

MAY 2017

# DISRUPTIVE MODELS OF HEALTHCARE FOR EUROPE

DISCUSSION PAPER



This publication is part of Friends of Europe's Health and Wellbeing programme. It brings together the views of Friends of Europe's large network of health professionals, policymakers, scholars and business representatives on disruptive innovation for health. It closes a series of three high-level roundtables that Friends of Europe organised to examine the steps needed to create 'disruptive models' for overhauling and improving healthcare systems across the European Union.

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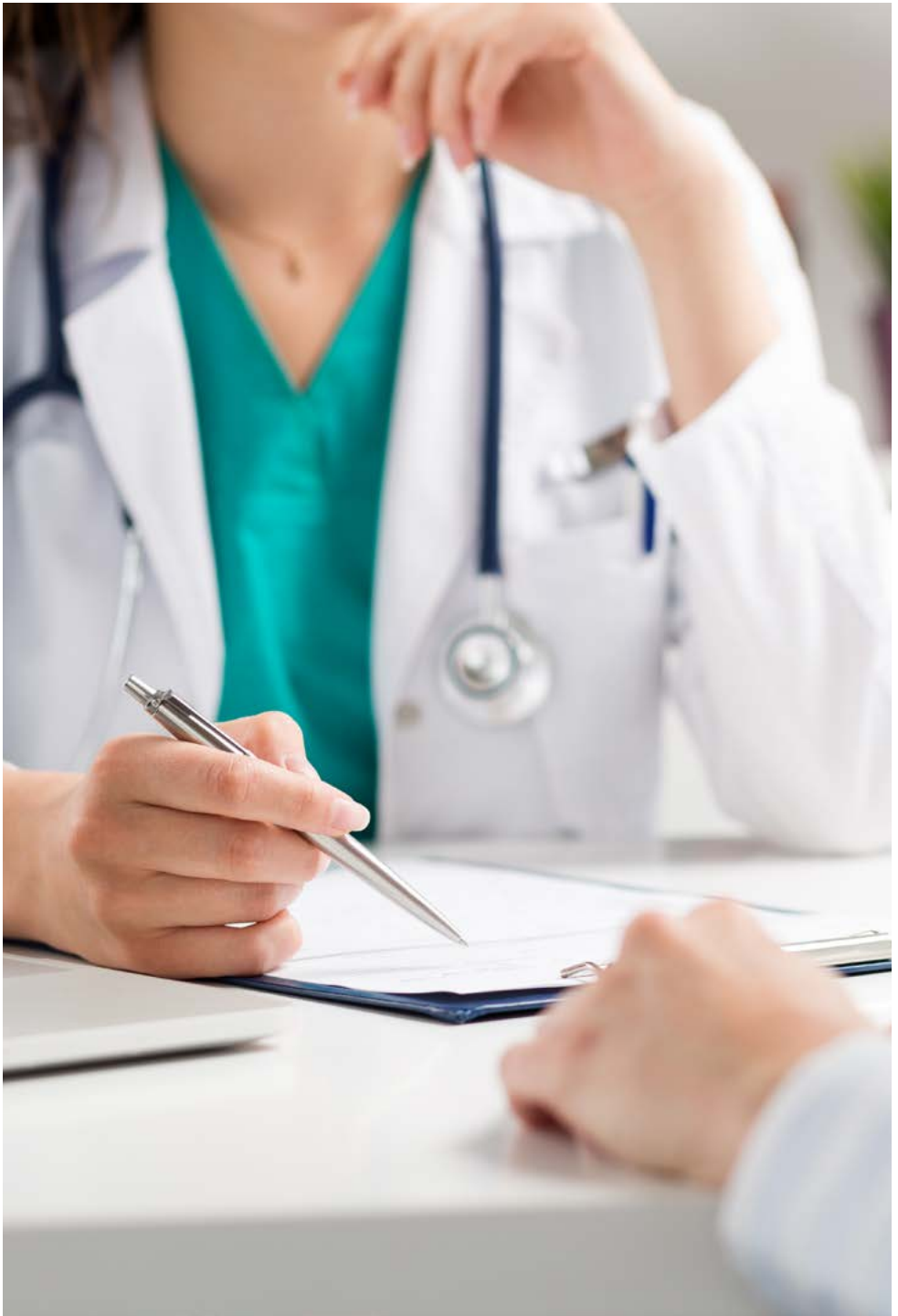
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# PREFACE

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It is high time to reform Europe's healthcare systems. Converging pressures of an ageing population, the growing burden of chronic diseases and unhealthy lifestyles, shortages of healthcare workers and increased demand for care are significant challenges for the sustainability of healthcare systems.

If healthcare could be transformed by the kind of 'disruptive innovation' that has revolutionised other sectors of the economy, such as banking, retailing and tourism, the potential efficiency and cost gains would be huge. But this means introducing sometimes radical reforms to long-established institutions and practices.

Disruptive innovation means involving non-traditional actors who bring new concepts with different value propositions that undercut the existing offer and open up choices for a broader range of consumers to engage differently in a newly-created space. Could this type of innovation pave the way for a much needed shake-up of our healthcare systems?

On this basis, the independent Brussels-based think tank Friends of Europe launched a one-year reflection process on disruptive innovation for health in Europe. It convened a series of high-level roundtables to examine the steps needed to create 'disruptive models' for overhauling and improving healthcare systems across the European Union.



The roundtables brought together a diverse group of stakeholders from across Europe representing policymakers at EU and national level, international organisations, academia, health-related industries and non-governmental organisations. These sessions explored the role of regulatory frameworks, new business models and how to build a value network that will initiate and implement change on a large scale.

The series built on the outcomes of the Health Working Group, convened by Friends of Europe in the run-up to the last EU elections, which identified 21 recommendations for what the EU should 'Start', 'Stop' or 'Do Differently' during the 2014-2019 mandate to improve the health status of Europeans.

This discussion paper includes the key outcomes of the roundtables as well as a number of original guest contributions from leading authors in the field, adding food for thought to the perspectives raised during the debates. It sets out seven key recommendations to reform Europe's healthcare systems and extend the number of years Europeans enjoy good health.

This paper shows that we have the means to overcome the challenges faced by our healthcare systems. What we need now is political courage and leadership to allow a mindset shift that will drive health innovation across Europe. Let's go the extra mile to make Europe a champion of health innovation – a forward-looking continent where new ideas can flourish.

# FOREWORD

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## EUROPE NEEDS AN OFFENSIVE STRATEGY TO LEAD THE 4TH INDUSTRIAL REVOLUTION

**T**he digital revolution is rapidly reshaping the world in which we live. What a few years ago appeared to be mere science fiction is now entering our homes, our streets, our workplaces, our personal lives: refrigerators automatically ordering new stock; thermostats autonomously regulating your heating based on your lifestyle; smart cars finding their own parking spot. These digital innovations make our daily lives easier, but they also bring profound change in other areas.

Businesses and economies are fastening their seatbelts for the deep disruption of the 4th Industrial Revolution, pushed by three important megatrends with an unseen transformative impact: the internet-of-everything, big data and extreme automation.

Disruptive, technology-driven transformations have always been part of history. We have to avoid falling into the trap of extreme views, whether a naive techno-optimism or an ultra-conservative techno-pessimism. Although we are going through a major societal and economic transformation, it is not the first fundamental disruption humans have faced. As these debates are not new, we should learn from the past.

One of the most important lessons is that technological revolutions allow core questions to surface regarding education, employment and societal organisation. This is because technology is part of our human nature. A human being is a technological being. We have always used tools to supplement our own physical abilities.

If Europe wants to take the lead in the 4th Industrial Revolution, it will have to decide on an offensive strategy to deal with these new digital megatrends. The European mindset has too often been one of suspicion and mistrust. Europe has been playing defence: partly because it was confronted with global technology leaders from outside Europe, but also because new technologies provoke negative emotions among parts of the general public.

This is not new. Technological revolutions have always generated anger and fear because disruption means that some people feel they are losing or risk losing. But behavioural economics has shown that acting on negative emotions such as anger and fear leads to bad decisions, both individual and collective.

Legislators faced with disruptive evolutions have the very delicate task of seizing these new opportunities while mitigating the risks. Let me focus on two fields that are ready for a bold, European offensive strategy.

The first is (big) data. The digital revolution is a data revolution. Between 2000 and 2012 the global production of data grew 2,000-fold and the amount of all available data is expected to double every two years. In the years to come, this data will increasingly drive our economy. The OECD identified big data as one of the most important sources of growth and innovation. In Germany, studies have shown that the use of big data can enable companies to boost their productivity by up to 30%.

A data-driven economy is a stronger economy; therefore the European Union has to bolster data-driven innovation and growth. The strategy on big data, launched in 2014 by the European Commission Vice President for the Digital Agenda, already charted the key steps for the European Union to seize the opportunities of the data revolution and to be able to compete in a global data economy. Three years later, the Commission has outlined the next steps towards a European data economy.

For a strong data-driven economy, it is crucial to have a free flow of data between countries. A strong European data-driven economy relies on cross-border transactions including collection, processing and use around the world. Unjustified data localisation requirements are barriers that have an adverse impact on innovation. Uncertainty about the legality of international transfers of personal data has the same negative effect. Strong data protection agreements and rules on international data transfers are therefore the foundations for the free flow of data across borders. If we want the Digital Single Market to prosper, we have to avoid the EU becoming an isolated island that relies only on its own rules of protection and prefers data to be stored on its own territory.

The second field is digital skills, an area where Europe has to step up. The digital revolution will be a net job creator, but the nature of jobs is going to change. By 2020, nine out of ten jobs will require basic digital skills. At the same time, there will be 825,000 unfilled positions for digital jobs. Our start-ups, small companies and large players will need thousands of front-end and back-end developers, data analysts and web marketers. Leadership in the 4th Industrial Revolution will require a massive upgrade of Europe's current workforce. Every European citizen, regardless of age and background, should be able to take advantage of all the digital opportunities that lie ahead.

The EU should take a leading role in making sure that all citizens are schooled in digital skills so that the potential of the digital economy and the knowledge society can be fully exploited. It is time to take action. We need massive investment in digital skills and education, while at the same time strengthening those other qualities – creativity, critical thinking and emotional intelligence – that make us humans different from machines.

### **Alexander De Croo**

Belgian Deputy Prime Minister and Minister for the Digital Agenda

# FOREWORD

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## OUTCOMES AND VALUES MUST GUIDE HEALTHCARE INNOVATION

**D**emographic changes. An ageing population. Rising rates of chronic diseases. A squeeze on health spending. These are a few of the health challenges that we are currently facing in Europe. To overcome these challenges, we will need to rethink our perception of ageing and look at new ways of organising and financing our healthcare systems.

I am a big supporter of a Schumpeterian approach to health policy: using innovation as an opportunity to both improve public health and achieve sustainable and efficient solutions in healthcare.

In the area of public health, technology can be used to enable people to live longer and in better health. Apps and devices can help us modify risky behaviours such as alcohol consumption, physical inactivity, smoking and unhealthy eating.

But while longer life is good news, it will put European healthcare systems to the test. This is why our major focus should be on disease prevention and health promotion – an area where the necessary investment has been lacking in Europe. Only about three per cent of current healthcare expenditure is allocated to public health and prevention programmes. This is not enough. If we don't spend on prevention now, we will end up paying double or triple the cost for care in the years to come.

This observation applies all over the EU, and beyond. While healthcare systems are different in each of the 28 EU member



states, and decisions on the organisation of healthcare have to make sense in a national context, many challenges are common, especially when it comes to public health. More can be done collectively at an EU level.

Every year the European Commission gives concrete recommendations to a number of EU countries on how they can improve the effectiveness and sustainability of their health systems. A key principle underpinning these recommendations is that ageing provides an opportunity to strengthen health promotion and prevention and to modernise health systems. The aim of the Commission's advice is to help member states design health systems that are function effectively as the population ages.

Disruptive innovation means looking at new ways to invest in health. In February 2016, the Commission's independent Expert Panel on Effective Ways of Investing in Health (EXPH) adopted a paper entitled 'Opinion on the implications of Disruptive Innovation for health and healthcare in Europe'. The paper provides an analytical framework for the discussion on disruptive innovation in healthcare in Europe.

As well as providing the definition and characteristics of disruptive innovation, the EXPH has identified drivers of and barriers to its implementation, and strategic areas of focus. Examples such as the introduction of general anaesthesia and the shift from disease-oriented to goal-oriented care confirmed that disruptive innovation can be an important mechanism for improving health and healthcare in Europe.

Technology is also set to change medical care. Apps can remind us to take our medication on time. Devices are able to store and transfer medical records and prescriptions. Interactive communication provides us with support from peers. Such experiences empower patients and their families, making them key players in their own health.

Among our tools at EU level, the eHealth Action Plan 2012-2020 sets out a long-term vision for eHealth in Europe, and the Commission will continue to work within the eHealth Network, with stakeholders and member states, to maximise the potential of innovative electronic technologies in health for the benefit of all patients.

Disruptive innovation means a shift to different models for organising and financing care (for instance, person-centred care or medicine pricing systems). Disruptive innovation provides new and different perspectives that, in the long run, tend to reduce complexity in favour of improved access and greater patient empowerment. I am particularly interested in new models of person-centred community-based health delivery that allow for decentralisation from traditional healthcare venues such as hospitals and integrated care models (for instance, the transfer of records to patients).

