamin D synthesis on sunlight has led to the hypothesis that there might be a connection between vitamin D and cancer. It was reported in 1980 that there was an inversed association between latitude and colon cancer; people living closer to equator have less colon cancer mortality rate than those living far from it. This connection was later extended to several other forms of cancer. The ecological evidence serves as a stimulator to further explore the mechanisms of this association at the cellular and molecular levels.

1α,25$(OH)_2$D acts through its receptor called vitamin D receptor or VDR. Its binding to VDR can regulate a gene through the interaction of 1α,25$(OH)_2$D/VDR complex with a VDR response element (VDRE). VDR has been identified by gene expression profiling approach not only in tissues involved in calcium, phosphate and bone metabolism, but in almost all cell types in our body, implying that vitamin D must play important roles beyond bone. Today, it is speculated that vitamin D may regulate more than 600 genes. Among the genes

affected are those closely linked to cancer biology, including genes regulating cell cycle, differentiation, apoptosis, angiogenesis, inflammation, and immune function. More recent studies using human cell cultures and animal models have provided unequivocal data supporting the vitamin D and cancer connection and, more importantly, the potential use of the active form of vitamin D, 1α,25$(OH)_2$D, in cancer prevention and therapy.

"The increasing burden is anticipated because cancer will surpass heart diseases as the leading cause of death in the US in the next few years."

In early clinical trials, unfortunately, 1α,25$(OH)_2$D, was found to cause serious hypercalcemia and hypercalciurea in patients, and was not suitable for clinical practice. Aiming to eliminate the unwanted side effects and at the same time to enhance its anti-tumor activity, several thousands of vitamin D analogues have been synthesised. Knowing that the addition of 2α-(3-hydroxypropyl) group to C-2 of 1α,25$(OH)_2D_3$ molecule enhances VDR binding, and that the 19-nor analogues of 1α,25$(OH)_2$D, such as 19-nor-1α,25$(OH)_2D_3$ and its sister compound, 19-nor-1α,25$(OH)_2D_2$ (also called Zemplar or Paricalcitol, which is an FDA-approved drug for treating secondary hyperparathyroidism), are non- or less-calcemic while maintaining the other potent cellular activities of 1α,25$(OH)_2$D, Professor Kittaka rationalised that a vitamin D skeleton having a combined structure of "2α-(ω-hydroxy)alkylated" and "19-nor" moieties could have enhanced biological activities without inducing a significant hypercalcemic effect. One of the analogues synthesised, called MART-10 (2α-(3-hydroxypropyl)-1α, 25-dihydroxy-19-norvitamin D_3), shows remarkably potent anti-tumor activity which is about 2-3 magnitudes more active than 1α,25$(OH)_2$D in prostate, liver, pancreatic, breast, and head and neck cancer cells in cultures.

In a xenograft animal model inoculated with pancreatic cancer cells, MART-10 showed a 10-fold greater antitumor activity than 1α,25$(OH)_2$D without raising serum calcium. The higher biological activities exhibited by MART-10 in vitro may be attributable to its tighter binding to VDR, more resistance to CYP24A1 degradation inside the cells, and lower binding to vitamin D binding protein in circulation, making it more bio-available inside the cells. The less dramatic effects in vivo may suggest that further modification may be necessary to make MART-10 more suitable as a drug. Based on the existent literatures, we have further synthesised two conjugates of MART-10, and showed that it was released upon the incubation of these two compounds with rat serum. We further demonstrated that these two compounds had similar antiproliferative activity as MART-10 in prostate cancer cell cultures.

Recent advances in vitamin D research by several laboratories, including the laboratory of Professor Sakaki, has demonstrated that 1α-hydroxylation of 25(OH)D molecule may not be a prerequisite step for the manifestation of vitamin D biological activity as long as there is a sufficient level of 25(OH)D. The finding suggests that vitamin D analogs without 1α-hydroxyl group could be developed as drugs for cancer prevention and treatment.

