UBIQUITOUS AND COST EFFECTIVE TECHNOLOGIES

HOW TECHNOLOGIES CAN PROVIDE EUROPEAN CITIZENS A BETTER ACCESS TO HEALTHCARE?

Working Group 2 Report

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1. Foreword

Universal and public health coverage is a fundamental of most European countries. But recent trends jeopardize the underlying statement of an access guaranteed to the most appropriate cure for each individual:

- On one side: the recent demographic, epidemiologic and economic curve have put lot of pressure on cost management, urging for transformations
- On the other side, new cure practices (robotics,..) or profile specifics treatment offer always new and greater perspectives (acceptability, life expectancy,..) while their "unit" costs of care is corollary soaring.

This situation may result in a growing asymmetry between public and private system, according to the practices a private insurance premium cover or not, coming in any event in addition to a base of solidarity

Three areas of investigation may be addressed to tackle this medical and economical challenge:

- How can technologies transform the way care is today delivered (how can we follow more patients and people within the same level of resources)? - *Productivity of the system*
- How can technologies help improve the choice of appropriate medication and maximize the medical and economical impact? Efficiency of the system
- How can new technologies or innovation reduce the cost of care? Unit cost reduction

The working group try to cover the following topics:

- How to take advantage of innovation such as tele-health solutions in the European countries?
- How to integrate medico-economic factors in prescription and reduce the inequality of access to appropriate cure?
- How to promote models where new technologies are generating cost savings (Public Private Partnerships, incubators, value chains,)?

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3. Introduction

The common standpoint of observers is that the eHealth take-off is slow. This should not be a surprise. Internet was slow to take off, eCommerce was slow to take off, and the adoption of mobile phones as well as tablets took time as well, as the first ads (business to business at that time) for tablets were aired 15 years ago. However, the pace of technology adoption is growing faster and faster. With regards to eHealth, initiatives in European countries are numerous. Some pilots are managed at national level, some at the regional level, and even the occasional hospital connects with others to pool scarce resources using telehealth support.

4. Health technologies: a wide spectrum of tools and applications

Health technologies encompass a wide spectrum of solutions, activities and usage. Diagnosis and treatment have seen tremendous progresses thanks to technologies like IRM, non invasive techniques, robotised surgery. There is more to come with genomics, predictive medicine and nanotechnologies, which will allow for smarter drugs and "tailored" protocols.

Below is a table summarising the functions, benefits and challenges discussed in depth by the working group regarding the five key different segments of health technologies:

TECHNOLOGY	EXAMPLES	FUNCTIONS	BENEFITS	CHALLENGES
Interactive Tele- medicine	Tele-cardiol- ogy / ECG at scale	Health-related ac- tivities, services, and systems, carried out over a distance by means of ICT.	 Better access to health care Increases in efficiency Diminishes medical error 	-Physician and patient acceptance -Volatility and reim- bursement of costs - Liability problems
Remote Monitor- ing/ Monitoring "On-the-go"	-Biper for diabetics in Spain -Bio-sensing textiles	Health-related ac- tivities, services and systems, carried out over a distance by means of ICT for the purposes of preven- tion, early detection / diagnosis and disease control	-Disease Man- agement and Control -Patient Em- powerment	-Blurred boundary between medical de- vices and consumer goods -Need to create a new incentive model for physicians/ laboratories
Personalised Medi- cine	-Oncotype Dx for breast cancer treat- ment	Use of genetic or other molecular bio- marker information to improve the safety, effectiveness, and health outcomes of patients by risk strat- ification, prevention, and tailored manage- ment approaches	-More cust- omised and responsive medicine -Improved health outcomes -potential cost savings	-Incentives are not aligned between stakeholders -Operational chal- lenge between provider and patient education privacy
Medical Equipment	- I-snake: mini-invasive surgery	Specific preventive, diagnostic, treatment or rehabilitation pro- cedures which can be delivered in small size, cost effective health care facilities.	 Total cost reduction More effective Less invasive Equipment reduces need for complex sur- geries 	-Critical need for training -Creation of new operating models -High initial cost
Information Man- agement	-Consolidated and shared information -Cloud com- puting -Analytics	Used by clinicians, wider healthcare pro- viders and patients to provide or benefit from improved care	-Supports workflows and processes -Ease of access -Efficiency from data consolida- tion	-Privacy concerns -Interoperability -Need uniform train- ing standards -Liability concerns

5. Expected benefits

It is well known in literature that health technologies can contribute to improved health outcomes. Furthermore, health technologies also have the potential to empower health providers so that they are able to deliver high quality care. Through the evidence compiled within this report, there are proven benefits that range from increased health outcomes and increased cost efficiency to the potential to significantly boost the European economy. As a result, health systems can be strengthened significantly if the appropriate health technologies are implemented.

For the purposes of the report, the benefits of health technologies have been segmented into: i) improvements in health and ii) driving economic benefits.

The remainder of this section highlights global case studies noting these benefits.

5.1. Improved Health

5.1.1. Better Prevention of Chronic Diseases, Aftercare, and Monitoring of Chronic Diseases in Developed Countries

The implementation of health technologies have been shown to drive both the better prevention of chronic diseases in developed countries, better aftercare and monitoring of chronic diseases.

Indeed, eHealth technologies are of great interest for prevention. The prevention model is to invest small now to spend less later. The economic pressure on our health systems is so strong that the short term savings are by far more valued than the benefits expected in the future.

Case Study: Philadelphia, United States

A 2003-4 study in Philadelphia showed that a significant percentage (20%+) of Medicare patients admitted for heart failure (HF) and chronic obstructive pulmonary disease (COPD) were readmitted to the hospital setting within 30 days. This large re-hospitalisation rate ultimately results in high costs and the inefficient use of public resources.

There is a growing body of evidence that points to the positive benefits of leveraging telehealth to proactively attend to symptoms once these high-risk patients are discharged from the hospital. For instance, those treated with remote patient monitoring and telehealth were 50 % less likely to be readmitted to the hospital compared to those patients in disease management programs and 40 % less likely compared to patients undergoing standard care².