Of course, the implementation of disruptive innovation requires the creation of new organisational models and management plans, the presence of favourable framework conditions, and new models of commissioning and financing. Education is needed to ensure that the reasons for changes are well-understood and accepted and that disruptive does not become a synonym for abrupt or violent – on the contrary, creative innovation can often mean successful change.

I am pleased that a broad reflection process is underway in the area of health. While there are signs that disruptive innovation could be part of the solution for the various challenges faced by our healthcare systems, I would like to stress these two key points: first, what really matters is outcomes for citizens and patients; and second, the fundamental EU values of equity, solidarity and universality must be respected.

### **Vytienis Andriukaitis**

European Commissioner for Health and Food Safety

## PART 1

# RE-THINKING THE REGULATORY FRAMEWORK TO ENCOURAGE DISRUPTIVE INNOVATION IN HEALTH



### ROUNDTABLE HIGHLIGHTS

A EUROPEAN VIEW OF DISRUPTIVE INNOVATION IN HEALTHCARE

THE POTENTIAL OF HEALTH 3.0 FOR MORE EFFECTIVE AND INTERACTIVE HEALTHCARE

A MINDSET SHIFT IS NEEDED FOR EUROPE TO BECOME A CHAMPION OF HEALTH INNOVATION



# ROUNDTABLE HIGHLIGHTS

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This section highlights the first of three high-level roundtables Friends of Europe hosted on disruptive models of healthcare for Europe. This event discussed the revolutionary potential of innovative healthcare technologies and determined how the present regulatory framework could be improved to encourage fresh thinking.

## DATA IS KEY

Disruption will not come from individual gadgets, but from the overall transformation process, the new models of service delivery and concepts that will emerge. Reform in healthcare policy means evolution. Real revolution will come from patients who are already monitoring their health and will demand opportunities to use this data

in their healthcare, explained **Sabine Koch**, Director of the Health Informatics Centre and Strategic Professor of Health Informatics at Karolinska Institutet.

But the key principle is that patients should be the owners of their data, which is not yet the case in all member states. Some of the data generated in health systems is both incomplete and of poor quality. The best way to drive up quality is to give patients access to their own records so they can correct inaccurate information. To underpin this, regulators need to put in place a system that guarantees all citizens the same level of data protection and security.

However, there are questions about whether we really can deliver this – whether the algorithms to anonymise the data are sufficient and maintain the cyber security of hospitals.

***Reform in healthcare policy means evolution. Real revolution will come from patients who are already monitoring their health and will demand opportunities to use this data in their healthcare***

There have already been examples of serious data intrusion. Medical equipment is also increasingly autonomous and connected to the internet, which raises concerns about security breaches leading to the remote management of equipment.

In addition, the data needs to be made to work. There exists a treasure trove of information (largely in paper form) held by health insurers and authorities. This resource could be used by others to generate new insights on health conditions, patient adherence to treatment and health outcomes.

#### REGULATION AND INNOVATION MISMATCH

**Philippe De Backer**, Member of the European Parliament Committee on Industry, Research and Energy and Member of Friends of Europe Informal Group on Health Policy, said we need in Europe to change from the mindset that if something is not covered by regulation, it is not permitted. In other regions, there is more

market experimentation and users are the ones who decide if something succeeds or fails. Policymakers need to stop reacting to crises and fears with control. Europe should let go and trust people to make decisions themselves.

The momentum for change is coming from social demand rather than a push from technology. Healthcare is already divided between the statics, regulated market of healthcare and the fast-changing, unregulated area of apps, devices and gadgets. In some countries, innovations in areas not yet regulated can come to the market faster because they are not constrained by the wait for regulation. This issue will be taken up by the new European Innovation Council, which will advise on how regulation affects the potential for innovation.

Regulation and innovation happen at very different speeds. Legislation is framed according to the situation 2-3 years before the law was drafted and it then takes another 4 years to be agreed on and enter into force. Innovation moves incredibly fast, so there will always be a mismatch. Because of this, some companies

***Standards have largely been developed at EU level, but the challenge is the implementation by hospitals and local providers. If care providers choose not to apply the standards, EU regulation cannot present a fix***

choose to go ahead and implement their innovative processes and wait either to be sued or for regulation to catch up. Similarly, court cases on data protection have moved ahead of the public debate, creating legal certainty but societal unease.

#### APP OR MEDICAL DEVICE?

Solutions are more frequently being developed that cover many different elements of healthcare, but it is unclear who is liable if a product is used in a different way than the manufacturer originally intended. **Cristina Bescos**, European Innovation Partnership Coordinator at Philips Healthcare, said that industry is looking to the EU for guidance on what is considered a medical device or an app.

**Peteris Zilgalvis**, Head of Unit for Health and Well-Being at the European Commission Directorate General for Communications Networks, Content and Technology, explained that apps are a focus in the

European Commission's 'Digitising European Industry' Communication. It has supported the development of a new Code of Conduct on mHealth applications, which has been submitted for review to the Article 29 Data Protection Working Party. This code covers advertising, consent, data retention and transfer.

#### STANDARDS AS A PATH TO INTEROPERABILITY

Standards have largely been developed at EU level, but the challenge is the implementation by hospitals and local providers. If care providers choose not to apply the standards, EU regulation cannot present a fix. This is a particular problem for devices to be used for home care, where EU support is needed for accreditation. There is currently an insufficient uptake from industry for public tenders.

Big data holds promise for health both in terms of medical breakthroughs and efficiency gains. But the assumption is that all the data is of good quality, which isn't the case. Two things hamper the use of data for research: real or

***The momentum for change is coming from social demand rather than a push from technology***

perceived fears of breaking data protection rules and inconsistency in the use of Electronic Health Records (EHRs) according to European or global standards. The problem is such that most of the automatic decision support tools for medical teams are now based on data from peoples outside Europe, which may not be applicable to much of the European population's genetic background. ○

## KEY MESSAGES

- Technology alone does not solve everything and not everything can be done by regulation.
- Not everything that is 'new' is innovative or an improvement. Remove regulatory barriers when it is safe and improves access for all.
- There is leadership and new thinking at EU level but implementation is blocked by cultural differences and regulatory barriers at national or local level.
- Collecting data strengthens the evidence base for political choices in healthcare. Policymakers have the right to their opinion but not to their own version of scientific facts.
- The EU should do big, not small. Infrastructure needs to be put in place at EU level, but individual consumers will drive the revolution.
- Public procurement tends to focus on the short term issue of getting services for a cheaper price. A more holistic view of the overall healthcare system and its needs could prioritise innovation as a criterion for public tenders.
- Technology may deliver efficiencies in healthcare, but not necessarily cost savings.
- If policymakers want different aspects of the healthcare system to collaborate seamlessly then they need to create financial incentives for them to do so. Get the buy-in from stakeholders to re-think the system and adjust the incentives.

# A European view of **DISRUPTIVE INNOVATION** in healthcare

**Pedro Pita Barros**, Professor of Economics at the Universidade Nova de Lisboa

**Jan De Maeseneer**, Chairman of the European Forum for Primary Care (EFPC) and Chairman of the Department of Family Medicine and Primary Health Care at Ghent University

**Walter Ricciardi**, Professor of Hygiene and Public Health at the Catholic University of Sacred Heart

The three authors are part of the European Commission Expert Panel on Effective Ways of Investing in Health.

The concept of ‘disruptive innovation’ was initially developed in the United States. Given its novelty, the European Commission asked its Expert Panel on Effective Ways of Investing in Health to assess the relevance of the idea to health systems in the European Union.

The word ‘disruptive’ literally means innovative or ground-breaking, but not everything causing an industry to be shaken up and for previous incumbents to stumble should be considered a ‘disruptive innovation’. The Commission’s Expert Panel ultimately defined disruptive innovation in healthcare as “a type of innovation that creates new networks and new organisations based on a new set of values, involving new players, which makes it possible to improve health

outcomes and other valuable goals, such as equity and efficiency. This innovation displaces older systems and ways of doing things”.

A useful way to look at innovations is by their impact in existing domains, fields and markets. An innovation that improves a product or a service in an existing market in ways that customers are expecting is a ‘sustaining and continuous’ innovation. Whenever the innovation is unexpected but does not displace existing markets, it is a ‘sustaining and discontinuous’ innovation. In contrast, a ‘disruptive’ innovation creates a new market or expands an existing market by applying a different set of values, which unexpectedly overtakes an existing market.

A disruptive innovation can often be recognised for improving health outcomes, creating new services and overcoming challenges regarding accessibility to existing or new services, leading to cost-effective methods that create new sets of values, improve access, promote person- and people-centred healthcare delivery, empower the patient, disorder old systems, create new professional roles and capacities, create new sets of values, and introduce transformative cultural changes.

High-technological content is neither necessary nor sufficient to constitute a disruptive

and often only identifiable after the event. Although there are relatively few examples of successful disruptive innovations, many potential ones fail to be adopted and diffused.

The successful implementation of a disruptive innovation greatly depends on several elements. A major one is the creation of new organisational models and management plans, for instance the shift from ‘top-down’ command-and-control towards horizontal ‘complex adaptive systems’ approaches. The engagement of all relevant actors is also necessary. Framework adjustments need to accompany new

***A ‘disruptive’ innovation creates a new market or expands an existing market by applying a different set of values, which unexpectedly overtakes an existing market***

innovation. In other words, an innovation with low-technological content (e.g. strengthening the position of the citizen/patient in the care process) but able to transform the culture and the way a service is provided will be disruptive, while a more technology-intensive innovation that retains the same culture and organisation will not. As such, policy support for disruptive innovations in health systems must not rely solely on recognising new technology, which will be relevant only to the extent that it contributes to the key features of a disruptive innovation.

All innovations carry some risk, but incremental and continuous innovations do have a higher predictability of success and effects. By its very nature, a disruptive innovation is unpredictable

organisational models, introducing or changing conditions that make it possible to finance new models of healthcare delivery.

These elements have counterpart potential bottlenecks that need to be addressed. If a new organisational model emerges, the decommissioning of older structures should follow. Such decommissioning will likely be harder in healthcare systems mainly based on public procurement or funding. It is also often noted that stakeholders of the traditional structures may have much to lose and therefore have a vested interest in blocking these changes.

The policy focus should be on mechanisms that facilitate the experimentation of potential

disruptive innovations, accepting failure as part of the process and overcoming the barriers that may emerge. The high rate of failure requires caution in the rollout of new organisational and business models and pilot projects are a way of gaining information on the impacts on health, on the economy and on the feasibility of adoption. Such mechanisms should have a broad scope because disruptive innovations are often context-specific (socio-economic, political and cultural). The implementation of any disruptive innovation should take into account the system-wide issues of relevance, equity (including access), quality, cost-effectiveness, people-centeredness and financial sustainability (including ecological, financial and social dimensions).

Different barriers will require different approaches, which need to address workforce, cultural, organisational, institutional, economic and legal barriers. For example, within workforce and cultural identity issues there is resistance by healthcare professionals to changing current practice to a more participative, proactive and prevention based system. Also, on the patient side, there are cultural barriers to be addressed that limit user engagement in the development of innovative solutions. Mechanisms will likely involve developing tools to share information, training for professionals and building in transition periods to allow healthcare workers to adapt their working patterns. Other mechanisms need to address the training of end-users and increasing health literacy.

***The policy focus should be on mechanisms that facilitate the experimentation of potential disruptive innovations, accepting failure as part of the process and overcoming the barriers that may emerge***

On the organisational front, mechanisms are needed to ensure interoperability between technological solutions. In addition, there need to be strategies for decommissioning services that are no longer useful or efficient. Payment mechanisms should not create barriers by rewarding volume, but should rather accommodate innovative delivery models that find new ways to integrate care. When legal and regulatory frameworks protect existing business models, this is a further barrier to innovation. Finally, the role of political leadership and support is critical as is regular monitoring of the impact of changes on the system. ●

# THE POTENTIAL OF **HEALTH 3.0** FOR MORE EFFECTIVE AND INTERACTIVE HEALTHCARE

**Madis Tiik**, CEO of the Estonian eHealth Foundation (2007-2011)

The success or failure of our present healthcare systems depends to a large degree on developments in eHealth. Technological innovation and associated new business models can make a tremendous difference to the lives of patients and the work of doctors in the near future. But to understand that future, we need to understand the past and present. How has 'Health 3.0' evolved from 'Health 1.0'? Different countries are at different stages of development, so this process is not based on time but on how and to what extent information is used, analysed, and shared.

Health 1.0 is the first stage of digitalisation: the transition from paper to paperless. The now widely-deployed electronic medical record (EMR) is a digitalised version of the traditional paper-based individual medical chart. It contains all clinical and medical data history of a patient

in a single facility such as a clinic, a GP office or a hospital. It is used by healthcare providers to manage and monitor care delivery within the facility. At the same time, there are different devices and services that individuals can use to collect data for their own personal health records (PHRs). At this stage they are stand-alone solutions with a single device or service having its own data storage.

***Health 3.0 will generate faster  
and smarter action to cure  
and prevent disease***



Most developed nations are currently in Health 2.0, the integration stage, where different systems are able to interact and share data. Once healthcare organisations have adopted complete EMR systems, an electronic health record (EHR) can be implemented, accessible instantly and securely among multiple healthcare facilities within a community, region, state or, in some cases, a whole country.