In conclusion, ecological and biochemical evidence strongly suggests a potential use of non- or less-calcemic analogues of vitamin D for the prevention and treatment of cancer. By making a simple substitution at the A-ring of the 1α,25$(OH)_2D_3$ molecule, our team has obtained an ultra-potent vitamin D analogue, MART-10, as demonstrated in both in vitro and in vivo pre-clinical studies. Its further derivatisation has produced potentially more effective drugs for the prevention and treatment of different forms of cancer.

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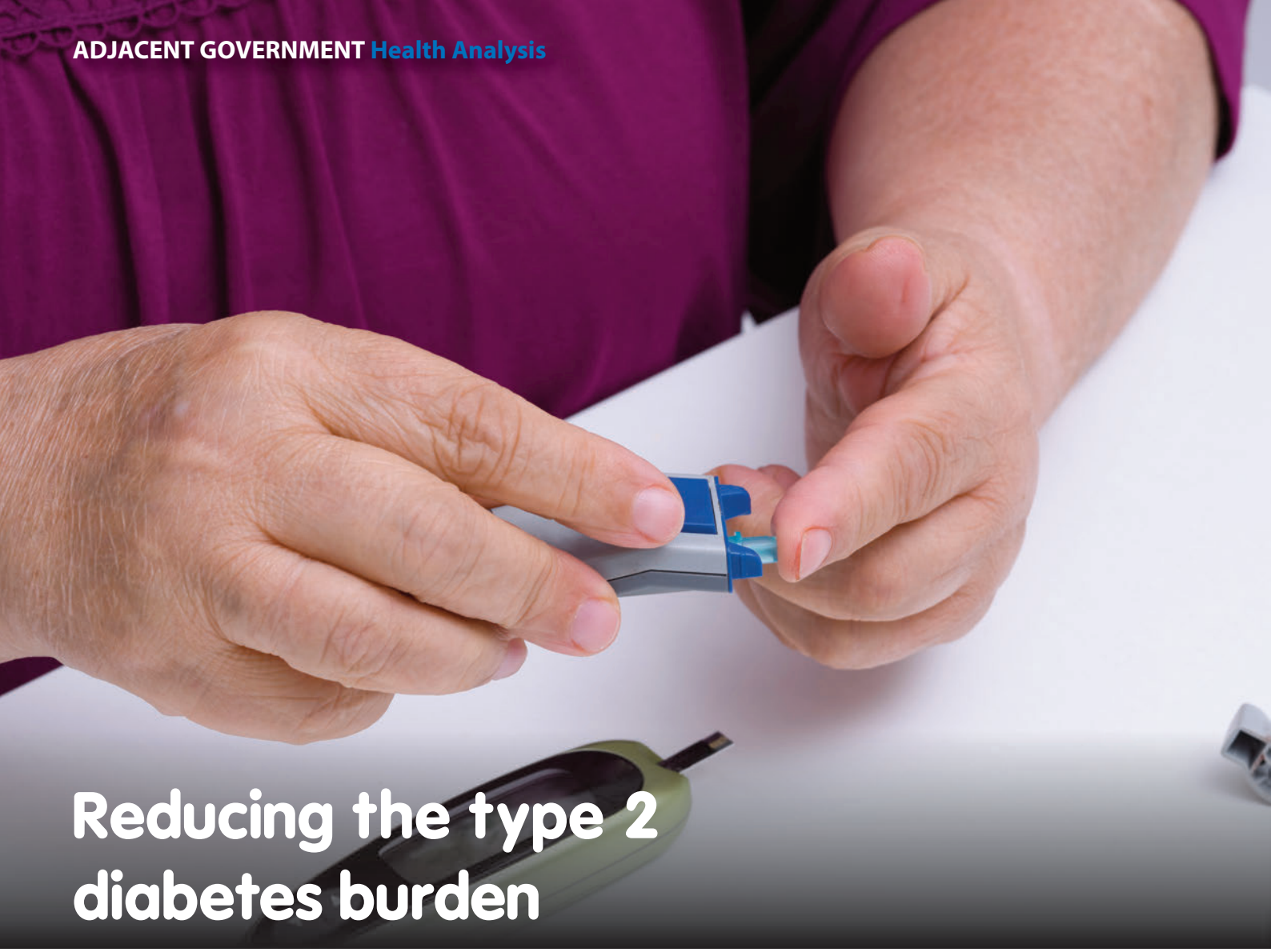