In 2008, the Visiting Nurse Association (VNA) of Greater Philadelphia, a non-profit agency dedicated to providing home and community care, integrated telehealth to meet its chal-

lenges of treating high-risk HF and COPD patients in the face of controlling costs. Since their pilot implementation in 2008, the VNA of Greater Philadelphia has seen promising results including a reduction in readmission rates (45% prior to implementation; 35% six months post-implementation; 25% by the end of the first year), a large improvement in HF symptom severity, a higher percentage of patients who remain at home after their episode (73% versus 68% which is the national average), and good patient satisfaction.

Given the rising rates of chronic diseases, the implementation of a telehealth programme seems to be a logic choice to control the overwhelming effects on the health care system, while ensuring a high quality care solution³.

5.1.2. Better Quality of Service and Minimises Health Care Professional Shortage

Furthermore, health technologies can also provide better quality of service to patients, as well as minimise the effect of health care professional shortage.

Case Study: University of Massachusetts, United States

It is a well-documented fact that the presence of an Intensive Care Unit (ICU) specialist in hospitals can reduce the mortality rate by an average of 30%, but despite this, the vast majority of hospitals do not have a specialist working at night or on weekends. To combat this problem, the UMass Memorial Medical Centre implemented a telehealth care solution called "eICU" that provided ICU specialists that oversaw the unit from a nearby building and acted as a second set of eyes for the on-site doctors and nurses.

The study results reported major gains in patients' outcomes, including a reduction in the death rate from 10.6 to 8.6%, a reduction in infection rate from 13 to 1.6%, and the use of "best practices" guidelines in treating patients increased from 33 to 52%.

The case study also mentioned the possibility of remote monitoring as a solution to the shortage of ICU specialists. The president of the HealthAlliance Hospital and part of the UMass Memorial system, Patrick Muldoon states, "Nurses and doctors can't be with every patient every minute. The eICU is constantly monitoring patients and will spot trouble in between visits."

The overwhelmingly positive results from this study provide a model that can be replicated by many hospitals to combat a worker shortage as well as drastically improve the quality of care.

5.1.3. Shorter Hospital Stays and Lower Admission Rates

Another benefit of health technologies is their contribution to shorter hospital stays and lower hospital admission rates.

Case Study: United Kingdom

Demonstrating this is an audit by the National COPD in 2004 that determined the cost of treating Chronic Obstructive Pulmonary Disease (COPD) is £818 million per year in the United Kingdom. The study also reported that in a typical trust area, there are 1,000 hospital admission and 25,000 primary care consultations due to this condition. Additionally, 30% of emergency admissions are re-admitted within 90 days. This places not only an enormous financial burden on the health care system, but also blocks hospital beds for other deserving patients.

In 2002, a project was proposed and implemented by Carlisle Housing Association and District Primary Care Trust that aimed to reduce the length of hospital stays while also increasing the independence of COPD patients by providing them more information about their condition. By creating a home-monitoring system, doctors have managed to decrease the hospital stay from 10 days to 5.5 days, a drop of almost 50%. The project also reported reduced anxiety levels from patients and fostered a better understanding of their condition.

Additionally, a 2012 English study was published that mirrored these results. The study was one of the largest telehealth studies ever conducted and it sought to determine the effect of telehealth on hospital stays for patients with long term conditions, such as diabetes and COPD over one year. At the end of one year significantly fewer telehealth patients were admitted to the hospital (43%, compared to 48% of control patients), significantly fewer telehealth patients died during the duration of the study (4.6% compared to 8.3%), and there was a significant reduction in mean number of emergency hospital admissions per head (0.54 for telehealth compared to 0.68 for the control).

The value of telehealth implementation cannot only be measured in monetary value; as these studies prove, there is a drastic increase in the patient's health as well as a significantly smaller burden on the health care system⁵.

5.1.4. Promotes Patient Self-management and Provides Equal Access

Additionally, Health technologies promote patients' self-management of their health, as well as provide equal access to medical services to less equipped areas.

Case Study: Canada

In Canada, as in many places across the globe, policy makers are constantly searching for strategies to reduce costs, improve access, quality, and productivity. The emergence of eHealth has provided a boon of opportunities that can be used to achieve these goals. Across Canada in 2010 and 2011, a number of studies were conducted by Canada Health Infoway (CHI) that prove the effectiveness of the integration of health and technology.

The studies found that with the implementation of telehealth programs quality was improved by 20% to rural hospitals, giving patients outcomes comparable to major hospitals, access was improved by reducing wait times for a number of specialities. In one study, wait time was reduced from 3 weeks to 48-72 hours, and telehomecare helped the health system avoid an estimated \$21 million by increasing patient awareness of their disease and selfmanagement techniques.

The drastic decrease in the wait times and increase in patient knowledge found in this study speak volumes to the possibilities that telehealth holds, most notably in rural areas. Improving health care access to rural communities can be drastically improved with the implementation of telehealth, a fact that is becoming increasingly evident as the results of telehealth studies are published⁶.

5.1.5. More Responsive and Customised Health Services

Finally, health technologies can also help to provide more responsive and customised health services.

Case Study: United Kingdom

In many cases of hospitalisation, health problems are exacerbated because of the delay between the onset of symptoms and the doctor's visit the treat the problem. According to research carried out by Telehealth Solutions, one day in a hospital in the United Kingdom costs the health care system £230. For patients who have chronic diseases such as COPD, the average hospital stay is 12 days, leading to cost of up to £2.500.

The "HomePod", which allows patients which COPD or heart failure to measure key medical statistics each day, has the possibility to reduce hospital admissions by almost 90% by providing a more responsive health care service. The HomePod allowed patients to ask questions, as well as receive advice or encouragement from a doctor. If the medical statistics seemed troubling, it would send them to a doctor instantly. The result is a responsive and customised health service that could save the United Kingdom up to £70 million in 2 years' time⁷.

5.2. Economic Benefits

5.2.1. Same Level of Service for Lower Cost and Better Cost Effectiveness than Secondary Care

Of the benefits, one of the most touted is the cost efficiency of telehealth implementation. For instance, health technologies can provide the same level of health service for a reduced cost and improve cost effectiveness when compared to secondary care.

Case Study: Aquitaine area, France

In 2006, a cost-minimisation analysis of a wide-area teleradiology network was performed in the Aquitaine area of France. This study provided the direct comparison of care procedures for hospitals with and without the teleradiology implementation that enabled the management of remote emergencies and elective radiology consultations.