EHRs are longitudinal patient-centred records that contain the full health profile of a patient (or more accurately, sickness profile since they primarily carry medical history), starting from their first admission or attendance to a medical facility. The sickness episodes of patients are

Health 3.0 is the personalisation stage. The first precondition for Health 3.0 is a personal health account (HA) fully managed by citizens themselves. It will combine data from EHR and PHR service providers. Most importantly, the HA must be easy for them to manage. This requires a unique international health account number (IHAN) that is based on clear and open standards, allowing data to flow seamlessly from different providers. It would operate similarly to the IBAN system that facilitates cross-border transactions in the banking sector.

The second precondition is consent management. When a citizen decides to use a service, they must also give a certain level

## ***The success or failure of our present healthcare systems depends to a large degree on developments in eHealth***

documented in the EMR and shared among medical professionals through the EHR. The primary aim of the EHR is automation of tasks, data-sharing between healthcare providers, integration and streamlining of healthcare provider's workflow. It is very important to ensure that information generated in an EHR is accurate and available at all times. PHRs on different devices and services are more sophisticated at this stage, but their data is still separated from EHRs.

of consent to the service provider. This could be solved using the MyData model, which "equips individuals to control who uses their personal data, to stipulate for what purposes it can be used and to give informed consent in accordance with personal data protection regulations. It makes data collection and processing more transparent and it helps companies or other organisations implement comprehensive privacy protections"<sup>1</sup>.

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<sup>1</sup> [www.lvm.fi/documents/20181/859937/MyData-nordic-model/2e9b4eb0-68d7-463b-9460-821493449a63?version=1.0](http://www.lvm.fi/documents/20181/859937/MyData-nordic-model/2e9b4eb0-68d7-463b-9460-821493449a63?version=1.0)



Health 3.0 will generate faster and smarter action to cure and prevent disease. It will use algorithms, computer power and machine learning elements to analyse, collect and interpret the ever-increasing amount of data being generated. With these new tools, genomic data can be added to the mix. As knowledge about every individual grows, the possibility of personalised care becomes more real.

Artificial intelligence (AI) can help identify problems and suitable services, which will lead to faster cures. In the Health 3.0 future, decision

support systems will be in the hands not only of healthcare providers, but also of users as tools for self-care. People will be able to decide for themselves which data to share and which services they need the most. The role of the GPs will evolve towards health coaching, working with AI to assist people in their treatments.

We have come a long way, but there is still a long way to go in creating real personalised care. What is clear is that Health 3.0 has the potential to revolutionise how people think about their health and medical care. ●

# A **MINDSET SHIFT** IS NEEDED FOR EUROPE TO BECOME A CHAMPION OF HEALTH INNOVATION

**Frank Westermann**, Founder and CEO of mySugr

When I was diagnosed with type 1 diabetes 20 years ago, I soon discovered that managing diabetes is a full-time job. Each day as a diabetic, you need to make around 50 therapy-related decisions, and every one of these decisions can be life-threatening. A mistake such as over-injecting insulin, for instance, is potentially fatal. The difficulties of managing my diabetes while travelling and working led me to ask myself how I could improve my therapy. When smartphones became a mass phenomenon, I realised that they could offer the solution I was looking for as they had the capacity to store all the diabetes data needed to make these daily decisions.

In 2012, I co-created mySugr, a health app that aims to ease the daily life of diabetes patients through data analysis and practical advice. Over

the years, we grew from 4 to more than 30 employees in our headquarters in Austria. As many of my co-workers live with diabetes, the patients' perspective is really at the heart of our project. Today, there are roughly 800,000 registered users of the application, 55% of which are based in the United States, 40% in Europe and the remaining 5% in other countries, including Australia and Canada. While mySugr continues to be Vienna-based, we have recently opened a physical office in San Diego to better connect with our American users.

mySugr started as a European company, but we have been active in the US for quite a long time. My experiences of operating across the Atlantic have given me a good perspective on the challenges faced by medical technology

developers in both regions. Europe's main advantage lies in the regulatory framework for medical devices: regulation is less strict and approval more easily gained, so many medical technology companies choose Europe to launch an innovation. However, there are other ways in which the United States presents a more attractive option for medical technology developers.

In Europe, any form of digitalisation is frequently met with concerns, for instance about data security, which oftentimes overshadow all positive aspects of digital innovation. In the US, however, the response to innovation is overwhelmingly positive, with investors focusing on potential benefits rather than potential setbacks. This optimism leads to greater investment, and developers seeking funding of \$10m to \$20m are much more likely to find it with American venture capital firms than in Europe.

This cultural divide in attitudes also extends to medical professionals. In the US, doctors are more likely to be open to digital innovation; even if they do not like it, they see the need to adapt to the changing landscape. In Austria and Germany, doctors immediately perceive a risk for patients' health and for data security, without understanding the potential benefits for patients and for themselves. They also mistrust a system that they see as financially unviable. It is challenging to persuade doctors to take the time to understand how the technology works and to accept that patients and other stakeholders should have access to data and the tools to process it.

An additional challenge in Europe is the lack of a centralised healthcare authority. In the US, guidelines on digital health are provided by a single agency, the Food and Drug Administration (FDA), while in Europe, each country has its own healthcare system. A single EU health authority would greatly help developers seeking to make their technology available across the continent.

The US holds a further advantage for me and other developers: the country, and specifically California, is the home of the world's most successful technology companies. With our new US office, we gain a physical proximity to a strong diabetes technology cluster in the San Diego area and the Silicon Valley based companies just a short flight away.

The US is also a global centre for medical technology. Currently, one of the greatest innovations in diabetes diagnostics is continuous glucose monitoring, a small wearable device that monitors the glucose levels of diabetic patients throughout the day. Almost the whole market share of this technology is held by US companies. While this example is specific to diabetes, most digital innovation, in all fields of technology, is happening in the US.

In my opinion, Europe's problem in encouraging and retaining developers in the field of medical technology does not lie in its regulatory framework, which does not present a significant barrier to the launch of new digital services. Instead, Europe needs to make digital innovation a priority, competing in all areas of the technological market, rather than allowing the US to dominate the field. A single healthcare

authority for Europe, with a single set of guidelines governing medical technology, would facilitate the development process and ease the availability of technology across Europe. Finally, and perhaps most importantly, Europe needs a mindset shift towards embracing digital

innovation, acknowledging the benefits it can bring to overburdened healthcare systems and overworked doctors, and understanding its considerable potential for patients in improving quality of care and quality of life. [▶](#)

## CASE STUDY

# IT AND NANOTECHNOLOGY REDESIGNING HEALTHCARE

Working at the nano scale is valuable for medicine as it is the same scale as biological mechanisms. Nanomedicine therefore has the potential to produce very precise solutions for disease prevention, more accurate diagnosis and better treatment strategies to tackle the causes of diseases at the molecular level where they originate.

imec, a Flanders-based centre for innovation, is a pioneer in nanoelectronics bringing smart chip technology to the world of healthcare. Its work spans several areas: the modernisation of structures and processes to keep up with the changes brought about by new technology; the development of technologies for gathering health data, especially in the realm of wearable devices; and the advancement of systems for analysing

data to support healthcare workers' clinical decision-making processes.

Its projects include smart textiles, clothing incorporating electronics that can move and stretch with the fabric whilst providing precise data from sensors; an app that can monitor all factors relating to the user's weight to provide tailored weight loss advice to the individual; and software that can trace the origins of genetic disorders with unprecedented accuracy.

Miniaturisation of chip technology opens up a new horizon for health applications such as the ability to accurately scan hundreds of thousands of blood cells every second. This could lead to identifying cancer metastasis earlier and more efficiently, significantly increasing patient survival rates.

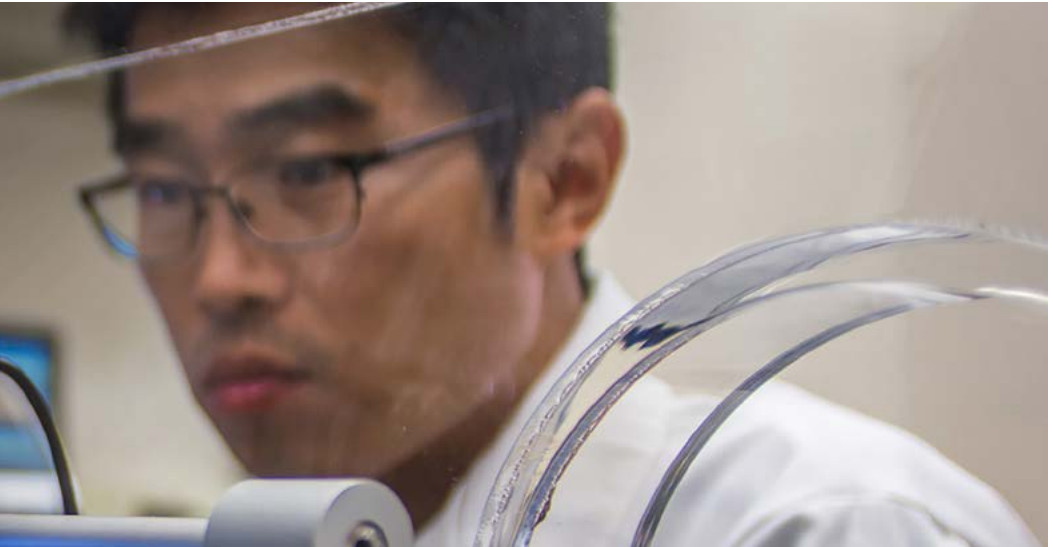


EXTEND YOUR KNOWLEDGE

# 3D PRINTING: THE FUTURE OF ORGAN TRANSPLANTS?

3D printing involves the creation of a physical object from a digital file: the file is fed to a printer that uses materials provided to print the object, layer by layer. The 3D bioprinter is a variation on this technique. As its 'ink', bioprinters use a gel consisting of living cells and nutrients. When printing, this gel is layered with a synthetic hydrogel material that provides structural support to the cells. This finished tissue can then be implanted in a living organism, where the hydrogel biodegrades, leaving only the cells.

The benefits of this technology are numerous. Printed tissue can be designed specifically for each patient: a patient's own cells can be used in the printer so that the new tissue will be accepted by their body once implanted. Another example of this is treating a patient with only one ear; by printing a new ear based on their existing ear, medical professionals



can provide a shape which provides better acoustics for that individual than a generic prosthetic could.

Bioprinting human stem cells is one way of bypassing the controversy surrounding stem cell harvesting from human embryos. Printed tissue has been used in drug trials to replace animal or human test subjects, and the ethical concerns that accompany such testing. In the future, if the technology continues to progress, it may be possible to print organs, eradicating long waiting lists for organ transplants and preventing the thousands of deaths that occur when a suitable organ is not found in time.

Printing organs is the final goal of decades of research into the capabilities of this technology. For some time it has been possible to print plastic and metal implants to replace human

bones, muscle and cartilage. The next stage was printing simple tissue, for example skin tissue for grafts. Then bioprinted tissue was placed in animals to test its ability to adapt and survive.

The big breakthrough was successfully printing capillaries, the smallest blood vessels that convey nutrients and oxygen to cells and remove waste. This development allowed for the printing of more complex tissue that could survive for longer. Trials showed that once transplanted, this tissue could begin to grow and renew itself, developing its own blood vessels, cartilage tissue or bone tissue within the host body. If trials show bioprinted tissue lasting longer than a few months in animal test subjects then printing viable human organs will be a real possibility.

# HOW CAN TECHNOLOGY BE USED TO IMPROVE HEALTHCARE IN EUROPE?

debating europe

friends europe

## THE MARKET FOR TELEMEDICINE\* WILL REACH €45 BILLION BY 2020

\* THE REMOTE DELIVERY OF HEALTHCARE SERVICES, SUCH AS HEALTH ASSESSMENTS OR CONSULTATIONS, OVER THE TELECOMMUNICATIONS INFRASTRUCTURE



SMART INVESTMENT AND INNOVATION IN NEW TECHNOLOGIES IS NEEDED, DUE TO FACTORS SUCH AS CHRONIC DISEASES, AN AGEING POPULATION AND HEALTH WORKFORCE SHORTAGES

### HEALTH

75% OF THE BRITISH POPULATION GOES ONLINE FOR HEALTH INFORMATION



TOP PHARMACEUTICAL COMPANIES HAVE 63% MORE APPS AVAILABLE IN 2014 VS. 2013

## THE INFLUENCE OF SMARTPHONE APPS

PHONE APPS HAVE THE POTENTIAL TO TRANSFORM HEALTHCARE, INCREASING QUALITY AND EFFICIENCY

HEALTH APPS ALLOW PEOPLE TO IMPROVE HOW THEY MANAGE THEIR HEALTH AND DISEASES

DATA CAN BE COLLECTED TO MAKE MORE ACCURATE DIAGNOSES AND TREATMENTS

APPS CAN PERSONALISE MEDICATION WHILE ENCOURAGING HEALTHIER LIFESTYLES

## HEALTH APPS AVAILABLE FOR IOS AND ANDROID DEVICES

2013: 43,000

2015: 100,000

### FACTORS THAT INCREASE THE USE OF HEALTH APPS

TRUSTWORTHY, ACCURATE DATA:	69%
EASE OF USE, SIMPLICITY, DESIGN:	66%
GUARANTEE OF DATA SECURITY:	62%

### THE MOST IMPORTANT SERVICES PROVIDED BY HEALTH APPS

UNDERSTANDABLE INFO ON SYMPTOMS:	23%
COMMUNICATION WITH DOCTOR:	17%
EXAMINATION OF HEALTH RECORDS + MEDICAL TESTS:	16%

### THE MOST POPULAR APPS FOR DIABETES FEATURE

INSULIN + MEDICATION RECORDING:	62%
DATA EXPORT + COMMUNICATION*:	60%
DIET RECORDING:	47%
WEIGHT MANAGEMENT:	43%

### PATIENTS' SINGLE MOST IMPORTANT USE OF HEALTH APPS

2<sup>ND</sup> 17%

1<sup>ST</sup> 23%

3<sup>RD</sup> 16%

HELP WITH HCP\* COMMUNICATION  
\* HEALTH CARE PROVIDER

PROVIDE INFORMATION ON SYMPTOMS AND MEDICAL CONDITION

EXAMINE OF HEALTH RECORDS / MEDICAL TESTS



### BENEFITS OF DIGITAL HEALTH FOR PROVIDERS

- PROMOTES PATIENT INDEPENDENCE
- IMPROVES OUTCOMES
- FOCUSES ON PREVENTION

### HEALTH TECHNOLOGY BENEFITS FOR NURSES

-60% PAPERWORK  
+25% PATIENT FACETIME  
2 EXTRA PEOPLE SEEN DAILY



### OPINION POLL 2014

WILL TECHNOLOGICAL INNOVATION HAVE A POSITIVE IMPACT ON HEALTH AND MEDICAL CARE IN 15 YEARS?