Reducing the type 2 diabetes burden

Professor Jonathan Valabhji, National Clinical Director for Diabetes and Obesity, NHS England, details the main impacts of type 2 diabetes and how the NHS National Diabetes Prevention Programme (NHS DPP) aims to limit these impacts...

Diabetes is associated with in excess of around 22,000 deaths every year in England. Type 2 diabetes accounts for over 90% of all cases of diabetes. The health impact on the individual is stark – it is a leading cause of preventable sight loss in people of working age as well as being a major contributor to kidney failure, lower limb amputation, heart attack, and stroke. Financially, the cost of treating type 2 diabetes accounts for almost 9% of the annual NHS budget – £8.8bn a year.

There is a direct association between the growth in the number of people with type 2 diabetes and Britain's expanding waistline, as those who are overweight or obese are at higher risk of developing the condition. Currently two thirds of adults and one third of 11 year olds in England are overweight or obese and this figure is increasing. We estimate that over 5 million people in England are currently at high risk of developing type 2 diabetes and worryingly, if current trends persist, one in 10 people could have type 2 diabetes by 2034, meaning that if nothing is done these devastating health and financial burdens will get a lot worse.

"The programme will establish and implement simple and effective referral mechanisms so individuals identified to be at high risk of developing type 2 diabetes can be offered appropriate, evidence based interventions."

Studies suggest that a large number of cases of type 2 diabetes are related to modifiable lifestyle factors and

the risk of developing the condition can be significantly decreased by reducing weight, increasing physical activity and improving diet. The evidence shows such interventions can reduce the incidence of type 2 diabetes in those at high risk by 26% on average. This is why NHS England, Public Health England and Diabetes UK are establishing the first national at-scale diabetes prevention programme in the world, aiming to reduce the future incidence of type 2 diabetes.

The NHS Diabetes Prevention Programme (NHS DPP) is an evidence-based behaviour change programme focused on lowering weight, increasing physical activity and improving the diet of those individuals identified as being at high risk of developing type 2 diabetes. It is about supporting people to take control of their own health and reduce the risk of developing the condition. It's about prevention.

The programme will establish and implement simple and effective referral mechanisms so individuals identified to be at high risk of developing type 2 diabetes can be offered appropriate, evidence based interventions. It will also allow outcomes and follow up activity to be captured so that we can evaluate and improve the programme over time.

The NHS DPP will be available for adults identified as at risk. This will include people who have already been identified as at risk through previous blood tests and have existing results on practice registers and will also provide a referral option from the NHS Health Check programme, which invites adults between the ages of 40 and 74 for cardiovascular risk assessment, including an assessment for diabetes, every 5 years.

Public Health England has commissioned reviews of the available evidence from existing diabetes prevention programmes and from real-world translations of the evidence from the clinical trials. This will be published, following peer review, over the summer.

The evidence reviews have informed the development of the programme, ensuring it is driven by the best available and most current evidence.

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Alongside this we are currently working with 7 local areas, known as demonstrator sites, to learn practical lessons from delivery. These sites were selected to work with us to co-design the service model and support us in developing and implementing a national programme. In particular they will support us in examining local perspectives on the service model, including potential barriers and facilitators to implementation, and strategies for the recruitment and retention of at risk individuals and alignment with existing services. ■

For updates on the programme please visit: www.england.nhs.uk/ndpp . You can also sign up to our regular e-bulletin by emailing: diabetesprevention@phe.gov.uk .