The study measured effectiveness based on the number of transfers, hospitalisations, and consultations avoided or added. The results found that in emergency situations, 48% of transfers were avoided, in elective situations, 37% of transfers were avoided and 12% of hospitalisations were avoided, and annual savings were estimated at EUR 102,779.

Based on these results, the cost efficiency savings across a region of hospitals has enormous potential. By reducing the number of non-emergency hospital visits, money, time, and labour are saved⁸.

5.2.2. Work Flow Efficiency

Aside from the reduction in patient visits, telehealth also increases work flow efficiency. According to a study conducted by a group of researchers in 2005, interviewees from clinics with electronic health records reported that lab interfaces were important in avoiding scanning and medical record costs, improving access to data, reducing providers' time spent seeking information, and improving quality of care. By reducing and streamlining the amount of paperwork that health care professionals must do, there is a drastic increase in productivity and cost savings⁹.

5.2.3. Reduction of Costs

Health technologies also have the potential to reduce costs in other manners by reducing travel costs, reducing costs across the value chain, and improving health professionals' productivity.

Case Study: Veneto, Italy

In the Veneto region of Italy, a system called . It allows for the creation of digitalised clinical documents, produced by diagnostic departments to be forwarded to six local health districts, which can then be forwarded to patients (with their consent) through the mail, or Internet. This creates less necessity for patients to travel to and from the clinics.

Previously, the entire process was based solely on paper which called for more labour and more delays. There was also a need for patients to come collect diagnostic information, physically, and the necessity to create hospital copies (creating even more paper with great cost.) The system is now more efficient, with paperless documents that can be accessed by

patients in the comfort of their own home via the Internet. However, the patients may still come in if necessary.

Internally the process of production was cut by 50% and the health care professionals and hospital staff were no longer needed to prepare tedious paperwork. The hospital quantified that the reallocation of staff combined with less paperwork saves upwards of **EUR500 000**. The number of clinical errors was also decreased with this new initiative, overall lessening these mistakes by approximately 10%. One more added benefit was that the wait time for patients to receive results was decreased by more than 50%, which created much faster treatment.

Externally, the access to care became much cheaper in the aspects of transportation and time 10 .

5.2.4. Increases Retention of Nurses and Physicians

The economic benefits of this system don't stop at the monetary value. Studies have proven that the implementation of telehealth increases the retention of nurses and physicians and promotes continuous education of health care professionals. Both lessen the impact of the health care professional shortage and boost the sector's economic potential, especially in rural or under-developed areas.

Case Study: Canada

For example, during the period of the 2010-2011 a study was issued by Praxia and Gartner that tracked 46, 000 tracked educational Telehealth events. Among these included video-conferencing sessions as well as educational seminars geared towards remotely based physicians, medical students, and residents.

This method of communication fosters the creation of a network of health professionals, which brings about a series of benefits. The ability to engage with professors and peers allows medical students and residents the ability to develop social networks, which is a proven recruitment and retention strategy. The remote viewing of educational events helped physicians to avoid the need to travel far and leave their rural communities, which was another strategy that boosted recruitment and retention of physicians.

Additionally, all of these tele-education events made the continuous education of health professionals possible, no matter their location. Via webcasts, remotely based health care providers can keep up-to-date with educational seminars and lessons that would otherwise not be available to them¹¹.

5.2.5. Potential to Boost European Economy

Lastly, a prominent benefit for telehealth is the potential that new technologies give for growth of European economy. Based on figures from a 2008 Eucomed report, the eHealth market in Europe has a potential value of EUR20 billion. In a 2007 report by BBC, the worth of the telemedicine sector worldwide was worth \$5.8 billion, with the potential to grow by almost 20% annually over the next four years. Given the immense growth opportunities of this up-and-coming sector, there would be a substantial return-on-investment for any potential stakeholders.

As evidenced, there are numerous health and economic benefits that have been proven through a variety of telehealth methods and techniques. The following section will discuss the barriers that are currently obstructing the full potential of this telehealth programmes.

6. Barriers and challenges

Many eHealth initatives have been carried out across the world, in Europe as well in emerging countries. However, the footprint of these technologies and the healthcare operating model leveraging the potential of the ICTs is progressing rather slowly. Several obstacles are commonly encountered. These include: a) technical barriers such as interoperatability and privacy issues and b) supply-side policy barriers such as financing and regulations. We will look at these barriers in turn.

6.1. Technical Barriers

The lack of interoperability prevents the operators to reach a size which would enable them to bear the "set up" investments, especially in terms of infrastructure, impacting the value of the services they can provide.

The confidentiality and the necessity to protect private data are some of the main remaining obstacles.

6.2. Supply-Side Policy Barriers

The main supply side barriers to the widespread use of health technologies are related to its financing (e.g., high upfront investment, unproven returns, insufficient financial support, lack of reimbursement) and regulation. Related to its financing, as the costs of health care continues to grow and health budgets are further constrained, policy advisors and decision makers have to make important decisions on where to spend limited resources. From a regulations perspective, as technology continues to advance, governments must ensure, through regulations, that health technologies are safe and clinically effective.

In this light, there is a growing global trend of critically assessing technologies from an effectiveness and cost-effectiveness perspective through the use of health technology assessments (HTAs) (See Box 1.1 for more background information on HTAs). More and more, HTAs are being used to influence decisions, such as what health technologies are covered in health benefits packages and which health technologies get reimbursed with public funds. Additionally, regulatory bodies continue to assess technologies and control their access into the market.

However, there is potentially a need to shift how technologies are assessed. Most of the eHealth initiatives are at pilot stage. More often than not, benefits related to the patient's quality of life have been measured and "recorded". However, the economic value has not been fully assessed or could not be assessed for several reasons. The patient's quality of life has been improved, a key achievement, but the economic impact cannot be assessed. In other examples, the economic impact can be assessed with good precision but the healthcare "ecosystem" does not allow the investor to capture the benefits. For instance, the physician will spend time filling an electronic patient record if she is paid for the time she dedicates to this activity or if she draws a direct benefit from this information. In most countries, this activity is not rewarded, and the health professional entering data will not be necessarily the one who will benefit from this information. Hence the interest for individuals remains weak.

