committed to Europe

The Digital Transformation Series

Policy ideas for the development of eHealth and mHealth in Europe

Definitions:

eHealth refers to tools and services using information and communication technologies (ICT) that can improve prevention, diagnosis, treatment, monitoring and management. Medical eHealth can improve access to care and quality of care and make the health sector more efficient. Consumer eHealth can empower individuals to improve their health and healthcare thanks to ICT. mHealth (or mobile health) refers to medicine and health services supported by mobile devices, and can be considered a subset of eHealth.

Introduction

Life expectancy is increasing worldwide. In Europe, the number of people over 80 is expected to double by 2030. Because of this and other causes, the needs of patients and citizens are changing. Overall, it is becoming harder to maintain equality of access to healthcare and improve the efficiency by which it is delivered. At the same time there is an increasing need for secure environments to help maintain the elderly in their homes.

Ageing Europeans also experience more chronic conditions. These are a significant cost to health services: illnesses of this kind account for between 60 to 70 per cent of overall health expenditure. The impact of these conditions also includes a loss to the wider economy as employees whose medical needs go unmet can affect productivity or be blocked from earning and contributing financially. With these various pressures, there is an evident need for a preventative approach to healthcare - and the wider use of technology to improve services, quality of life and reduce costs.

The market potential for e-Health – using various ICT technologies to deliver services - is considerable and growing and it holds out a promise of being part of the solution to some of the issues described above. However, adoption has so far proved challenging. There are a number of reasons for this, among which the main ones are:

- Safety and privacy concerns
- Organisational and economic adaptation of markets and business models
- Market fragmentation
- Interoperability and standardisation issues
- Governance

July 2015

orange

e-Health and m-health: different markets, distinct policy issues, some grey areas

The fields of eHealth and mHealth often overlap. To grasp why, it is helpful to understand their scope. In some environments or organisations, the terms refer to medical solutions aimed at health staff and hospitals, in a mainly business-to-business market that also has to consider patients' needs and rights, for example when it comes to medical data. In other cases, in the rapidly growing 'wellness' market for example, patients use data related to their own health – weight or cholesterol levels – for their personal use,. Thus the processing of personal data used for wellness/health objectives doesn't require the same level of sensitivity as medical data in the formal sense.

Depending on the context, eHealth and mHealth can involve either medical data or personal data, a characteristic that should trigger different regulatory compliance issues in each case. Yet, Orange notes that the new data protection framework proposed by the European Commission does not offer any clear distinction, submitting health data used in medical and personal contexts to the same rules.

Moreover, these blurred lines between medical and personal data also fail to take into account another important dimension, namely data quality. This is an essential point, whether for medical or personal use, even though data quality might have different meanings from a user, citizen, patient or health professional point of view. The importance of data "quality" makes it useful to define "true" data – for a better assurance with regard to the source of the data and its quality. In this respect, the experiences of a few countries – including France – can be a useful starting point for a homogeneous definition of data quality.

In addition to the core data issues, another grey zone area created by ICT in healthcare – and particularly in the case of m-Health - relates to the remit of the Medical Device Directives, in particular safety and performance. As the framework defines medical devices as '*equipment or software involved in the diagnosis, prevention, monitoring, treatment of a disease and which does not achieve its principal intended action by pharmacological, immunological or metabolic means*', an expansive interpretation could markedly affect the regulatory compliance of ICT-enabled e-Health and m-Heath technologies and developments.

"medical" eHealth is conditioned to the digital transformation of the industry

E-health is key for the deployment of tomorrow's healthcare systems, but for it to play a more prominent role there needs to be a profound modification of the way care systems are organised and changes in the daily habits of health professionals. Many countries are now setting up e-health organisations to better cope with the social challenges the new services can create but more needs to be done ahead of larger scale deployments At European level, it would be useful to promote eHealth with a new, unified framework to define sustainable financial models and foster new industrial strategies. These changes must come hand-in-hand with patient empowerment and autonomy.

A unified evaluation and recognition framework could integrate and support new financial models

Evaluation is going to be a central step in the creation of new financial and re-imbursement models to establish their credibility. This is especially the case at the present time as:

- Telemedicine, or medical aid at a distance, is a new area in which practices such as telediagnostics are not yet fully taken into account. Research so far – especially on medical effectiveness - presents contradictory results that depend on the evaluation method and criteria used. It is important that a shared evaluation method is validated for Europe. It could be based on lessons learned from Model for Assessment of Telemedicine applications (MAST) project. Evaluation tools for telemedicine and eHealth as well as for mHealth – are necessary not only as a foundation for the development of new reimbursement models but also to allow this sector to reach its ideal scale in terms of cost-efficiency and industrial deployment.
- Perhaps surprisingly, eHealth and mHealth have yet to fully demonstrate their effectiveness, from either a therapeutic or financial point of view: for example, there are as yet no conclusive results on return on investment (ROI) in the current projects being tested in Europe, either nationally or under EU leadership.

Despite consensus on the need for a common evaluation approach there is little agreement on the objectives to be pursued or methodology to be adopted. We need to define proper evaluation as a decision tool for the effective implementation of future projects. Such assessments would enable

the development of models for integration with current healthcare financial and reimbursement schemes, used by insurers and healthcare organisations.