THE NETHERLANDS: 84%  
SWEDEN: 83%  
DENMARK: 82%

WILL TECHNOLOGICAL INNOVATION HAVE A NEGATIVE IMPACT ON HEALTH AND MEDICAL CARE IN 15 YEARS?

ITALY: 19%  
GREECE: 18%  
GERMANY: 17%



## PART 2

# EUROPE'S SEARCH FOR NEW BUSINESS MODELS



ROUNDTABLE HIGHLIGHTS

DEVELOPING BUSINESS MODELS FOR BETTER HEALTH

MAKING EUROPE A PLACE WHERE NEW IDEAS CAN FLOURISH

LESSONS LEARNED FROM USING DATA TOOLS TO SHAPE HEALTHCARE REFORM

# ROUNDTABLE HIGHLIGHTS

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This section highlights the second of three high-level roundtables Friends of Europe hosted on disruptive models of healthcare for Europe. This event focused on new business models in the healthcare sector that could create much more cost-effective preventive healthcare systems and increase patients' empowerment.

## eHEALTH

Health data should be a public good, owned by the patients and health systems. The future of data should not be left to digital giants. Big data will help to drive change. Two new types of data – genomic and patient-generated – will soon be more accurate and exceed the amount of data entered into medical records by doctors. Cognitive computing capacity can analyse this data and extract new insights. This is a future goldmine for health.

The job of the regulator is to ensure that eHealth is properly integrated into reimbursement mechanisms, said **Clemens Martin Auer**, Director-General of the Austrian Ministry of Health and Coordinator of the eHealth Governance Initiative (eHGI). But it has been a slow process at EU level to agree on profiles, standards and terminology for eHealth. EU funding through the Connect Europe Facility (CEF) has helped bring member states to the table for a framework agreement on the national eHealth contact points, though the challenge now is that few senior decision-makers appreciate the importance of the technical aspects of interoperability or have the cultural aspects of change management high on their agenda.

It is disappointing that no viable business platform for electronic medical records standards has been created at European level. Systems continually need to adapt to the evolving requirements from national

governments, but for each country to do this alone is costly and inefficient. EU funds have been invested in setting up quality accreditation standards for Electronic Health Records (EHRs), which were published and largely accepted by most stakeholders. These standards have been taken up by new member states, but largely ignored by France, Germany, Italy, Spain and the United Kingdom.

Standards and interoperability matter across federated health systems. Member states are making slow progress in negotiating this, but new governance structures and legal frameworks are urgently needed to foster real change.

## DEMAND, SUPPLY AND VALUE

The key elements for disruptive innovation for health already exist – demand, supply and value, explained **Stefan Biesdorf**, Partner at McKinsey & Company and Leader of McKinsey's Healthcare Informatics Group. Patients want

***Few senior decision-makers appreciate the importance of the technical aspects of interoperability or have the cultural aspects of change management high on their agenda***

more involvement (demand), lots of new tools are being created often funded by venture capital (supply) and health systems could get big potential savings from digitisation (value). But the lack of sustainable business models is keeping real change at bay.

Start-ups with great ideas approach insurers or providers for funding, but payers are wary about spending taxpayers' money on unproven concepts. Going down the route of offering services that patients pay for themselves means that only a small proportion of those who need such services could afford them. The alternative would be that patients get services for free in return for giving away their medical data, but this wouldn't be in the overall interest of healthcare systems.

Health systems could take the lead by creating an open technical platform allowing third-party providers to deliver accredited services. They would share their main item of value – data – in return for services that could provide a similarly valuable asset – better population health. For start-ups and innovators, this would mean being evaluated on health outcomes. If something works, they would be financially rewarded. If it doesn't, health systems wouldn't be harmed by sharing in the risk.

## CO-CREATION

**Petra Wilson**, Director at the Digital Health and Care Institute and Chief Executive Officer of the International Diabetes Federation (2013-2016), introduced the concept of co-creation, in which

the end user and provider work together on how a product or service is developed, evaluated and evolved. Co-creation is already common in other areas of our daily lives; rather than watching the programming scheduled by TV networks, a growing number of viewers watch content on demand for instance.

People leave online footprints wherever they go through digitisation. This could allow health systems to be more responsive to users and co-create care. Co-creation in health makes sense because well-being is linked to the physical environment, lifestyle choices as well as political and societal frameworks. This shift needs to happen to prove that the patient is part of the system, not just the end user.

There are interesting examples of co-creation such as *PatientsLikeMe*, which allows patients to monetise their data, and *Vitality*, which offers rewards for healthy choices and entering data for the system to evolve and help other patients.

## NEW BUSINESS MODELS

The problem of providing services in rural areas where there is a lack of GPs, nurses and pharmacists, was highlighted by **Max Müller**, Chief Strategy Officer at DocMorris. He gave the example of a small village in Germany where the mayor spent three years trying to replace the pharmacist who had retired.

***Businesses are ready to find inventive solutions, but they need a legal framework that allows them to be innovative***

To solve this issue, DocMorris implemented a virtual pharmacy service offering live consultations with a pharmacist at the company headquarters in the Netherlands. The pharmacist discusses with the patient, remotely dispenses medication into a secure box stocked with 10,000 medications and gives the patient a barcode to access the box. However, the Federal Union of German Associations of Pharmacists opposed this type of virtual service provision as a threat to its position.

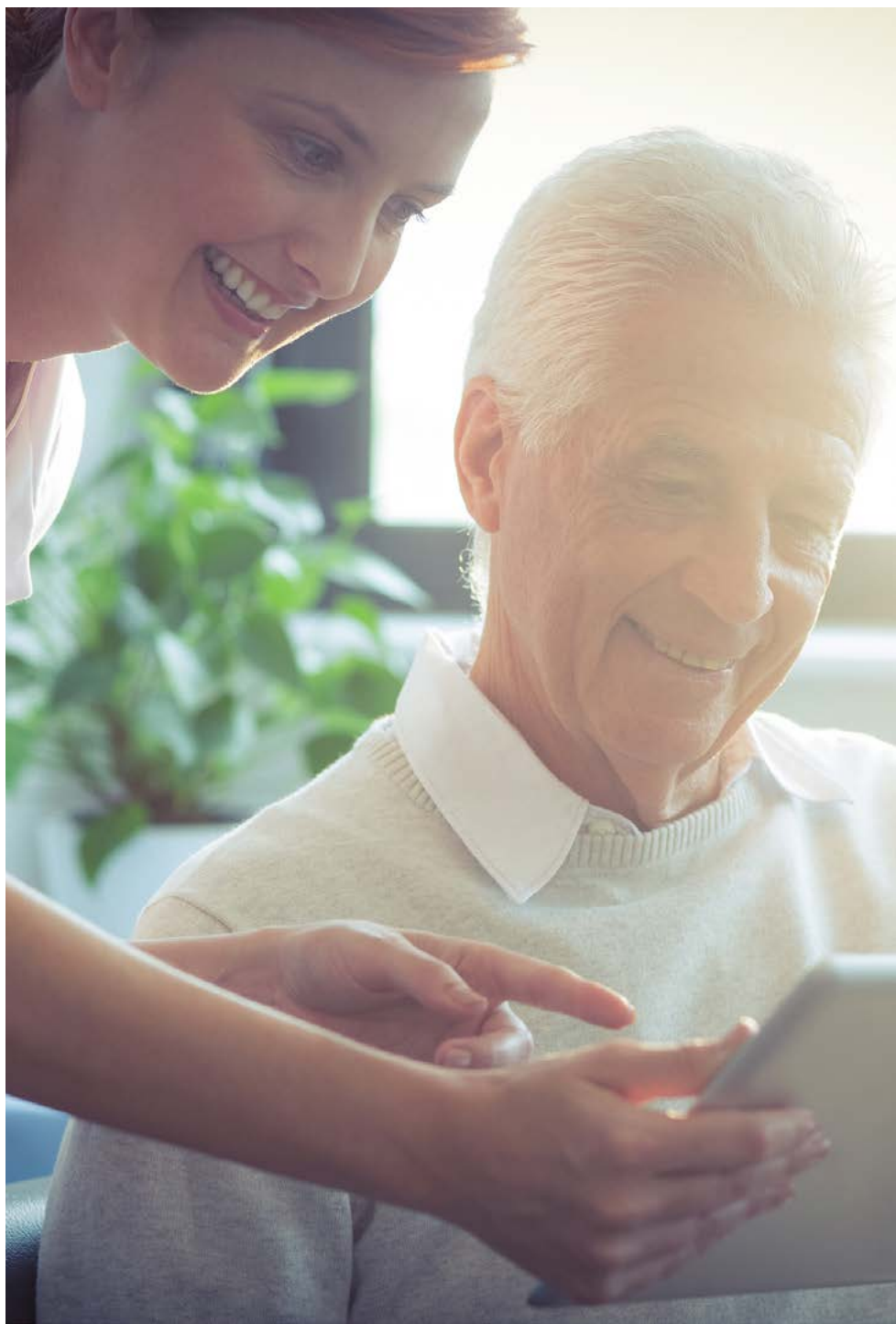
Existing eHealth services show that patients trust digital service provision. However, healthcare systems are not designed for a business model that allows this trust to be exploited. The current working models are largely for those willing and able to pay for it outside the health system. Many public and insurance systems won't pay for virtual consultations, reinforcing the traditional face-to-face model.

There are few barriers to the delivery of virtual health services, so let's use 21<sup>st</sup> century tools to solve problems and gaps in services. Businesses are ready to find inventive solutions, but they need a legal framework that allows them to be innovative. To create more space for innovation,

there could be a health service register at EU level that would set out the services and rights needing protection if a disruptive service is introduced. But right now there is a lot of frustration that change is not happening. ●

## KEY MESSAGES

- Universal healthcare is both a value and an asset worth fighting for. Policymakers need to exercise leadership and find the courage to bring all interests together to find difficult compromises.
  - Solve the conundrum that patients expect clinicians to have access to and use medical records to guide their treatment but when asked about sharing their personal health data, a significant proportion of patients refuse.
  - Integration of health and social services needs to be an explicit goal of policy implementation. This can be physical (locating services together and shared IT) or cultural. But the financial incentives are also key – don't reward fragmentation in service provision and 'silo' mentalities.
  - Update education curriculum for medical professionals to include the use of technology in healthcare.
  - Healthcare systems are designed and negotiated by healthcare professionals, meaning that care is accessible at times and places of their choosing. This needs to change because we are protecting the wrong things.
  - Innovation is happening in small ways in different parts of Europe. Governments need to get better at identifying pocket of changes and bringing them back home.
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# DEVELOPING BUSINESS MODELS FOR BETTER HEALTH

**Jorge Juan Fernández García**, Director of eHealth and Health 2.0 at the Hospital Sant Joan de Déu and European Young Leader

No country in the world is satisfied with its healthcare system. The truth is that most don't get the health outcomes they expect for what they pay. Societies everywhere are changing because of growing populations and rising life expectancy. People are living longer but more commonly with chronic diseases. As the demand for healthcare is increasing, more money will be needed to deliver it.

According to the OECD Health Statistics 2015<sup>1</sup>, one common feature to all OECD countries has been an ever-growing healthcare expenditure, rising considerably faster than GDP growth.

Over the past 50 years, total healthcare expenditures have increased at an average rate of 2 percentage points above GDP growth in OECD countries. But according to a 2015 McKinsey report, "healthcare has not achieved the types of productivity increases that most other industries have experienced. In fact, healthcare ranks near the bottom in terms of productivity improvements since 1990"<sup>2</sup>.