In this section, we discuss major supply side barriers facing the development and diffusion of health technologies that can provide European citizens with better access to healthcare. We take financing barriers and regulatory barriers in turn.

6.2.1. FINANCING

Health technologies and the need for evidence

Increasingly health technology utilisation and financing policy decisions are made on the basis of medical, societal and economic grounds. As such, evidence of clinical effectiveness and cost-effectiveness is therefore needed to positively influence decisions.

The main challenge arises when there is a lack of sufficient evidence for a new technology compared to a technology that already exists in the market. There are major consequences as a result of this lack of evidence. Firstly, a lack of evidence may impede innovation. Secondly, a lack of <u>local</u> evidence means that assessment efforts may be duplicated across jurisdictions, which create inefficiencies in the health system. We will discuss government responses to each of these barriers in the following subsections.

Impediments on Innovation

As the use of HTAs and evidence in health technology investment decisions become more formal and systematic in many countries (e.g., the UK, Canada, Australia), industry has been more hesitant to invest in new technologies given the financial risk (e.g., if a technology is not publically reimbursed if it is decided that there is a lack of sufficient evidence). In this light, policy makers, decision makers and funders must consider mechanisms to incentivise industry to continue investments in developing innovative technologies. Some governments have responded by initiating R&D collaborations and public-private partnerships; for instance, in the case of personalised medicines (See Box 1.2 on the Personalised Medicines Case Study).

More examples of innovation drivers are needed in the future.

Impediments on Efficiency

As HTAs typically use local data to assess the effectiveness and cost-effectiveness of new technologies in a local context, if there is a lack of data available, some governments have also leaned on analysis and decisions made by other HTA bodies. This can result in many governments duplicating assessment efforts based on the same evidence.

As a response, it remains a priority on the international agenda to decide how to better build the evidence base to facilitate HTA activities. From a European perspective, the European Commission has made recent efforts to coordinate health technology assessments across the EU. A notable example on this front is the European Network for Health Technology Assessment. This project was launched in November 2008 and unites government-appointed organisations from EU Member States, EEA and EFTA countries, and a large number of relevant regional agencies and non-for-profit organisations to facilitate the efficient use of resources available for HTA and to create a sustainable system of HTA knowledge sharing.

However, more work and investment is needed to ensure that each member state has capacity to assessment the appropriateness of implementing health technologies in their local context.

Health technologies and cost-effectiveness

When HTA bodies make an assessment on new technologies from an economic perspective, financing decisions are made on cost-effective technologies. Cost effective analysis compares any marginal benefit of diffusing new technologies (opposed to existing technologies) to the marginal costs of doing so. Indeed, economic analysis of new technologies has been more prevalent in decision making processes in countries globally given the push for "value for money".

On a positive note there is a growing body of evidence that demonstrate the cost-effectiveness of many eHealth technologies.

For example, a study published by the Australia and New Zealand Horizon Scanning Network (ANZHSN) examined the varying methods of detecting diabetic retinopathy. Currently, the best way to detect diabetic retinopathy is an ophthalmoscopic examination performed by an ophthalmologist. However, the number of these health care professionals in Australia is not sufficient to access the individuals who live in rural areas, far away from the well-populated city centres. In order to increase access for individuals outside of the city centre, a health technology programme was implemented. By using a retinal photography instead of a direct examination, patients can be remotely examined and tested. The study results found that cost-effectiveness for the technology depended on a number of factors, but it was deemed that mobile units in rural and remote areas are cost-effective.

More cost-effective studies are needed to help inform decision making.

Evidence, cost-effectiveness and reimbursement decisions

When it comes to reimbursement decisions on health technologies, from a payers perspective, it becomes a question as to whether there is sufficient evidence on the cost-effectiveness (and clinical effectiveness) of the new technology and whether reimbursing the technology, in a publically financed system, is fiscally beneficial in the long run.

A look on the international scale provides evidence of a number of successful reimbursement policies for telehealth when it is a political priority (regardless of whether there is / is not a lack of sufficient evidence).

For instance, the United States is currently the leading market for reimbursed eHealth solutions. In the States, the largest user of teleHealth Services is the Department of Veteran Affairs, with recently awarded contracts worth \$1.38B USD. The department works with six different Health IT vendors to provide better care, to improve access, and reduce costs for veterans. The significant investment with these contracts coupled with the recent implementation of healthcare bills to further facilitate the use of teleHealth services is a promising step for this secto¹².

In addition, twelve states require insurers to reimburse Telehealth consultants. Under this regulation, doctors are now able to monitor their patients remotely with the use of the patient's mobile device. This broadening of the reimbursement policies will provide patients in rural areas the access to health care that they require. Especially in the cases of non-communicable diseases, it can be difficult for patients in remote areas to access regular medical attention. By promoting the reimbursement policies, these patients are given the attention that they require in a way that is both efficient and cost effective¹³.

In addition to the United States, Spain is also promoting reimbursement policies for telehealth. For instance, telecare for elderly or disabled people is reimbursed. The creation of the "Dependency Law" created 300-500 thousand new formal regulated jobs, which included positions for caregivers. This increase in personnel as well as the rise of telehealth had lead to a significantly higher standard of health care for the elderly since the project's start in 2007¹⁴.

In cases where there is a real lack of sufficient evidence for reimbursement purposes, some governments have implemented interim funding decisions wherein governments decide to publically fund promising technologies and re-assess technologies financing decisions based on real-world evidence. For instance, in Bulfone's account of health technology assessments in Australia¹⁵, the author notes that the Medical Services Advisory Committee recommends the use of interim funding of an interven-

tion where the initial evidence is favourable but further testing is needed. The option to continue funding for new technologies while waiting for further evidence is valuable not only for drugs but also for medical interventions.

On a final note, from a financial perspective, investments must be made to scale up successful projects with proven positive health outcomes. As noted by Rajendra P. Gupta, Chairman to the HIMSS Asia Pacific India Chapter, noted, one of the major challenges faced by telemedicine is the lack of funding that will push these major projects past the "Pilot Programme" stage. The promotion of these programs will push the industry into an area of financial feasibility, which will increase the viability of these projects. Without investment in research and development, the medical community will not be convinced to uptake these new technologies¹⁶. Financial investment is needed for successful pilot programs to prove both their financial and medical effectiveness.