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Medicinal Chemistry – driving therapeutic discovery

Professor Craig Lindsley, co-Director and Director of Medicinal Chemistry of the Vanderbilt Center for Neuroscience Drug Discovery, Vanderbilt University outlines how medicinal chemistry plays a role in drug discovery...

Medicinal chemistry is the application of synthetic organic chemistry to biological problems with the end goal of developing a novel small molecule therapeutic agent to treat an unmet medical need. Medicinal chemists are charged with understanding all aspects of drug discovery (chemistry, pharmacology, drug metabolism and in vivo behavior), and utilising these diverse inputs to design molecules suitable for use in humans while also enabling intellectual property position, e.g., patent protection. Moreover, the chemistry (e.g., chemical matter) varies across programs, and the medicinal chemist must be an astute synthetic chemist with a broad repertoire of chemical knowledge to be successful. It is often unappreciated, but like medical doctors, most medicinal chemists spend more than 10 years in undergraduate, graduate and post-graduate education before landing their first pharmaceutical position.

While drug discovery is the very definition of 'big team science', medicinal chemists are perhaps the most well-rounded of all the scientists, following programs from conception to the clinic. Without question, medicinal chemistry is the major force driving therapeutic discovery and improving human health over the last 100 years – from antibiotics to chemotherapy to schizophrenia. Consider the past 25 years of medical advancement for which medicinal chemistry has led the charge. Medicinal chemists have developed revolutionary treatments for HIV/AIDs, rendering it a manageable disease from what was formerly a death sentence, fundamentally changed cardiovascular health (and CV-related deaths) with the statins (e.g., Lipitor), produced game-changing cancer therapies that can add more than 10 life-adjusted quality years, and in 2014, with the launch of Sovaldi, an HCV cure that eliminated the need for liver transplants.

Great strides have also been made in terms of brain disorders and therapeutics for the central nervous system (CNS). Here, medicinal chemists play dual roles, developing not only the small molecule drugs, but also diagnostic and imaging agents to enable personalised, effective treatments across diverse patient populations. New small molecule therapies are under clinical development for schizophrenia, Parkinson's disease (PD), major depressive disorder (MDD) and Alzheimer's disease (AD) that represent novel mechanisms of action with disease modifying potential and offer efficacy far beyond the standard of care. For schizophrenia, medicinal chemists rescued patients from asylums and electroshock therapy, with drugs that address the positive, negative and cognitive symptoms and enable them to integrate back into society. To this point, the top selling small molecule drug last year was Abilify, an antipsychotic with world-wide sales in excess of $9.2bn. In the case of PD, scientists have studied the brain circuit modified by invasive surgical procedure known as deep brain stimulation (DBS), identified molecular targets (proteins) that can be modulated to mimic DBS output, and then, medicinal chemists created small molecules to engage these targets and normalise these dysfunctional circuits. Three new drugs have launched in recent years for Multiple Sclerosis (MS), which have transformed how this neurodegenerative disease is managed, and medicinal chemists are now focused on neuroprotection/neuro-restoration strategies that will impact a broader array of CNS disorders. Here, in CNS drug discovery, medicinal chemists truly shine. Not only do they have to design and synthesise compounds to engage the desired target, but they must be orally bioavailable (e.g., a pill), cross the blood-brain barrier (evolutionarily designed to keep foreign chemicals out), and be safe to allow daily maintenance therapy for life. These are incredibly difficult requirements and challenging obstacles, but medicinal chemists surmount these issues, as they know patients are waiting, and driven to impact human health.