So what are the possibilities for creating new sustainable business models in healthcare? If we analyse in terms of the 'Ten Types of Innovation' methodology by Doblin<sup>3</sup>, there are clear answers by sector.

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1 [www.oecd.org/health/health-systems/Focus-Health-Spending-2015.pdf](http://www.oecd.org/health/health-systems/Focus-Health-Spending-2015.pdf)

2 [www.mckinsey.com/insights/health\\_systems\\_and\\_services/how\\_us\\_healthcare\\_companies\\_can\\_thrive\\_amid\\_disruption](http://www.mckinsey.com/insights/health_systems_and_services/how_us_healthcare_companies_can_thrive_amid_disruption)

3 [www.doblin.com/ten-types](http://www.doblin.com/ten-types)

**Providers** / Providers need to learn to be more efficient. Patients are becoming more actively engaged in managing their own health thanks to new affordable technologies. Providers will need to move away from a business model that is very labour-intensive and infrastructure-dependent into more digital technologies. The use of information technologies and sharing risks with others (mainly pharma, MedTech and digital health) should become the norm rather than the exception.

**Pharma & Biotech** / The model of blockbuster drugs derived from basic research and clinical trials is over. Pharma companies traditionally centred their innovation investments on product performance, but blockbusters are now increasingly rare and most major pharma companies are facing substantial patent expirations. Pharma and biotech companies have an opportunity to transform their products into new services, moving from being pill providers to being healthcare partners.

**MedTech** / As part of the change in approach towards value-based payment systems<sup>4</sup>, medical device companies will also need to evolve from their traditional role as medical technology providers into strategic partners for healthcare systems. The same approach that pharma companies followed with small biotech companies will be used by the MedTech industry, establishing new collaborations with suppliers and customers, with a focus on

***Pharma and biotech companies have an opportunity to transform their products into new services, moving from being pill providers to being healthcare partners***

smaller and non-traditional players, to capitalise on opportunities. In the years to come, we will see the big MedTech players acquiring SMEs in the field of service providers and digital health to transform their technological products into services that will not add cost to the budget.

**Digital health** / Digital health is the main driving force of change in healthcare<sup>5</sup>. We have started to see new ‘digital therapies’, which are being reimbursed. In Europe, there are two good examples: Caterna (digital treatment for amblyopia) reimbursed in Germany and mySugr (diabetes management) reimbursed in Austria. All the big tech players (Apple, Google, Facebook, Amazon and Microsoft) are involved in healthcare as well as hundreds of start-ups – more than 1,000 new ventures according to Venture Scanner<sup>6</sup>).

4 [www.hbr.org/2013/10/the-strategy-that-will-fix-health-care](http://www.hbr.org/2013/10/the-strategy-that-will-fix-health-care)

5 [www.cbinsights.com/blog/digital-health-versus-biotech-startup-investing](http://www.cbinsights.com/blog/digital-health-versus-biotech-startup-investing)

6 [www.venturescanner.com/health-technology](http://www.venturescanner.com/health-technology)



There are two usual approaches for dealing with rising spending pressures:

- Spending less by rationing access to care, imposing budgets and allowing waiting times to rise or by shifting the financial burden to employers or households;
- Spending more by increasing taxes to boost the healthcare budget or by prioritising healthcare expenditure over other public expenditures.

Since the first approach is highly undesirable and the second is very unlikely, we need to consider a third approach: collaborating to innovate across traditionally silo sectors and create new services and products that are not only clinically better but also cost-saving.

### **1) The future of innovation is collaboration**

Partnerships, rather than in-house efforts, will drive this industry. More collaborations are needed between companies that have traditionally been separated to create new value through new value chains: between providers and pharma/MedTech companies (since these companies contribute heavily to the healthcare expenditure), and between pharma/MedTech companies and digital health companies (especially in the fields of big data and artificial intelligence). The key challenge here will be how to balance the two seemingly opposed forces of competition and collaboration.

### **2) Risk needs to be shared among all the stakeholders**

Not only entrepreneurs need to take risks. Governments need to take risks and introduce new ways of financing healthcare and more cost-effective innovative products and services. Pharma companies need to share the risk with governments and health systems. If their drugs don't deliver the expected outcomes, they should not come at a cost to the system. And MedTech companies need to transform their products into services that allow reductions in healthcare costs.

### **3) Value-capture distribution will need to find a new equilibrium**

Traditionally, pharma and MedTech companies have been the main 'value capturers'. When creating new business models in healthcare, there will need to be a new equilibrium in 'who captures what' of the new value created.

Regarding business models, there are only four major possibilities for generating revenue:

- The national health system pays;
- The patient pays (out-of-pocket);
- Somebody else pays (a pharma, MedTech or digital health company);
- Nobody pays.

In synthesis, I foresee a future in which governments establish new financing frameworks to better align the incentives of all the sectors involved towards a value-based healthcare delivery, which alongside current and future scientific and technological advances will allow for new businesses and new business models to appear. In my opinion, we will see more new businesses in the future (as a result of the new scientific and technological progress), but fewer new business models. ○

***We need to consider a third approach: collaborating to innovate across traditionally silo sectors and create new services and products that are not only clinically better but also cost-saving***



# Making Europe a place where new ideas

can **FLOURISH**

**Max Müller**, Chief Strategy Officer at DocMorris

To promote disruptive and innovative healthcare models that are not immediately restricted by current laws or based on obsolete technologies is a dream scenario – especially in the European Union with its 28 different healthcare systems. But it is precisely overcoming this initial hurdle that drove the catalysts of change to introduce new solutions in the United States and in Asia.

Europe does not have any trouble identifying needs, but rather struggles to put solutions into effect. This can somewhat be attributed to Europe's cultural heritage and penchant for perfectionism, which is well-intentioned but often shoots beyond the target. Above all, people lack confidence. Why are Europeans so hesitant to try things out and continue optimising along the way? The developers and companies in Silicon Valley are neither smarter nor better than the minds here in Europe – in truth, they are often Europeans who have

emigrated. They try new ideas and if they don't work, they learn from the experience and try something else. This is seen as entrepreneurial spirit in the US, but as failure in Europe.

Europe has an obsession with certifying everything. I am particularly concerned by the upcoming European legislative framework around health apps. There are more than 400,000 health apps, but very few of them have any relevance. After all, it is the patient who determines if the app is worth using. This was the basic takeaway from a survey conducted on mHealth, which was presented at the eHealth Europe conference in Riga. Much greater priority should be given to recommending general frameworks instead of creating laws and guidelines. Attempts to function as a regulator defining everything from the outset won't work. The term 'disruptive' is by definition contrary to this.

***The developers and companies in Silicon Valley are neither smarter nor better than the minds here in Europe – in truth, they are often Europeans who have emigrated***

Specific changes can be made on an ongoing basis depending on the current state of development. I believe that the European Commission is moving in the right direction on this. But as pleased as I am that the EU is taking strides with the digital domestic market strategy, I have doubts about the utility of an agenda that was drafted in 2015, to be adopted in Brussels by 2017 and finally implemented at member state level in 2020. How can this succeed if we do not foster a less prohibitive culture?

Take just one example from Germany. In 2009, the Federal Union of German Associations of Pharmacists engaged with the European Court of Justice to discuss a potential liberalisation of the pharmacy market. At the time, the national advisory council on health services made the following call for action in a special report:

“The present role of pharmacies as a rather passive institution for the distribution of medicines [must shift] towards an institution which, together with the doctors and members of non-medical health professions, must be integrated into the framework of new organisational and financial structures [...] to become an active part in successful purchasing, proper selections, the effective use [...] as well as in the monitoring of drug therapy.”

Four years later, Professor Andreas Sönnichsen from the Witten/Herdecke University published an EU-funded study according to which there are as many as 58,000 deaths a year from drug side effects, most of which involve multi-morbid chronic illnesses. Josef Hecken, Chairman of the Federal Joint Committee, stated in Autumn 2014 that studies have shown that 30% of all hospital admissions of chronically-ill patients can be attributed to adverse side effects from

medications. This is where innovation and technology should provide assistance.

In 2015, we finally saw the long-awaited German eHealth Act. It includes the new Section 31a Medication Schedule, which states:

1. Effective 1 October 2016, insured persons who are taking at least three prescribed drugs at the same time are entitled to have a medication schedule prepared in paper form by a medical doctor who is a healthcare provider licensed under the statutory system.
2. The medication schedule is to include the following information:
  - a. All medications that have been prescribed to the insured patient;
  - b. Drugs the insured person is taking without a prescription;
  - c. Information concerning any medical products relevant to the medications listed under 1 & 2.

This example shows that it takes several years before the relevant insights are implemented as legislation, and even then it is too complex and addresses some of the wrong aspects. The end result of this new law is simply that

the patient has a written medication schedule. Meanwhile, app developers have already released applications that fulfil the same purpose but are more cost-effective, efficient and, most importantly, easier to use. But the apps are not certified and cannot fit into any legal framework because such laws do not even exist yet.

There is no shortage of ideas. In the early phases of a given process, we need a culture of allowing, not of banning. Regulatory intervention is and must be possible, but technical innovation or disruptive models cannot be predicted by legislators. This calls for a continual process of review and fine-tuning, which will foster innovation and provide the necessary frameworks, laws and legislation, and at the same time will open up opportunities and facilitate improvement. In turn, the discussion concerning infrastructure should be steered by competition towards finding solutions rather than towards stifling innovation. The experts, whether they are doctors, pharmacists or nurses, will benefit from digital solutions that offer a helpful tool for the right diagnosis and treatment – and above all, patients will benefit.

We are a continent of ideas, but unfortunately also a continent where many ideas take years if not decades to bear fruit and at far greater costs than were necessary. We must change this, or the market will change and shut us out of it. ●



# Lessons learned from using **DATA TOOLS** to shape healthcare reform

**Miklós Szócska**, Director of the Health Services Management Training Centre at Semmelweis University, Hungarian Secretary of State for Health (2010-2014), and Member of the EU Task Force on High-Level Advisors on eHealth

The human brain is a remarkable supercomputer, capable of making decisions and arriving at conclusions from surprisingly sparse data. While this characteristic of the species provides an evolutionary advantage by greatly increasing individuals' chances of survival, it is not very useful for scientific research, which has become the driver of modern medicine and the development of health systems all over the world.

The scientific approach to problem-solving requires impartial analysis, large enough datasets and unbiased observation to ensure that the results of research studies are accurate, reliable and applicable to the general population. But the generation and processing of large amounts of data have been very expensive, which has limited the extent to which decisions could be made based on evidence.

The unparalleled recent development of information and communication technology (ICT) has created the conditions to overcome this limitation by making both the generation and processing of scientifically valuable data inexpensive. ICT has infiltrated almost every area of daily life, generating oceans of readily accessible and analysable data. Ever-increasing processing power and faster connection speeds have made online analytical processing possible. It is not surprising that ICT development has quickly become one of the most fashionable topics of contemporary health policy discussions, which are now filled with buzzwords such as 'big data', 'deep data', 'long data', 'eHealth' and 'mHealth'.

Often the methodologies used do not reach further than traditional analytical tools and the new labels become inflated. There is

***There is no question that the impact of ICT in health service delivery can be paradigm-shifting, but it is important to remember that rapid technological development provides only the hardware for this change***

no question that the impact of ICT in health service delivery can be paradigm-shifting, but it is important to remember that rapid technological development provides only the hardware for this change. The availability of exabytes of data, for instance, can just as equally paralyse decision-making as facilitate it. To improve health system performance, you need to know how to use the data.

Under the 2010-2014 government in Hungary, one of the new avenues of health sector governance was to improve evidence-based policy-making with the 'big data' capabilities of the Hungarian health system. An interesting feature of the single-payer Hungarian social health insurance system (which replaced the overcentralised 'Semashko' model of the communist regime) is that, since output-based payment methods were introduced countrywide in 1993, provider activity has been reported using patients' social insurance identification number.

This means that Hungary has an extremely big database that spans more than two decades of

specialist healthcare activity. This data can be analysed down to the level of individual patients. We intended to take full advantage of the opportunities presented by this 'big' and 'long' data from the very beginning to support our efforts to reform the Hungarian health system.

A graphical representation of patient flow between Budapest hospitals helped us identify that patients were being transferred back and forth between two of the highest-level oncology care providers, Semmelweis University and the National Institute of Oncology, because neither had the capacity to provide the full spectrum of care needed to treat cancer patients. Being aware of this fact meant that we could reorganise the patient pathways. It is important to understand that interpreting and acting on the findings offered by big data analysis requires a thorough knowledge of the actors, structure and context of the system being analysed.

Another interesting application of the network analysis of big data is the identification of opinion leaders who are crucial to the successful implementation of any change. The visualisation of publication and reference networks is easily-implementable technology and is based on widely-accessible scientific publication databases. Using publication and reference networks could even be used as an effective tool to influence drug prescription habits.

From our projects, we have come to realise that the potential of big data analysis in this sector depends on three critical factors. First, you need to understand complex systems and the relevant approaches to analysing them. Second, you



need to know the technologies and methods for analysing big and long data. And third, you must understand the system and the context in which the analysis is carried out.

In these circumstances, it is indisputable that implementing eHealth solutions is an effective and important tool for saving both lives and public money. [▶](#)

## CASE STUDY

# THE HEALTHCARE MODEL KEEPING PEOPLE OUT OF HOSPITAL

In the Alzira model, hospital is reserved for the critically ill. Other healthcare is provided by primary care centres, accompanied by a focus on proactive and preventative care. Incentives are provided for patients to be treated in the least care-intensive and therefore most cost-effective setting.