Fortunately, most clinical guidelines for eHealth will also be applicable in mHealth.

standards & interoperability would support industrial scale but also improve the quality of care

While the healthcare industry has developed some standards, new systems still tend to be bespoke, provided by a single manufacturer and making minimal use of interoperable interfaces. Many companies and organisations invest large amounts of money and resources in the development and marketing of non-interoperable devices, services and data management tools, including electronic health record (EHR) systems. This is why there is an urgent need for core interoperable standards, to encourage the market development and to reduce fragmentation.

Standardisation is one way to foster security, accelerate innovation and lower costs. From an industrial standpoint, it allows for more efficient investment and gives industry the ability to quickly integrate innovation. From a patient's point of view, standards promote the improved quality and safety of medical solutions (since control is made easier); lower prices - thanks to scale - and benefits from the accelerated innovation.

Some standards have been developed by industry consortia, although seemingly in an uncoordinated and intentionally competitive way. This is why it is important that authorities take a stand on which standards they wish to promote, validate or adopt. A clear position would encourage their adoption and use as a mandatory feature in public procurement (still too rarely the case in current requests for proposals (RFP) or tenders).

While awareness of these issues has increased, for example in the EU eHealth interoperability framework in 2013, the scope of the framework is limited to cross-border eHealth services. For eHealth to gain momentum in the EU, it is important that such an approach be more systematic and coordinated with national, regional or project organisations.

In this context, the Continua Health alliance has, within its work programme on *personal connected health*, developed and published a set of interoperability design guidelines based on existing IEEE, IHE and HL7 standards.

- These guidelines have been updated continuously, with the latest version to be released in July 2015. The 2014 guidelines have been adopted by the ITU-T (Telecommunications Sector of the International Telecommunications Union) as official standards H.810.
- The standard includes specifications for device interoperability via various wireless technologies and USB as well as specifications for local and wide area network interoperability.

The Danish Ministry of Health has demonstrated that the Continua guidelines are well-suited for inclusion in an overall HIT architecture and other countries worldwide are about to follow this example.

medical data have particular security needs

Medical eHealth data, including data acquired and transferred through mobile devices, have a particular need to be kept secure. Thus secure hosting, traceability of access, and authentication should be mandatory for obvious reasons.

- Authentication of professionals: the SIM card can be a very secure means of authentication. In France, health professionals use a combination of their professional card (CPS) and their SIM to authenticate themselves.
- Data hosting: we recommend secure environments - as already in place in the US (HIPAA) and some European countries, France and the Netherland for instance - and technical guidelines to simplify security checks (access, confidentiality, integrity and availability).

The consumer wellness market

The consumer market of "wellness"-oriented eHealth is growing. People increasingly buy apps and devices for their own use, related to sport and nutrition for example, from app stores. As personal purchases, these do not entail any reimbursement mechanism. The market currently offers around 97000 apps, of which 90 per cent are free, and the financial models is based on the "wellness" device sale – bracelets or usb devices - and the possible monetisation of collected data, whether offered by consumers themselves, or by related industries (insurance, pharmaceutical).

Moreover, as use of mobile systems in healthcare is growing, it is important to bring security and credibility without delaying uptake and innovation. There are still questions concerning the status of mHealth apps and their environment, in particular whether an app should be considered a 'medical device' or not. This uncertainty needs be resolved or further clarified. In this context, while there are now a few guidelines to qualify apps, the grey zone between medical and non-medical devices still remains important.

summary

There is a growing consensus that digital transformation in health services is key when it comes to reducing costs, improving patient care and developing sustainable health systems.

Challenges are multiple, from demonstrated technology benefits thanks to harmonised evaluation methodologies that would support suitable remuneration models. In addition, work is needed in creating an interoperable market place, with flexible industry standards and their increased use in state procurement.

All this needs to take place alongside procedural and practice changes in the way healthcare is delivered, with health professionals also learning how to incorporate technologies in their work. A coordinated approach at EU level should boost the uptake of innovative eHealth services and foster investment while enhancing patients' trust in eHealth services and ensure continuous innovation.

Yet other points still need to be clarified, from the status of devices, to issues such as data sensitivity types (medical, non-medical) as well as data quality.

About Orange Healthcare

Orange Healthcare **focuses on four key domains:**

New care pathways: new care models such as telemedicine require strong coordination between healthcare professionals and patients. Orange plays a key role in enabling information flows in 'joined-up healthcare', where providers and other partners in care delivery have a better, controlled access to patient data, in compliance with medical data regulations, for an optimised care process.

Digital transformation of the healthcare industry: Orange supports the digital transformation of the healthcare industry by connecting medical devices and patient support programmes, enabling the seamless, automatic and secure flow of data from patient to care provider.

Healthcare data: Orange partners with specialists in healthcare data analytics to support the development of 'smart data'. In 2014, Orange initiated the Healthcare Data Institute, a think tank dedicated to big data and healthcare. In 2010, Orange was the first telecom operator in France to be accredited by the Ministry of Health to host personal health data.

Assisted living and prevention: as a signatory of France's Silver Economy Industrial Contract, Orange is committed to help elderly age well at home thanks to ICT-based solutions. Education and personal health monitoring as a preventative approach are considered key to such public health issues as obesity and diabetes. Orange develops sustainable services and tools for underserved populations for a better access to basic healthcare.

For more information on Orange Healthcare: *http://healthcare.orange.com/eng/Orange-Healthcare*