Despite these successes, medicinal chemists are under great employment pressure from the fiscal realities of outsourcing in developing nations, from downsizing/lay-offs due to mergers/acquisitions in the pharmaceutical/biotech industry, as well as pharma-coeconomics. Thus, the ranks have greatly dissipated, by approximately 70%, in the United States and Europe during the past 2 decades. These trends should alarm the public. When the next "HIV-like" epidemic emerges, we will have neither the needed number nor the diversity of medicinal chemists in place to effectively rally and combat such a scenario as we did in the 1990s, with disastrous results for society. Moreover, we should all consider Alzheimer's disease (AD), forecasted to affect 1 in 5 over 65 by 2030, for which we have no cure, only palliative treatments. Scientists and medicinal chemists need to focus on AD as the drug discovery challenge of this generation to find disease-modifying treatments.

Rest assured, it is not all gloom and doom – medicinal chemists are actively and passionately working on the design and synthesis of new small molecules to address the unmet medical needs of the day, gradually replacing invasive surgical procedures and extended hospitalisations with simple pills or capsules one can take at home, with great overall savings and benefits for society. The next time you have an ailment that a physician can prescribe a drug to treat, as opposed to surgery, you have a dedicated medicinal chemist to thank. ■

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The first purified chemical compound to be used as a drug is believed to be digitalis obtained from foxgloves in the mid 18th Century.

Where will our

A view from one of the drug discovery teams at the University of Strathclyde, Glasgow, Scotland

Earlier this year I completed a three-year term as a 'Public Partner' on the Scottish Medicines Consortium (SMC), which is the body that advises the National Health Service in Scotland on the cost effectiveness of medicines. My job was to make sure that the patient and the public had a voice in the debates. With that in mind, my blunt answer to the title question is that I don't care, provided that the new medicine is effective and safe. However working also in early stage drug discovery (at the University of Strathclyde, Glasgow, Scotland), I must have a starting point from which to begin the search for a new drug. In the history of therapeutics, many things have been used as medicines: plant and animal products, microbiological products, synthetic compounds including both small organic molecules and large proteins, and even a few elements. Almost all of these possibilities remain viable today but different people take different approaches.

Some pharma companies specialize in proteins, the so-called biologics. This is the most recent source of active compound to reach the market and has had an impact chiefly in the therapy of cancer and inflammatory disease. My experience on the SMC showed that these medicines were high cost, often required out-patient care for administration, and were

new medicines come from?

sometimes challenging with respect to side effects. Other companies maintain an emphasis on small, organic molecules as the active ingredient. Indeed there are pressures for the size of molecule to become smaller in order to get the best value for a drug. Cost and side effects matter with these compounds too. Outwith western industrial pharma an answer from an Indian physician might be "Very little, actually. We've have plenty of good drugs from Mother Nature in our traditional Ayurvedic medicine".

Everybody can't do everything and companies need to make choices but we can't afford to ignore any viable possibilities as a scientific and industrial community interested in improving health and well-being. There's no doubt that drug discovery is more difficult than it once was for many reasons including an increasingly challenging regulatory environment, a lack of good druggable targets (all the easy ones having been done), increasingly challenging disease states associated with aging populations, a lack of good quality new chemical entities, and so on. Overall an intrinsically risky business has become riskier.

Now as an academic, one of my principal concerns is to create opportunity from my research, specifically in the field new small molecule chemical entities for new drugs; most of the work in my labs concerns designed small organic compounds. Our central scientific input is the mature field of heterocyclic chemistry, which, almost uniquely, is able to bridge creatively chemistry and biology and to connect further with medicine. So I make no apology for plugging a science that still makes a difference at the cutting edge. We must continue to teach and train young scientists in chemistry so that they can translate its powerful methodology and creativity into products containing new chemical entities that will make a difference.

No surprise, therefore, that having found something new with potential, I'm very keen for it to be developed towards the market and happy to play an appropriate role in that. Gratifyingly I can speak to several new opportunities from my lab in immunomodulation, cardiovascular disease, and most significantly in anti-infective compounds where we have a new antibacterial compound that has entered phase I clinical trials developed by our partner company, MGB Biopharma in a formulation designed to treat Clostridium difficile infections. MGB Biopharma has also developed an intravenous formulation for the treatment of other Gram-positive bacterial infections building upon basic science from the University of Strathclyde [see http://www.mgb-biopharma.com].