The model is facilitated by enhanced communication systems. Each patient has a single electronic record that can be accessed in all healthcare locations. Expertise is shared between healthcare providers: a network of specialists and local care professionals makes specialised knowledge more accessible within communities, while hospitals' diagnostics departments are available to provide support to primary care centres.

Quality measurement is another key element. Performance indicators are made clear to hospital staff and published health

outcomes allow the comparison of care quality by the government and the general public. Patients have the option of switching healthcare providers, and money follows the patient: only the healthcare system that provides the care to the patient receives reimbursement, increasing the incentive to provide high-quality care.

Data from Spain, where the model was introduced in 1999, shows clear benefits. The model saw a 27% decrease in cost per capita and a 34% reduction in hospital readmissions within three days, while financial risk was transferred from the government to primary care centres. For patients, average waiting times for both A&E and elective admissions were reduced by more than half. The average length of stays was reduced by a fifth. And user satisfaction was high: 91% among patients and 93% among staff.

A man in a red shirt and sunglasses is operating a drone in a workshop. The drone is red and white, and is mounted on a stand. The man is looking at the drone and has his hand on the controls. The background shows a workshop with various tools and equipment.

EXTEND YOUR KNOWLEDGE

# DRONE DELIVERIES SAVING LIVES IN RWANDA

Healthcare services usually require major infrastructure like hospitals, laboratories and cold storage facilities. In both developed and lesser-developed countries access to healthcare is hampered by limited or poor infrastructure. In rural or remote areas, medical teams – if they can be deployed – need diagnostic and testing services to be able to offer appropriate treatment. Motorbikes and trucks carrying urgent medical supplies are prevented from reaching their destinations by impassable roads, difficult terrain and adverse weather conditions. Access to basic supplies such as blood for transfusions could prevent millions of deaths each year, including those of more than 2.9 million children under five, and 150,000 deaths related to pregnancy.

Drone technology has the potential to revolutionise health supply distribution, saving lives through the fast delivery of blood,



medication and vaccines. In late 2016, Zipline, the world's first drone delivery system, was launched in Rwanda using 15 custom-built drones to transport blood products from central distribution centres to hospitals. Healthcare workers send a text message requesting blood. Staff at a centre packs the delivery together with a paper parachute. When the drone reaches its destination, the package can be dropped from the air, meaning that no runway is needed, and the drone can immediately return to the distribution centre ready for its next flight.

Navigating with GPS receivers, the drones can cover up to 150km and deliver 1.5kg within 15 to 30 minutes. This fast turnaround period eliminates the need for on-board cold storage or insulation, thereby addressing one of the key barriers to health supply transportation. The Zipline drones are also able to withstand

wind speeds of up to 50kph, making them more versatile and efficient than similar systems using 'multicopter' designs.

This pilot project was made possible by multi-million dollar donations. These investments allow the Rwandan government to pay the same price per drone delivery as it uses for a motorbike. If Zipline's service is successful then it also could be used for vaccines or other drugs, and the company has hopes for international expansion. But although the Rwandan government was prepared to take the leap and permit the drones to use airspace, this innovation may not take off in other countries where governments have banned or introduced large fees or heavy licensing requirements for commercial drone services.

## PART 3

# BUILDING VALUE NETWORKS FOR CHANGE



ROUNDTABLE HIGHLIGHTS

SOURCES AND DRIVERS OF DISRUPTIVE INNOVATIONS IN HEALTHCARE

DIGITAL HEALTH ECOSYSTEMS: A RADICAL SHIFT TO DRIVE HEALTH INNOVATION ACROSS EUROPE

PATIENTS AND CLINICIANS AS PARTNERS IN CO-CREATING HEALTH

# ROUNDTABLE HIGHLIGHTS

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This section highlights the last of three high-level roundtables Friends of Europe hosted on disruptive models of healthcare for Europe. This event focused on how to create new value chains that combine traditional health actors like clinicians and insurers with technology and data companies. It discussed whether protected silos within healthcare can be opened up to engage relevant players from across the value chain.

## A FOCUS ON IMPLEMENTATION SCIENCE

The difficulties of integrating technology into healthcare in Europe are well known – from contracting and governance issues, data-sharing challenges, to environmental and legal problems, fragmented systems, multiple physical locations and poor coordination. The result is that people go into hospital when they shouldn't, stay in hospital too long, come out with uncoordinated follow-up care and have to keep repeating their stories.

Despite pockets of good practice or innovation, a revolution in healthcare in Europe has not yet happened. A key problem is the misalignment of incentives which can create huge differences in terms of uptake of technologies. For example, GPs in the United Kingdom are paid per patient that they manage, resulting in an incentive to invest in new tools such as telemedicine. In contrast, French doctors are only paid for face-to-face consultations, so using telemedicine may improve their efficiency, but would also reduce their revenue.

Switching to a focus on health outcomes implies identifying 'what' needs to be achieved rather than prescribing 'how' it is done. This is implementation or improvement science, which explores how healthcare can be delivered differently – better, cheaper, stronger. It covers the organisation of delivery of care taking into account elements like the concept of appropriate care (reducing both over- and under-treatment), overcoming administrative complexity, reducing waste (thanks to digitisation) and tackling fraud.

The supply side for innovation in health is flourishing, but the demand side is weak. New types of contracts that embed technology in healthcare are needed between commissioners and providers. These would allocate the sharing of risk and reward in a transparent way. A core set of indicators on health and technology could help innovators find business models that work and improve procurement.

The EU has a role to play, but existing funding mechanisms, from the European Structural and Investment Funds to Horizon 2020, are underutilised. On the one hand, health policymakers talk about funding shortages, on the other hand there are pots of money that are not being used because they are not known about, explained **Nicole Denjoy**, Secretary General of COCIR. For instance, there are instruments to assist faster adoption of technology, such as funding for pre-commercial procurement or bringing together public procurers to learn from one another.

***On the one hand, health policymakers talk about funding shortages, on the other hand there are pots of money that are not being used because they are not known about***

## IMPROVING THE DECISION-MAKING PROCESS

The combination of two trends – digitisation and personalisation – has been driving much of the recent innovation in healthcare. Stakeholders need to come together to co-create a new system designed for wellbeing. We need better evidence so that we can radically challenge models, said **Jenny Billings**, Professor of Applied Health Research and Director for Integrated Care Research at the University of Kent. Randomised Clinical Trials (RCTs) are considered the gold standard, but they neither process information on why things work nor provide rapid data. It is important that academics, clinicians, healthcare commissioners, industry and patients come together to co-design what is meant by failure and success at each stage of the process.

The capacities and responsibilities of people working in healthcare systems need to be redefined. For example, if a hospital's expensive new IT system disrupts the daily routine of nurses and is not relevant given the way that they work, it will not be used. Co-designing new processes would allow the rapid evaluation of outcomes at an early stage and help with potential upscaling.

Good evidence is critical for policy makers, but innovation comes from people, not legislation, said **Michal Boni**, Member of the European Parliament and Polish Minister of Administration and Digitisation (2011-2013). This is particularly important given the fast pace of technological change and the slow timetable of law-making. Medical apps will need a strong framework to

ensure the quality of information sent by these devices to healthcare professionals. In contrast, wellbeing apps might just require soft law tools such as codes of conduct and guidelines.

### SUPPORT HEALTH LEADERS AS CHANGE AGENTS

Within the next five years, healthcare models will evolve radically as new apps and digital devices that monitor individual health status in real-time become more widely used. This is a game-changer for patient care in terms of treatment, but also for prevention and wellbeing. Industry is increasingly shifting towards managed services delivered closer to the patient rather than selling large equipment to hospitals. This new approach requires new forms of contracting and public procurement with greater clarity on risk sharing, financing and quality assurance.

At the level of healthcare systems, change is not happening – not because Europe lacks the capacity to innovate and pilot test, but because implementation is inconsistent due to the fragmented nature of the system and because of incentives that support the status quo. The diversity of Europe's healthcare systems can be a strength if solutions can be deployed in different environments and the learning shared across Europe.

We need to prepare healthcare leaders to be open to innovation, explained **Sylvie Bove**, Chief Executive Officer of EIT Health. They can see the big challenges coming such as

demographics, but they are already struggling with the pressures of cost containment. Some of the resistance to change comes from the impact of innovation on how healthcare professionals work and, more importantly, how they are paid. The health ecosystem will have to be enlarged to bring in new players and update educational curriculums to cover the use of technology. This also means new types of professionals with different skill sets entering the health arena.

### CONNECTING REGIONAL INNOVATION TO NATIONAL AND EUROPEAN LEVELS

Regions could be key to implementing new technologies. Getting pilot projects or prototypes to a regional level means impacting on 5 or 10 million people. This is sufficient scale to prove evidence of effectiveness. Multi-stakeholder coalitions exist at EU level for innovation in health, but these need to connect to equivalent networks at national or subnational level. Innovation champions need to be linked up to help drive change.

The European Commission has already established networks, which could be the basis for a framework for multiple entry points to national and regional levels in health. But the participants in these networks are not necessarily the decisions-makers at the national level. This leads to extensive discussion at EU level, but no action at member state level.

The European Structural and Investment Funds are a valuable mechanism to support regions to implement change. Negotiations started last year on the priorities for cohesion policy after

2020. This is a political window of opportunity to prioritise health as a central element in these key EU investment funding programmes. ●

## KEY MESSAGES

- Regulators have a brief window of opportunity to manage the changes rather than just responding to external developments. Brave decisions will be needed to tackle the vested interests that stifle attempts to reform health systems. This is a pivotal disruptive moment that could be the catalyst for introducing disruptive innovation, but transforming this moment into real sustainable models of change will take a strategy, scale and time.
  - Healthcare has to evolve from treating illness to maintaining health. In terms of information management, this means starting to look forward using digital tools for insights and patient engagement. The first building block is trust – if people don't trust a technology, they won't use it regardless of the certification process. Buyers, providers and users need to collaborate to build trust in technologies.
  - Outcome and value-based measurements are the way to properly assess the benefits of disruptive innovations. Lessons could be drawn from experience across Europe of outcome measurements for health technologies and pharmaceuticals.
  - Building trust into the system is critical for people to feel comfortable sharing their health data. This requires authorisation mechanisms, robust third party authentication and smart regulation.
  - A focus on implementation science is needed that covers contracting, disinvestment strategies, evidence for decision-making, incentives and measurements. Attention also needs to be given to the human factor of changing behaviours and mentalities.
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# Sources and drivers of **DISRUPTIVE INNOVATIONS** in healthcare

**Spencer Nam**, Senior Research Fellow at the Clayton Christensen Institute for Disruptive Innovation

During the first half of the 20<sup>th</sup> century, healthcare was mostly about overcoming global infectious epidemics such as polio, small pox and tuberculosis. The high mortality rates and negative economic impacts from these diseases served as strong motivators for the medical community to find cures. Fortunately, scientific discoveries and innovations led to some diseases being fully eradicated during the second half of the century.

The worldwide impact of these life-saving discoveries has become palpable in recent decades, as the average life expectancy in developed countries has risen from the mid-50s in the early 1900s to over 80 by the end of the century. Longer living, however, has brought new challenges to healthcare. Chronic diseases

such as Alzheimer's, diabetes, heart diseases and obesity typically manifest later in life, making them rapidly emerging epidemics. New forms of cancer and genetic diseases are also more frequently being discovered, increasing the complexity and the cost to healthcare systems. Providing affordable yet high-quality care for everyone has become the new global challenge.

The theory of disruptive innovation explains how new products and services in healthcare can be simpler, more affordable and more broadly accessible without compromising patient safety. Initially, disruptive innovations do not compete directly against established options. They instead find a foothold among new customers who are not utilising the existing solution, either because the product or service does not meet

their needs or because it is too expensive or otherwise inaccessible. For these customers, the new solution may adequately address their problem. Over time, a disruptive innovation improves and creates an entirely new market, thereby 'disrupting' the established solution.

Where will these innovations emerge in healthcare? Most healthcare leaders and innovators associate disruptive innovations with technology, but that's only a part of it. A key element of a disruptive innovation is its business model, in which technology in the form of a product or a service generates a profit when adopted by consumers. Healthcare's established business model of consumers paying for each hospital or doctor visit through a third-party insurance plan has gone through several iterations over the past 50 years, but the core model has remained the same. Unless a

new model emerges where payments are fully integrated into patient-physician interactions, we can expect little change to the system whose costs continue to inflate.

Therefore, disruptive innovations in healthcare are those that leverage existing or new technologies to offer healthcare services outside of the established care model. Emerging technologies such as sensors, wearables, software and diagnostic instruments that promote prevention and behavioural changes have significant potential to disrupt how healthcare services are paid for and offered. Integrated health services models such as Kaiser Permanente and Intermountain Healthcare can potentially rewrite the rules on how healthcare products and services are valued because they process care services and payments under one roof. Retail clinics that



decentralise and unbundle routine healthcare services from centralised general hospital systems are also creating lower-cost models that can satisfy many customers who might find going to the hospital or doctor's office to be too much of a hassle for routine care such as annual flu vaccines. The common theme of these disruptive models is that they reduce costs by simplifying delivery of care and payment.