6.2.2. REGULATORY

Health technologies and the need for clear and efficient regulatory processes

In terms of the regulation of health technologies, the main challenge lies in finding the right balance. There are various regulatory motivations and many regional differences. Furthermore, regulation processes are often unclear and not linked to HTA agencies and decision making bodies, which make the system difficult to navigate for industry.

Again, we can look to the case of personalised medicines to find how government can respond to these regulatory barriers by clarify the regulation process and introducing greater efficiencies for bringing an innovative technology to mark (See Box 1.2 on the Personalised Medicines Case Study).

When it comes to mHealth technologies, regulatory barriers become even more complex. In the medical industry, there are closed, integrated solutions where the provider has control of the architecture and this will not allow mHealth as an industry to thrive. Since there are many blurred lines as to which devices are medical and what risks are associated with each, the regulations are not clear. As a result, there is a tendency for the initial regulations of these mechanisms to be too severe. The challenge here is allow innovation and diversity without an unacceptable sacrifice of safety, reliability or security.

Around the world, there are different standards and compliance laws for mobile and medical companies regarding the usage and creation of medical applications. For example, in the case of a mobile medical application for a telephone, the responsibility of the effectiveness of the application falls on the software creator, not the phone company. Governments must be able to provide a vital distinction between the "mobile" and the "medical" portions of new technology. As an example, in the case of Withings, a health care company based in the United States, the company has created a blood pressure monitor and cuff that connects to an iPhone. Under US regulations, this qualifies as a "medical device" and must comply with medical standards imposed in the States. How-

ever, the compliance of this device is a task solely credited to Withings; Apple Corporation has no responsibility or liability.

In the future, the freedom to create such applications on a mobile device provides the opportunity to greatly expand the market of similar mobile health applications.

<u>In conclusion</u>, the future development and diffusion of innovative health technologies that can bring access to healthcare for European citizens over the next few decades relies on a system that can foster innovation and reduce supply side barriers without supporting the entry of unsafe and inefficacious new technologies into the market. As discussed in this section, financial and regulatory policies as well as its related impediments are currently important health technology barriers to consider for the future.

Box 1.1

The Role of Health Technology Assessments (HTAs) and HTA Agencies

What is a HTA?

- ➤ HTA can be defined as "a form of policy research that systematically examines the short- and long-term consequences, in terms of health and resource use, of the application of a health technology, a set of related technologies, or a technology related issue" (Henshall et al. 1997).
- Health technologies include pharmaceuticals and medical devices; medical and surgical procedures; prevention and promotion activities; public health intervention (e.g., smoking cessation programs)
- Many countries globally have some form HTA agency (or agencies) for decisionmaking purposes; allows decision makers and policy makers to evaluate the impacts (clinical, organisational, economic and societal) of implementing health technologies
- ➤ HTA activities and the agencies that perform them are critical in light of the following drivers:
 - the raising costs of care / increasing health expenditure (largely due to the availability of expensive technologies)
 - Health budget constraints
 - Increasing need to ensure "value for money"; ensuring that limited resources are put towards interventions that maximise health outcomes (QALYs are typical measurement)

- > HTAs influence decisions made on policies re:
 - Investments (e.g., purchasing new equipment)
 - Approval, pricing, reimbursement and financing of medicines, diagnostics and medical devices (e.g., Australia, Japan)
 - National health coverage packages (e.g., Canada)
 - Organisation of health service provision (e.g., rules for referral to specialists)
 - Clinical practice guideline development

International HTA Efforts

- Efforts have been made at an international level to share experiences through HTAi (International Society of Assessment in Heath Care)
- International Network of Agencies for Health Technology Assessment (INAHTA) – established in 1993, comprises of 42 HTA organisations from 21 countries and provides access to a database of HTA reports and ongoing assessments; INAHTA also facilitates joint assessments where several HTA agencies have shared the work on the assessment of a technology (European Observatory on Health Systems and Policies, 2005)

Box 1.2

Personalised Medicines Case Study

In a study by the Department of Dermatology, it was found that a patient's "willingness-to-pay", which measures the maximum amount they would pay for services, preferred telemedicine treatments over in-person clinic visits. In the study, 73% of participants preferred telemedicine over in-person visits if access to the physician was quicker. (Qureshi, 2006). These results indicate that if telemedicine can provide speedy access to a doctor, they will be more likely to choose that method of treatment. These are promising results, given previous studies that have demonstrated the decreases in wait time that also come along with telemedicine implementation.

Limited resources can be allocated to the transformation of our health systems, conflicts of priority are permanent and technology investments do not win the game for the reasons mentioned above.

On the soft side, health professionals were not familiar with information and communication technologies, and did not perceive clearly the benefits they could get in their day to day practice.

Most of these barriers have been clearly identified in numerous reports issued by the WHO, the European Commission or other institutions. The European Union issued a set of recommendations aiming to accelerate the adoption of eHealth technologies. Standards enabling interoperability, coordination between professionals, more integrated governance architecture are part of these recommendations. The WHO and the ITU recently published an eHealth strategy toolkit, aimed to be used as a practical guide by governments.

The EIH workgroup did not intend to add another layer on these sound macro recommendations - infrastructure, national and European protocols and standards, governance, etc. - when it comes to implement and spread technologies across multiple countries.

The EIH workgroup focused on "meso-recommendations" related to the operating models and operational conditions facilitating eHealth technologies adoption. A quick review of the benefits and the barriers shows that accelerating technology adoption, more than in other domains, depend on the players' interests and the organizational settings in which they act. Consequently, most of the recommendations detailed hereafter are related to these organizational settings. Key questions addressed have been: how to make the case for eHealth technologies more compelling? What "value networks" would best leverage eHealth technologies? How to spread eHealth technologies without being too much dependent of macro-political agendas? How to foster simple and low cost solutions as often as possible?