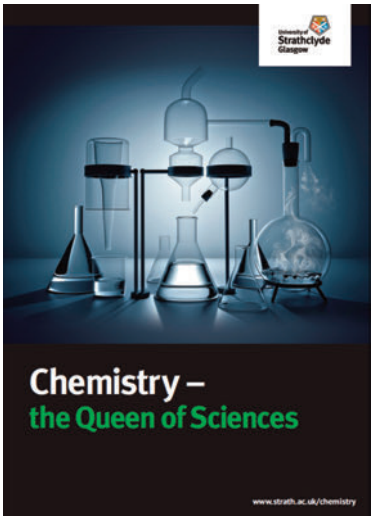
MGB-BP3 is the first in a line of new anti-infective compounds that ultimately work by controlling gene expression by binding to the minor groove of DNA in the target organism, according to the best evidence we have. It's one of a family of compounds that we call Strathclyde MGBs (S-MGBs). We now have S-MGBs that are effective against a wide range of infectious organisms in particular Gram-positive bacteria and trypanosomes, the disease causing agent of sleeping sickness. We've been able to make such progress and to create such impact for several reasons. Firstly the S-MGB platform uses very flexible heterocyclic chemistry so that we can tune the properties of our compounds to target different pathogens whilst remaining safe for the infected host. Secondly, we have strong team-work between many academic colleagues in chemistry and biology at Strathclyde but also at the University of Glasgow. Thirdly, we've worked in partnership with MGB Biopharma; the company's ability to raise funds in a difficult economic climate and to drive through the development programme for MGB-BP3 has been extraordinary.

The outcomes of our research are not just the important practical applications but the advancement of the underlying science. For example, we are developing new chemical technologies to synthesise the compounds we need to evaluate. Also in studying the effect of our drugs on the target bacteria and parasites we are discovering more about the internal workings of the infectious organisms. With such information available we would hope to devise new and more effective drugs for infectious disease.

Caption Left: MGB-BP3 formulated in capsules for treating Clostridium difficile. Right: a freeze-dried sample of MGB-BP3 for reconstitution as an intravenous medicine (courtesy MGB Biopharma).

So what does a heterocyclic chemist do to create opportunities for new drugs? Firstly, there has to be a promising and preferably novel starting point, which could be a new compound discovered by screening, usually plant or microbial products or occasionally a compound from animals, or it could be a molecular hypothesis. This is not new at all. In fact it's what has been done ever since chemists got into drug discovery. The new thing, however, is the stringency with which 'promising' and 'novel' can be defined. 'Promising' may relate to an unmet need in medicines currently available. 'Novel' may also reflect unmet need but will also concern the chemical class of compound being investigated. From there, the chemistry-biology interface is so much better developed now that a good deal can be discovered about important things like selectivity and toxicity before a synthetic chemistry programme is begun.

Choosing what to make and how to make it with due regard for the probability of a successful development and for chemical novelty is then the key contribution of the heterocyclic chemist. This is the essential link that both mediates between chemistry and biology and also creates the therapeutic opportunities through the new compounds that emerge. What makes today's science so exciting is that the tools and techniques that we have the power to explore the most detailed properties of molecules and the intimate workings of biology. This means that the coupling between chemistry and biology that is essential in drug discovery is stronger than ever before and is why we place such an emphasis on scientific teamwork at Strathclyde, as is discussed in my e-book which also gives more details of our projects and our approaches through heterocyclic chemistry [see "Chemistry, the Queen of Sciences" available here from the Adjacent Government website.



Cover page of my e-book, which describes in some detail the approach we take to drug discovery using heterocyclic chemistry. An editorial from the Royal Society of Chemistry provides a supportive context.

An overview of drug discovery at the University of Strathclyde can be found in the brochure 'New Medicines, Better Medicines, and Better Use of Medicines', which is accessible on the Stakeholder website of Adjacent Government.