Another important question is which healthcare stakeholders will drive these transformations? In many sectors, transformative power rests with consumers who determine which products and services succeed. But healthcare has a slightly different answer because it is highly regulated and because third-party insurance companies serve as payers. In fact, healthcare providers and payers have significant influence on patients and this asymmetry is likely to give them the central role in bringing change.

The spread of new business models will likely impact payers the most, as they determine how care services are paid, making them the key agent of change. The pressure on costs will only make the current third-party reimbursement system more difficult to sustain, as the reimbursement community will continue to demand that they are included in physician-patient interactions. Whether the model is a national single-payer system or a competitive model, payers will increasingly assert their presence between physicians and patients. We expect disruptive models in healthcare will either pull payers closer to providers and patients or cut payers out of the transaction.

***The spread of new business models will likely impact payers the most, as they determine how care services are paid, making them the key agent of change***

It is similarly vital that providers support these types of transformations. By virtue of their authority as certified health professionals, they can dictate their future by embracing new models of care. Although daily activities of physicians, nurses and other healthcare providers will continue to change in coming decades, they will remain the most influential voices for consumers in making healthcare decisions. It is an opportunity, not a threat.

Much like how antibiotics and vaccines substantially lowered the mortality rates and cost of care for some of the most dangerous infectious diseases, disruptive innovations are the perfect antidotes for the growing problems of cost in healthcare. But the global community needs to remember that an innovative business model is at the heart of disruption. Furthermore, no matter where the waves of healthcare disruption roll in, health providers and payers will be the stakeholders who scale the new model. Innovators will need to keep their channels open with these two groups and be ready to work with providers and payers to deliver transformations. ●

# DIGITAL HEALTH ECOSYSTEMS: A radical shift to drive health innovation across Europe

**Stefan Biesdorf**, Partner at McKinsey & Company and Leader of McKinsey's Healthcare Informatics Group

**Ulrike Deetjen**, Business Technology Consultant at McKinsey & Company

"We know that in healthcare we lag at least ten years behind virtually every other area in the implementation of IT solutions. We know [...] that information technology applications can radically revolutionise and improve the way we do things," wrote Toomas Hendrik Ilves, President of Estonia (2006-2016) and Chairman of the EU Task Force on eHealth.

This slow uptake manifests itself in various cancelled or delayed IT programmes across the EU, such as the UK's National Programme for IT or Germany's electronic health card. Throughout these projects, the complexities associated with achieving stakeholder buy-in, integrating legacy systems and managing security concerns led to significant cost overruns. This is particularly alarming given that health systems are struggling to reduce overall spending to deal with the demands of ageing populations.

The lag in introducing information technology in healthcare systems is also evident in digital health innovation. As in many areas of everyday life, consumers increasingly expect digital services to allow them to contact professionals, complete prescriptions and take care of themselves. Digitisation is largely driven by health start-ups: flexible, patient-centric app developers with innovation in their DNA. But while there are more than 150,000 health and wellness apps available, only few achieve substantial numbers of downloads, make their way into standard care and fundamentally change the patient experience or deliver measurable benefits to the healthcare system.

***Digital health start-ups often lack the resources to conduct costly and time-consuming evaluation studies to prove the usefulness of their innovations***

**WHAT ARE THE REASONS FOR THE SLOW PROGRESS IN DIGITISING HEALTHCARE?**

First, there are substantial hurdles associated with bringing digital health innovations to life. As opposed to many other areas of healthcare, such as drugs or medical devices, there are no established pathways for introducing digital health innovations. As a first step, Germany's medicines regulator, the Federal Institute for Drugs and Medical Devices (BfArM), has now published guidelines on when to classify apps as medical products<sup>1</sup>. However, classification creates an avalanche of requirements in terms of data protection, security and appropriateness of medical recommendations. The associated costs, particularly in the light of insecure revenue prospects, create entry barriers and may impede innovation.

This links to a second reason for slow progress: the lack of sustainable business models. While start-ups attracted substantial venture capital funding of more than €3.5bn in the first half of 2016<sup>2</sup>, the path to profitability is steep: customers across EU countries are used to social security systems that provide medical services free of charge, thereby limiting people's willingness to pay for apps. Other revenue sources are difficult to tap into, given the activity-based reimbursement schemes for healthcare providers in the EU. In Germany, a handful of apps have made their way into standard care through selective contracting with statutory health insurance. These apps include Tinnitracks for tinnitus relief or Caterna for amblyopia treatment. However, this does not yet represent a scalable basis for innovation.

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- 1 Federal Institute for Drugs and Medical Devices (BfArM), Guidance on 'Medical Apps' (2015), [www.bfarm.de/EN/MedicalDevices/differentiation/medical\\_apps/\\_node.html](http://www.bfarm.de/EN/MedicalDevices/differentiation/medical_apps/_node.html)
  - 2 Startup Health (2016). Digital Health Funding Rankings, 2016 Midyear Report, [www.slideshare.net/StartUpHealth/startup-health-insights-2016-midyear-report-63790166](http://www.slideshare.net/StartUpHealth/startup-health-insights-2016-midyear-report-63790166)



A third and related reason is the questionable usefulness of digital health innovations. While it may improve patient experience to receive tailored advice and track health conditions, does it shape health outcomes? Digital health start-ups often lack the resources to conduct costly and time-consuming evaluation studies to prove the usefulness of their innovations. To do so, they would need access to outcomes data, such as improvements in lab values like HBA1C for diabetes patients, or avoided hospitalisations. However, such data resides either within the IT systems of doctors or payers, to which start-ups do not have access, since they cannot prove their positive contribution to patient health. This fundamental chicken-and-egg problem is hard to resolve.

### WHAT CAN A POTENTIAL SOLUTION LOOK LIKE?

A solution to this conundrum may be a radical shift in the fundamental approach to digital health: establishing an innovation ecosystem with a central platform at its heart. With Airbnb, Alibaba or Uber, this development is tightly embedded in a larger shift towards platform-enabled business models in the digital age. In healthcare, this open innovation platform may hold various kinds of patient data – at first, highly-standardised claims. This data could then be made accessible to digital health start-ups through common application programming interfaces, with the respective health system, as the platform owner, remaining

in control. Of course, basic features such as access, consent management and identity are indispensable to safeguard data security and maintain patient trust. In the end, this platform allows start-ups to responsibly address privacy and security challenges, and so may represent the foundational layer of an ecosystem of digital health services.

However, the full potential of this approach is unlocked only by coupling it with a shift towards outcomes-based reimbursement for healthcare providers. Outcomes-based reimbursement models are built on the fundamental premise that providers assume responsibility for their patients' health while remaining cost-effective. Examples of such models are population-based or 'total cost of care' approaches that reward management and prevention of chronic

The opportunity needs to be seized now – a wait-and-see strategy is not an option. In the United States, outcomes-based reimbursement models are expanding rapidly. The Department of Health and Human Services aims to have 50% of Medicare payments in these models by 2018<sup>3</sup>. The US Food and Drug Administration has long enacted guidelines for introducing medical apps onto the market. In this realm, existing digital champions and start-ups have already built strong positions and are now seeking opportunities to expand their footprint to the healthcare industry globally.

EU countries currently lag behind, both in terms of their reimbursement models and due to the traditionally more cautious approach to data protection and privacy. The open innovation platform caters to the desire to drive efficiency

***Outcomes-based reimbursement models are built on the fundamental premise that providers assume responsibility for their patients' health while remaining cost-effective***

conditions, episode-based approaches for acute or well-defined treatment pathways, or capitation-based approaches more generally. Under these scenarios, providers may have an incentive to use digital health innovations to improve their patients' care. At the same time, bringing together app activity and outcomes data allows providers to evaluate the usefulness of digital health innovations and share profits with successful innovators.

and outcomes, while allowing health systems to maintain control over the data. It so provides a useful solution to advance digital health innovation in the EU's current political and regulatory climate.

EU health systems should act sooner rather than later. They need to consider developing open innovation platforms to enable data-sharing in the health system and move to

3 Centers for Medicare & Medicaid Services (2015). Better Care. Smarter Spending. Healthier People: Paying Providers for Value, Not Volume, www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2015-Fact-sheets-items/2015-01-26-3.html

outcomes-based reimbursement schemes. By doing so, they can enable innovators to build sustainable business models, while acting as a central gatekeeper in the system and maintaining control over data. In the end, this

radical shift provides a leap into a digital health ecosystem – finally an innovation that leads not to a higher cost, but to a more effective and efficient health system. ●

## CASE STUDY

# MAKING PATIENT SATISFACTION A PRIORITY IN SOUTHERN DENMARK

The Health Innovation Centre of Southern Denmark aims to increase the involvement of patients, their relatives and caregivers in improving healthcare provision. This includes field work consisting of observation, qualitative interviews with patients, relatives and employees, and group workshops. These methods of research are supplemented by expert interviews and more traditional research into existing data.

The Health Innovation Centre's physical environment includes a laboratory where researchers can test their own new products and designs. This is complemented by 'living lab' tests where prototypes are assessed in users' natural surroundings to help reveal flaws or shortcomings. Support extends to the implementation stage, with an assessment of the users' perception of the pros and cons, and a consideration of the needs of different user 'types'.

Projects include the use of technology to facilitate communication – not only between patients and their healthcare professionals, but between healthcare professionals in different hospitals, for productive sharing of information. Telemedical ulcer assessment is one field where this is taking place: patients can discuss their symptoms with their doctor via a digital platform, and their symptoms are compared against a digital ulcer record.

As well as pioneering its own solutions, the Health Innovation Centre supports other organisations, such as hospitals and municipalities, in finding relevant funding sources for projects that aim to use innovation to improve Danish healthcare. In this area, as in the rest of its work, collaboration is seen as crucial to improve users' healthcare experience.



# Patients and clinicians as partners in **CO-CREATING** health

**Petra Wilson**, Director at the Digital Health and Care Institute and Chief Executive Officer of the International Diabetes Federation (2013-2016)

'Co-creation' and 'eHealth' are terms that often arise when policymakers attempt to grapple with the challenge of providing increasingly expensive care to a growing population of patients with a shrinking workforce of healthcare professionals. This is particularly true in Europe, where projections show that by 2050 there will be fewer than two working-age people per non-working age person in many EU member states<sup>1</sup>. The cost of care is also due to continue rising as more specialised interventions become available and the prevalence of chronic conditions increases<sup>2</sup>.

It is, however, not only statistical projections of increased demand and reduced supply that are leading politicians and healthcare planners to look for new ways to provide care and prevent illness. Wider social changes are also driving

the trend. As everyday consumers, European citizens are accustomed to the freedom of choice over goods and services at their convenience. We are no longer dependent on the opening hours of banks or shops to make financial transactions, or on TV schedules to define viewing times. New technologies have allowed us to become co-creators of many of the goods and services we use. The challenge is to bring this spirit of co-creation into healthcare too.

The basic tools in this form of co-creation – the internet, location tracking and wearable devices – are already well used in healthcare. One in twenty Google searches is reportedly health-related, while Pew Research states that 72% of Internet users searched for health-related information in 2014. IMS Institute for Healthcare Informatics reported in September 2015

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1 [http://ec.europa.eu/eurostat/statistics-explained/index.php/Population\\_structure\\_and\\_ageing](http://ec.europa.eu/eurostat/statistics-explained/index.php/Population_structure_and_ageing)

2 [http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare\\_statistics](http://ec.europa.eu/eurostat/statistics-explained/index.php/Healthcare_statistics)



that over 165,000 health apps are currently available<sup>3</sup> and the recent rise in popularity of wearable fitness devices has led market analysts to suggest a ten-fold growth of such products in the market over the next five years.

Yet use of this technology for co-creation in healthcare is still limited. IMS noted in particular that the lack of integration between health app data and electronic health records is a fundamental unmet requirement and underlined that only 2% of apps they studied have that capability. This number points to one of the key barriers to co-creation between patients and healthcare professionals in eHealth: technical

interoperability. The good news is that this is within relatively easy reach. In November 2015, the European Commission adopted the Refined eHealth Interoperability Framework (ReEIF)<sup>4</sup>, which is to ensure that disparate and diverse organisations can share information and knowledge between their respective ICT systems. However, the focus of the ReEIF is on exchanges between healthcare providers (hospitals, physicians and pharmacies) and makes few recommendations that would allow patients to participate in that data exchange.

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3 IMS Health Study: Patient Options Expand as Mobile Healthcare Apps Address Wellness and Chronic Disease Treatment Needs

4 [http://ec.europa.eu/health/ehealth/docs/ev\\_20151123\\_co03\\_en.pdf](http://ec.europa.eu/health/ehealth/docs/ev_20151123_co03_en.pdf)

To take a real step forward towards co-creation between healthcare professionals and patients, we need to move beyond concepts of interoperability at institutional level to addressing integration with consumer electronics and ambient information from patients' everyday interactions. Here again, technical standards will be a very important tool and early integration platforms are emerging with tools such as Apple HealthKit, ResearchKit and CareKit and

based on expert services paid for by unit of consumption – we do not pay doctors to keep patients well but to respond to their acute needs, and neither do we reward citizens for maintaining their health. For the potential of co-creation in health to be realised, our systems will have to be adapted to create short-term returns for providers and patients for maintaining health, rather than treating illness.