7. Recommendations

Recos' sand box

- Economies of scale
- Integrated P&L and "TCS" (total cost of subscription) responsibility at an operational level (not the state or the social security: region, hospital, practice group....)
- Evolution of roles along the value chain (reminding that technologies are only an enabler), use technologies to support cost effective roles in the healthcare value chain
- Business case (waterfalls) including a comprehensive view of costs and benefits, of cash in and cash out
- Leverage existing platforms
- *Reimbursement (FDA said to sort what exists by enacting norms and standards on applications, Germany and UK too)*

7.1. Foster "clusters" fully accountable for cure and care, treatment and prevention, with a continuous improvement agenda and clear performance measurement aligning all contributors.

eHealth technologies help health systems overcome time and space constraints by co-ordinating and bringing together complementary skills and professionals - primary, secondary or tertiary care - for diagnosis and treatment protocol, or with preventing patients at risk from worsening their condition.

Technologies are a powerful lever for breaking silos. However, in the real world, transverse organisations and "end to end" processes need to pave the way. Otherwise, the motivation to invest in technologies or to use them remains too low.

"Clusters" means manageable geographical scopes or networks of patients. Clusters mix vertical and horizontal dimensions. Let's consider diabetes as an example. The vertical dimension of the cluster would be a network of diabetologists plus a hospital unit specialised on diabetes plus units involved in treating diabetes complications. The horizontal dimension would be the geographical scope of this cluster, either in terms of location or in terms of attractiveness. Such a cluster covers a full and consistent scope of problems, processes and measurable results.

"Fully accountable" means a clearly identified leadership embracing cure and care, acute diseases, chronic diseases and prevention. Prevention would be at least preventing deterioration of health condition for patients with a disease. Prevention could be increasing awareness of people with behaviours putting their health condition at risk. All players in the cluster don't have the same interests. Physicians may have an interest to avoid hospitalisation of their patients. The hospital does not necessarily share the same interest: the hospital manager is eager to maximise the utilisation of the equipment, especially when there is over-capacity. Misaligned interest due to "multi-layer" objectives is common in organisations and companies. To address this issue, common practices are to adjust the supply capacity to the demand, to assess each component of the organisation with a mix of performance indicators reflecting the trade-off expected from managers and to position arbitration roles as close as possible to the field.

The benefit of eHealth technologies in this configuration is twofold: it helps manage the cluster through co-ordination, information sharing, etc., it allows patients located outside of the geographical perimeter of the cluster to benefit from the cluster's capabilities through telehealth or it allows to expand the geographical perimeter served by the "node": the hospital in this example.

As a counter-example, in a centralised healthcare system, the benefits of an e-health enabled prevention could be measured only at country level, which does not encourage professionals at regional or local level to invest time and money upfront in e-health technologies. Local

players are delivering healthcare services in silos. Hospitals focus on cure. Their performance is primarily assessed against productivity: equipment utilisation in a productive way. In this environment, the hospital doesn't have a vested interest in preventing hospitalisation.

Examples of "fully accountable" entities are emerging. In emerging countries, when healthcare systems and infrastructure are missing, for instance through local initiatives mixing cure and prevention leveraging tele-health (see case studies). In European countries as well: in regions (Spain) or locally (Groupements de Coopération Sanitaire in France, *other examples to be added*). Incentives can be granted to health professionals joining the cluster when local facilities or professionals join their activities or some of their resources: two hospitals merging and mutualising some of their resources or a group practice of physicians.

Hospitals are a cornerstone in this configuration. They can be the spearhead of the cluster because of their assets (size, management positions and tools, spectrum of professionals, etc.). They can be a road block if the capacity exceeds the needs and if they are too much focused on capacity utilisation.

In such a configuration, the benefit is in the "managed" cluster with performance objectives and continuous improvement, the enabler is the ehealth technologies, the investment is the incentive, be it a temporary charge exemption for joining or a reward attached to performance objectives.

These "local" operating models should be promoted in the UE countries.

7.2. Reach critical size and leverage economies of scale

Healthcare related technologies cover a very diverse spectrum in terms of capital requirements and cost structure: a surgery robot, a picture archiving and communication system, a remote monitoring platform for chronic heart failure or a Skype based telehealth app have very few common characteristics. These technologies could be mapped across two axes: the acquisition/set up cost and the operating cost. The surgery robot would rank high on the two axes. The PACS would rank high on the set up cost axis and low on the operation cost axis. The A 24/24-7/7 remote monitoring solution for chronic heart failure would position relatively low on the acquisition quadrant and high on the operating one. The Skype base telehealth app would rank low on both axes.

To be affordable these technologies need first to be delivered at a reasonable cost per use in proportion to the price of the service provided and second with a set up cost in proportion to the investor resources.

From a more general standpoint, the conjunction of a growing percentage of chronic diseases, more sophisticated medical treatments and interventions, ambulatory care is developing. In most European countries, ambulatory care services are provided by small organisation, be it local associations or freelance professionals. This configuration can

evolve in two directions. A first scenario will see the characteristics of the sector unchanged. Weak interfaces management will need significant progress in ICT infrastructure and equipment. This will happen at high cost: high set up costs because of disparity, no economies of scale also because of disparity. A second scenario will see a consolidation of the sector with bigger "industrialised" organisations able to leverage economies of scale and to implement more harmonised platforms and tools. It is very likely that in this scenario, the pressure to continuously improve the efficiency of the information and communication solutions would be higher.

Home care services for dependent people (elderly people or disabled persons) illustrate one area where services in most European countries are provided by small organisations: local not-for-profit organisations, free-lance professionals, etc. Information and communication technologies are critical in this domain: they allow patients to stay at home as long as possible. However the more dispersed is the value chain, the less investment in technologies are affordable. Many pilots have demonstrated the efficacy of ehealth solutions in this domain. Here again, financial returns have not been clearly established for all initiatives. A review of the players and the "operating models" in several countries tend to show that in this sector, health solutions bring a benefit on the condition that they are deployed at scale by "integrated" operators providing a wide of full set of services covering most of the needs of dependent persons. We Care in Canada, Nichii or Secom in Japan are a few examples.

Reaching a minimum size to be able to leverage heath technologies, more specifically when it comes to make the required upfront investment or to spread the cost of technology and decrease the unit cost of technology is critical. Economies of scale are required. They need to be encouraged through consolidated or joint activities.