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Everyday chemistry

David Cole-Hamilton, President of the European Association for Chemical and Molecular Sciences (EuCheMS) explains how chemistry is all around and plays an integral role in many sectors...

Chemistry pervades everything we do. It is all around us and we could not live the lives we do without it. Manmade chemicals are all around us too. Without them, we would not be able to feed the world or have safe drinking water. We would not be able to drive our cars or cure diseases. Life would be much less comfortable without modern textiles, plastics, paints, etc. and we would have no mobile phones computers or televisions.

All of these very important uses of chemicals lead to a huge economic advantage for regions which have well developed chemical industries, and Europe is a good example of this. About a quarter of the balance of trade surplus of the EU comes from the chemical industry and about 1.2 million people work in chemistry and a further 2.4 million in jobs dependent on chemistry.

A renewable chemical landscape

However, there are still huge challenges. Most of the manmade chemicals now in use are made from oil based feed stocks, but oil is becoming scarcer and more expensive, threatening our current way of life. This presents a huge opportunity for chemists to develop new processes for making the many things we currently take for granted but from renewable resources. Most of these resources will be plant based, but they have to be developed without threatening the food supply. This means that they should mostly come from by-products of food production, especially cellulose and lignin. Current research into using these chemically rich but very difficult to work with resources is growing fast and will lead to a whole new chemical landscape.

Tackling climate change

Climate change arises from burning fossil fuels in power plants, vehicles and industry. If we do not stop this endless pumping of carbon dioxide into the atmosphere, the planet will not be able to sustain our children and grandchildren. It has been suggested that climate change is the very worst problem affecting future life on earth.

David Cole-Hamilton, President of the European Association for Chemical and Molecular Sciences

Hydrogen is the perfect fuel because when it burns it gives very large amounts of energy and produces only water – no pollution and no greenhouse gases. At the moment hydrogen is made from fossil fuels, but it can be made from water using sunlight if the right catalysts are added. Potentially, this allows us to make a fuel from abundant water and to burn that fuel to regenerate the water used. Current research is aimed at increasing the efficiency and especially lifetimes of the catalyst.

"About a quarter of the balance of trade surplus of the EU comes from the chemical industry and about 1.2 million people work in chemistry and a further 2.4 million in jobs dependent on chemistry."

Controlling life-threatening diseases

Tackling diseases of ageing, antibiotic resistant bacteria and cancer are all chemical problems. Huge progress has been made but much more needs to be done. Chemists, working in collaboration with biochemists and medical doctors hold the key to conquering these and many other diseases.

How can EuCheMS help?

EuCheMS, the European Association for Chemical and Molecular Sciences is an overarching body for all the chemical societies in Europe and as such it provides an independent and unified voice for 160,000 chemists. It aims to ensure that the European Parliament and the Commission are aware of the chemical aspects of any legislation that is being considered; it responds to consultations concerning chemical matters issued by the European bodies and provides early information on chemical issues as they arise. It does this by running awareness events in the European Parliament. Recent or forthcoming examples include workshops on:

- Energy storage through chemical means;
- Using carbon dioxide as a feedstock for chemicals production;
- Preserving endangered elements; elements that are used in everyday consumer goods such as computers and mobile phones, but for which the total supplies are only sufficient for < 100 years.

EuCheMS also attempts to raise public awareness of these critical issues with recent public lectures related to securing clean food and water supplies for an increasing population, as well as to ways to make energy without producing any carbon dioxide or other greenhouse gases.

Finally, EuCheMS, through its Divisions and Working Parties, as well as through its biennial chemistry congresses – the next one of which will be held in Sevilla in September 2016 – keeps the chemistry community updated on the very latest developments that are occurring in all areas of chemistry. ■

If you would like to be involved in this exciting work, please sign up at www.euchems.eu .

EuCheMS
European Chemical Sciences

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