***A significant challenge to co-creation in health lies in changing the relationship between healthcare professionals and patients so that the patient is seen as an equal and active partner in care***

Google Fit, which provide the tools for app and device developers to build interoperability into their solutions. The challenge, though, is not only technical. New governance models will have to be established that allow data from outside the healthcare establishment to be integrated into clinical records and used for clinical decision-making. These models are slowly emerging in the field of chronic care, in particular Chronic Obstructive Pulmonary Disease (COPD) and diabetes. But there is still resistance to integrating ambient data and data added directly by the patient.

A further significant challenge to co-creation in health lies in changing the relationship between healthcare professionals and patients so that the patient is seen as an equal and active partner in care. Our current systems are largely

Yet as we seek to make those changes to empower the patient as an equal, we must keep in mind that patients can also be vulnerable, weak and temporally unable to actively engage. The biggest challenge in driving real co-creation in health is therefore flexibility. We need to envisage a new concept of healthcare in which patients can share all the data and information they want to bring from their everyday life into the decision-making process, but in which the system can support them in times of weakness and need. The challenge is big, but the prize of co-created care is even bigger because it will ultimately lead to a society that rewards wellness and uses a wide range of resources to promote health. ●



EXTEND YOUR KNOWLEDGE

# IS ARTIFICIAL INTELLIGENCE THE FUTURE OF HEALTHCARE?

Even in developed countries with high-quality healthcare systems, problems persist. Costs are high, staff work long hours under high levels of pressure, and appointments and treatment are not always convenient or easily accessible for patients. Diagnoses, treatments and analysis of data are inevitably affected by human error, and there is always the potential for more effective treatment that is tailored to each individual patient.

The use of artificial intelligence (AI) can address all of these issues, and more. AI includes multiple capabilities: the capacity to recognise objects and respond to human speech, the power to process vast amounts of data, including accessing data from the cloud, and the ability to make decisions based on that data, even adapting that decision when new information is made available.



When applied to healthcare, there are endless possibilities. Patients' health can be monitored on a long-term basis through the use of implantable or wearable sensors that record health indicators such as temperature, blood pressure and organ function. Such devices provide highly accurate and reliable data that can be assessed remotely in real time by healthcare professionals, who can then make judgments accordingly, or even respond instantly to an emergency. This kind of monitoring can promote a preventative approach to healthcare, identifying risky lifestyle factors years before serious negative impacts start to manifest.

In some cases patients can use AI to diagnose themselves from their own homes without needing to see a doctor or nurse. AI can make a visual assessment and record of symptoms, which it can then compare with available data to identify the likely cause, directing the patient to where they receive treatment.

In the examples above, AI can also use its data processing ability to identify data from similar patients – those of the same age, who share a similar lifestyle and who have a comparable health profile. This means that patients can be given treatment recommendations based on what has worked for others like them, increasing their own chances of successful treatment.

In the future, the role of AI in healthcare looks set to increase. Robots that contribute to surgical operations, providing a higher level of control and accuracy than can be achieved by a human surgeon; implantable devices that release doses of medication into a patient's body when sensors indicate that it is needed. In just a few years these, along with many other innovations, might be added to the list of technologies that make our healthcare increasingly efficient.



**THE WAY FORWARD**

Disruptive innovation has already transformed many business sectors, from retail to communications and banking. This has largely been driven by companies seeking to drive down costs, and consumers adopting new technologies. Healthcare is not subject to the same supply-demand pressures. It is obviously a highly regulated sector and involves more players than just users and providers. Policymakers and payers often define the healthcare environment, giving them a key role in bringing about change.

Disruptive innovation for health means fundamentally re-designing European health systems with a revised concept of who does what, when and how. Vytenis Andriukaitis, European Commissioner for Health and Food Safety, described disruptive innovation

as looking at new ways to invest in health, shifting to different models for organising and financing care. Just as our series emphasised that new technology does not necessarily mean innovation, disruptive should not be synonymous with abrupt or harmful change. Given the long-standing health inequalities in Europe, a key test for innovation is certainly whether it delivers improved access and higher quality.

Innovation is happening in small ways in different parts of Europe. The task is to gather the data from where innovation is taking place and strengthen the evidence base for political choices in healthcare. Governments need to get better at identifying positive change and implementing it on a wider scale.

## RECOMMENDATION 1:

### USE INCENTIVES TO RE-DESIGN HEALTH SYSTEMS TOWARDS HEALTH OUTCOMES

Health systems are very different across the European Union in the ways that they are organised, financed and delivered. But fragmentation is a challenge that is common to all health systems. There are gaps and lack of connectivity between primary care and hospital settings, between promotion and curative services, between healthcare and social care. The series underlined that incentives matter as they ensure that vested interests seek to maintain the status quo. The central element of most current health systems is the payment for expert services per unit of consumption. These transaction-based systems don't provide citizens with an incentive to promote their own health, or medical professionals to keep patients well.

Moving towards an outcomes-based reimbursement model requires buy-in from stakeholders, to rethink the system and change the incentives. Even if the right regulatory framework is in place, there is a need for financial incentives to get all elements of the system to collaborate. Miklós Szócska, Director of the Health Services Management Training Centre at Semmelweis University, explained that successfully applying big data analysis requires an understanding of complex systems, the technologies of analysing big and long data, and a deep understanding of the system and its context.

## RECOMMENDATION 2:

### MAKE SURE THAT THE EU LEADS ON GUIDELINES AND STANDARDS, NOT JUST ON REGULATION

There is no shortage of both needs and ideas in Europe, but there is a problem in encouraging and retaining developers in the field of medical technology. According to Frank Westermann, Founder and CEO of mySugr, this is not a regulatory problem, but that Europe does not make digital innovation a sufficient priority. He calls for a single healthcare authority for Europe, with a single set of guidelines governing medical technology that would facilitate the development process and ease the availability of new tools.

There is a lack of confidence in innovation in Europe – particularly digital tools. This is partly explained by cultural barriers present among both regulators and potential users in healthcare. There is a need for a pragmatic approach that encourages early-stage experimentation and allows for failure within a framework that ensures patient safety. Regulation is critical, but since disruptive innovation cannot be predicted, some flexibility is needed to allow change rather than ban it. Max Müller, Chief Strategy Officer at DocMorris, called for greater priority on general frameworks and guidelines rather than new laws. Regulators attempting to define everything at the outset will stifle innovation.



### RECOMMENDATION 3:

## **USE PUBLIC PROCUREMENT STRATEGICALLY TO DROP INVESTMENT IN WHAT NO LONGER WORKS, AND SUPPORT CHANGE**

The nature of healthcare in Europe means that public procurement is a key lever for promoting innovation. The series concluded that public procurement tends to focus on the short-term issue of getting services for a cheaper price. Taking a more holistic view of the overall healthcare system and its needs could mean a higher priority for innovation as a criterion for public tenders. As new models are explored and the knowledge base is strengthened, there needs to be a strategic approach to ending investment in older structures that have become redundant. Members of the European Commission Expert Panel on Effective Ways of Investing in Health warned that such decommissioning could be challenging in healthcare systems heavily reliant on public funding or procurement.

No healthcare system is perfect, and all countries seek to get better health outcomes for their investment – particularly as productivity improvements in health have lagged behind other sectors. Outcomes-based reimbursement models are built on the fundamental premise that providers assume responsibility for their patients' health while remaining cost-effective.

### RECOMMENDATION 4:

## **IDENTIFY WHAT EVIDENCE IS NEEDED FOR INVESTMENT AND POLICY DECISIONS**

Within healthcare, there are well-established pathways for the introduction of new pharmaceuticals or medical devices. No such pathway exists for digital health innovations, which leads to a lack of sustainable business models. Stefan Biesdorf and Ulrike Deetjen from McKinsey & Company highlighted that a few high-profile large ICT projects that were delayed or cancelled, and the complexity of achieving stakeholder buy-in, integrating legacy systems and managing security concerns, led to significant cost overruns. This high rate of failure commands caution in the roll-out of new organisational and business models.

The series also discussed the issue that payers require proof of efficacy or efficiency before they invest, while innovators need funds to prove that they can deliver better outcomes. Pilot projects, particularly in partnership with local or regional governments, can build the necessary evidence base on the impacts on health, on the economy and on the feasibility of adoption. However, some attention needs to be given to developing a wider spectrum of evidence for decision-making. The gold standard of blind randomised control trials is appropriate for introducing new medicines, but may be impossible to achieve for new, innovative

ways of working. A range of lower evidence thresholds is needed to support different decision points about investment in prototypes or pilot-testing. Similarly, a new approach to monitoring and evaluation would develop the evidence base to move up to the next level of implementation, such as scale-up or roll-out.

## RECOMMENDATION 5:

### **PAY ATTENTION TO SUPPORTING CHANGES IN ATTITUDES AND BEHAVIOURS, AS TECHNOLOGY TOOLS ARE DESIGNED TO BE USED BY PEOPLE**

The series emphasised that disruptive innovation is not an end in itself, but a means to ensuring a more efficient and cost-effective health system for those working in it and using it. Many contributors also highlighted the importance of changing mindsets through updated curriculums for medical professionals and greater acceptance by the public about ICT tools for health. Frank Westermann contrasted the openness to technology by medical professionals in the United States with reservations expressed by European practitioners about the potential benefits for patients and themselves. Innovation tools need enthusiastic users. The human element of potential innovation needs to be central, whether building trust or ensuring that it is easy

to use and is relevant to the needs of both patients and professionals.

Miklós Szócska reminded us that the impact of ICT in health service delivery can be paradigm-shifting, but it is only the hardware for this change. The huge amount of potential data available to decision-makers can paralyse the system or facilitate the process of reform. The difference is made by understanding how the data can be used to improve the performance of the health system.

## RECOMMENDATION 6:

### **ENSURE A FREE FLOW OF DATA FOR HEALTH WITHIN EUROPE, AS THIS WILL DRIVE CHANGE**

The concept of the 4th Industrial Revolution is built on the power of automation and digitisation, which are rapidly transforming our economies. Alexander de Croo, Belgian Deputy Prime Minister and Minister for the Digital Agenda, highlighted that a European data-driven economy relies on cross-border transactions with a free flow of data between countries. This data would flow for collection, processing and use around the world. Madis Tiik, a former CEO of the Estonian eHealth Foundation (2007-2011), described the emergence of Health 3.0, which uses algorithms, computer power and machine learning elements to interpret the ever-increasing amount of data being generated.

The aim of such decision-support tools is to generate faster and smarter action to cure and prevent disease. In this future, patients will chose for themselves which data to share and which services they need. Medical professionals would increasingly be health coaches, working with artificial intelligence (AI) to assist patients in their treatment and self-care.

An intermediate stage towards this future would be co-creation. Petra Wilson, Director at the Digital Health and Care Institute and a former CEO of the International Diabetes Federation (2013-2016), explained that the basic tools – the internet, location tracking and wearable devices – are already widely used in healthcare. The series emphasised the importance of building trust into the system so that people feel comfortable sharing their health data. Authorisation mechanisms are needed, as well as robust third-party authentication and smart regulation. Buyers, providers and users need to collaborate to build trust in technologies.

***Disruptive innovation for health means fundamentally re-designing European health systems with a revised concept of who does what, when and how***

## RECOMMENDATION 7:

### DEVELOP NEW BUSINESS MODELS TO BUILD SUCCESSFUL PARTNERSHIPS BETWEEN HEALTH AND OTHER SECTORS

Spencer Nam, Senior Research Fellow at the Clayton Christensen Institute for Disruptive Innovation, recalled that disruptive business models reduce costs by simplifying delivery of care and payment. All innovations carry some level of risk, but incremental and continuous innovations are more likely to be successful. The key in European health systems are the providers and payers, who will be the stakeholders to scale the new model. Because disruptive innovation is unpredictable and often only identifiable after the event, innovators need open communication channels with these two groups.

The future of innovation for health is collaboration – silo thinking can no longer continue. This will mean stepping outside traditional boundaries to create partnerships between companies and sectors: for example, healthcare providers, medical technology companies and digital pioneers. Jorge Juan Fernández García, Director of eHealth and Health 2.0 at the Hospital Sant Joan de Déu and European Young Leader, described the key challenge as how to balance the two seemingly opposed forces of competition and collaboration.

# CONCLUSION

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Leadership and new thinking at EU level exists, but implementation is lacking. Policymakers need to be open to experimentation, creating space and incentives for change. Technology revolutions in other sectors are spilling over into healthcare and momentum for change will be bottom-up, led by patients – and not top-down.

Europe can support the creation of robust open innovation platforms that create opportunities for innovators and space for new business models to emerge. The EU must provide the legal certainty about data processing that will enhance trust, allowing the flow of data across borders. Finally, the EU is already committed to strengthening the digital literacy of citizens so that they can play a more active role in managing their own health.

The series showed that universal healthcare is both a value and an asset worth fighting for, despite Europe's ageing population and rising healthcare costs.

Health systems must change fundamentally to survive but there are cultural, economic, institutional, legal, organisational and workforce barriers to change. Each of these requires a different approach. Policymakers need to exercise leadership and find the courage to bring all interests together to find difficult compromises. If the mantra of Jean-Claude Juncker's European Commission is to be 'big on the big things', then driving the development of Health 3.0 in the EU will be a fitting legacy.

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