7.3. Leverage eHealth technologies to develop more efficient patient pathways and points of care

Today health services are provided primarily by hospitals, primary and secondary care professionals, nurses, clinical laboratories, or pharmacists. One of the benefits to be expected from health technologies is to improve the efficiency of the value by shifting some activities from expensive roles. The benefit pursued is either to leverage less expensive roles to address simpler activities, or to compensate a shortage of resources, without deteriorating the service provided. A couple of examples of such a shift, with no technology enrolled in these examples, are the transfer of activities between physicians and nurses or between dentists and dental hygienists.

eHealth technologies are used as a channel to filter client issues, to resolve the simplest ones and redirect client toward relevant experts for the other ones is the next step. This role has been traditionally played by primary care physicians. Today even if physicians still play this role, patients have started using the internet to get a first understanding of their symptoms and of potential treatment protocols. This first entry point ranges from the most passive and disputable version of information to more active forums with lively communities sharing information and experience on a wide spectrum of diseases or on specific ones. Websites in the first category are funded by advertising; portals in the second category are social networks. 20 years ago, these channels would have faced strong opposition.

The applications launched by the NHS, NHS Choices and NHS Direct, are a further step. This application goes further than providing information. It allows patients to transmit data with feedback from their physician is one of the parameters is going wrong. The purpose is explicitly to reduce unnecessary visits for patients with chronic diseases. 10 years ago, this channel would have faced strong opposition.

The next step will be the development of platforms with health professionals on line delivering diagnoses and prescriptions of treatments for the lightest and most obvious cases or redirecting patients for the others. This will be a 24/24-7/7 tele-consultation service using voice and video, potentially based on widespread solutions such as Skype, with our without access a patient file, owned and hosted by the patient, with an access right limited to the visit, to the "session".

Security, quality of care, and data privacy are obviously challenges to deal with. Safety and privacy of patient data are crucial in healthcare. These two imperatives drive sound and passionate discussions among stakeholders in European countries. From an "operating model" perspective, privacy brings significant constraints in terms of workflows, e-safe, etc. As a result, information sharing solutions can be blocked or the cost of implementation can dramatically rise, deteriorating the cost-benefit ratio. Deploying patient health records for example in some countries can be a slow process paved with stop and go decisions. In the meantime we can see the emergence of services available on the web or on mobile devices requesting data inputs from subscribers without triggering any specific concern relatively to data privacy and protection from these subscribers. Citizens, as customer of health services, could be less reluctant to share some information related to their health condition...under certain conditions. The lesson here is that data privacy should be addressed as a single question. Segmenting this topic could open possibilities to provide efficient technology based services. Some data are sensitive data per se, some data are sensitive only when linked to other data, some data are sensitive when accessed to by specific recipients, etc. Patients are in favour of apps for smart phones, physicians and social security are more reluctant¹⁷. Telemonitoring for specific diseases like heart failure, arrhythmia, or diabetes brings undisputed value, however it remains expensive. Here again, leveraging "platforms" already existing and commonly used needs to be considered in priority. The mobile app will be one component of the treatment/disease management protocol.

At this point we move from a classical patient pathway where the face to face contact with the physician is the first point of care, to a configuration with 4 points of contacts before or in addition to the face to face contact. However this evolution shows that stakeholders should split the patient pathway in bits, consider each component and promote the most open, patient centric eHealth technologies with low set up costs, running on the most widespread tools and platforms. Different ways of promotion can be envisaged. One interesting option is the open innovation mode chosen by the NHS which minimises R&D investments, with a "market" evaluation based on the number of applications downloaded and used.

We feel that the most valuable opportunities are in the first steps of the patient pathway, and for chronic diseases in the follow on components of the value chain. As a consequence the skills of the professional in contact with the patient will be significantly different from the primary care physician skills today.

7.4. HTAs

As discussed in the financial barriers section, a large obstacle for the widespread use of new technologies is the collection and dissemination of the evidence which shows the effectiveness of such new technologies. In many cases, there are known inefficiencies and duplication of efforts as countries in Europe and internationally assess the same technology and build their own evidence bases. Over the past few years, there have been initiatives to address this specific barrier; the EUnetHTA discussed in the barriers section is one such initiative. Another new initiative to further support collaboration is the Health Evidence Network (HEN).

HEN is an Internet-based resource that aims to provide evidence-based answers for questions posed by decision-makers (<u>www.euro.who.int/HEN</u>). The HEN provides concise and standardised reports on available evidence in the European region on "hot" and current topics such as reduction of hospital beds or the implementation of disease management programmes.

Although there have been many inroads to build the evidence base across the Europe over the past few years, it is recommended that HTA agencies in member states be encouraged to leverage HEN as well as contribute to the database of evidence. By doing so, there will be a reduction of duplication efforts between HTA agencies; saving costs (HTAs are costly exercises) and improving efficiency.

As discussed, there are currently ongoing efforts both on the European and international fronts to harmonise HTAs across the EU and globally. Although there are inherent differences in HTAs given differences in local contexts as much as possible, HTA methods should be standardised to facilitate cross-border technology assessments thus avoiding duplication and inefficiencies.

Furthermore, from a HTA perspective, it is also recommended that payers understand and respond to patient and public preferences and willingness-to-pay. As most HTA methods are grounded in qualitative clinical and cost-effectiveness analysis, the public's values (normally qualified rather than quantified) are missed. That said, potential preferences of patients to be treated at home by family supported by telehealth may not be considered in the decision making process. By incorporating the public into HTA and decision making processes, health systems will be geared to be more responsive and transparent. Some HTA bodies in countries such as the UK, Canada, Denmark and Australia have already taken action to incorporate patient and public engagement.

7.5. Regulations

From a regulatory perspective, the main recommendations is that agencies responsible for regulations must improve the clarity and efficiency of regulatory-approval process and align regulations with other industries that develop medical and health related products. A similar approach that was taken with telecommunications must be leveraged. In the case of telecommunications, successes in this industry were a result of a more globalised mindset with interoperable attitudes of cooperation. Furthermore, we can also look at remote telera-diology for best practices given its wide adoption. A key success factor for teleradiology's adoption by a large number of providers is its standardised regulations¹⁸.

7.6. Reimbursement

From a reimbursement perspective, a key recommendation is for governments to understand that reimbursement priorities and decisions can result in long term reduction of health care costs (e.g., by eliminating the need for patient travel, doctor travel, manually written paperwork, etc, the cost of the health care services can be steeply reduced). Therefore, while there is a great initial investment, the savings that these technologies will provide over their span of use will be much higher and will lead to improved health outcomes and higher productivity, among other benefits. By focusing on the long term benefits as opposed to the short term costs, health technologies can be adequately funded; thus, providing industry with appropriate incentives to develop innovative technologies that could provide better access to healthcare for European citizens. Indeed more evaluations on exact cost savings are needed to inform such key financing health decisions.

- ¹ Jenks, 2009
- ² Alston, 2009
- ³ Alston, 2009
- ⁴ Source: JAMA, 2009
- ⁵ Source: BMJ 2012;344:e3874
- ⁶ Source: Canada Telehealth Report/Canada Health Infoway 2011
- ⁷ Source: Telehealth Solutions, 2010
- ⁸ Source: Int J Qual Health Care, 2006
- ⁹ Source: Miller 2005
- ¹⁰ Source: Europa, 2010
- ¹¹ Source: Praxia and Gardner, 2011
- ¹² Bowman, 2012
- ¹³ The Hill
- ¹⁴ Eurofound
- ¹⁵ "Health Technology Assessment: Reflections from the Antipodes", Bulfone, 2009
- ¹⁶ Gupta, 2012
- Emerging mHealth paths for growth» réalisée récemment et pour laquelle l'Economist Intelligence Unit (EIU) (Dropbox/Are patients ready/Patients are ready)
- ¹⁸ Zanaboni and Wootton



How to contribute to EIH working sessions ?

1- Why the European Institute for Health (EIH)?

Europe is facing many Health challenges: by 2025 about one-third of Europe's population will be aged 60 years and over and there will be a particularly rapid increase in the number of people aged 80 years and older. EU Member states must develop strategies to meet this challenge. EU Member states have to promote good health and active societal participation among the older citizens, to fight the burden of chronic diseases and keep their health budgets under control. The opportunity to use technology to improve health challenges will be crucial.

To achieve this goal, Europe needs to build solid partnerships across borders and to address strong and efficient messages on health challenges.

There are some obvious diagnosis, before proceeding with any forward-looking approach, that we found at the same time that we see the growing awareness of European citizens ,of the strong principle of the European Union: "The equality of all Europeans in access to quality health and safety of a high level."

The European Institute for Health was created to raise EU health challenges and is willing to provide recommendations to decision makers, NGOs and practitioners, on how to get into action to promote appropriated answers. The EIH goal is exchange of knowledge and experience among the European Union Member States. The main aims have been to review and analyse existing data on health, to produce some reports with recommendations and to develop a comprehensive strategy for implementation of these recommendations.

Today, Europe needs medium/ long term decisions on Health for the greater benefit of European citizens.

2-What is the EIH?

EIH is an european body

- ► Type : AISBL (Association Internationale Sans But Lucratif)
 - An Independent and permanent structure, a think tank not a pressure group.
 - Foundation date : End 2008 (Kick-off : European Health Ministers Council)
 - Location : Brussels

GOALS

- To contribute to the improvement of health in Europe:
- By anticipating the changes on health at large
 - ► Science & technology
 - ► European consumers expectations, lifestyle and ageing
 - Medical practices and actors

► Health governance

• By developing guidelines for health in Europe

► Through studies, seminars and various publications

➤ Through work groups (task forces)

• By sharing effective and innovative solutions

<u>APPROACH</u>

A prospective project

1- First study dealing with health in 2030

A multi-states, multidisciplinary approach

2- Gathering of all actors of « Global Health »

3- Establishing working links with all the EU bodies

An European initiative

4- Helping the European Community in its addressing of European consumers interests

5- Providing to European actors a new opportunity to contribute to policy development at an early formative stage

- Our First study In partnership with Accenture

« Emerging Health Challenges for Europe over the next 20 years » was presented during a symposium at the European Parliament, June 7, 2010

- Allowed the attendance of a wide panel of experts and professionals of the \ll Global Health \gg

- Allowed the emerging of leads for our future works

A Facilitator:

In the sharing of diagnosis and in the implementation of actions to improve health decisions in social and economic terms.

3-What has made by EIH?

After its founding Symposium June 2010 on the theme: "<u>Emerging health challenges for</u> <u>Europe over the next 20 years</u>" at the European Parliament, and from a study by Accenture, EIH is entering a new phase of works (2011/2012). Following the recommendations made by various actors from the symposium and by many experts, always from our initial assumption and in a prospective way two working groups worked on a regular basis on the following themes:

"Prevention as a new paradigm" (Should Prevention be integrated in European healthcare strategies?)

"<u>Ubiquitous and cost effective technologies</u>" (Could technologies provide European citizen a better access to healthcare?)

"Long Term Care: What Challenges for Europe": A symposium: devoted to dependence given that it represents a major issue in European countries, taking into account the European cultural differences and the various senses of dependence across Europe" we will consider successively: definitions and various problematic, key facts figures, learning

from international perspectives and experiences, and we conclude by recommendations to reinvent long term care in Europe.

You can find documents relating to the founding symposium and to these works by visiting our website: www.eih-eu.eu

4- What are the future activities of EIH?

In the coming years, EIH will continue to develop subjects from health challenges identified, in the broadest consensus of global health actors.

AGENDA 2014/2015:

We are also considering a symposium on an economic subject as Healthcare as an engine of growth for the European economy:

In most European countries, the health sector is considered as a constraint to the extent that it contributes greatly to budget deficits. The share of health expenditure in the budget deficits of European countries is significant and no improvement is expected: the European population ages, chronic diseases dominate the quality of care is improving with technologies more and more sophisticated but more expensive. In this context, the health sector is rarely seen as a contributor to economic growth and as a source of competitive advantage for Europe. The objective of the symposium is to better characterize this opportunity. This will be based on a study by Accenture which is a partner of EIH.

If you are interested in our approach and our works, you can join us:

Contact us on our website www.eih-eu.eu or by email: ceo@eih-eu.eu