BIG DATA
IN HEALTHCARE

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Executive summary

The spread and evolutions of information technologies and digital tools have enabled an entire new dimension of big-data storage and analytics that can bring tremendous improvements across industries, including healthcare. This paper recommends the creation of a European wide connected Electronic Health Records Organisation (EHRO) empowering patients by enabling the effective collection and usage of patients' health data across member states, revolutionising healthcare and ultimately leading to better health outcomes for patients and payers irrespective of national borders. The creation of the EHRO aims at overcoming past hurdles and challenges faced by various member states, and catapults Europe to the forefront of the new digital century of health. A raft of recommendations and steps are provided, explaining how such an organisation would support member states to build, connect and use this platform. The proposal illustrates a scale-up approach leveraging on prototypes and building from existing pillars of success, while using an open and transparent approach to platform creation. A patient driven opt-in system will lead to fast adoption, while targeted education campaigns and an incentive-based system at health provider level will accelerate uptake and build trust. The system will not only empower patients and assist clinicians, but also will provide a wealth of knowledge to advance medical science, preventing diseases and improve health for everyone.

I. SITUATIONAL ANALYSIS

Introduction

As acknowledged in 2013 by Stanford professor Atul Butte, *"hiding within [existing] mounds of data is knowledge that could change the life of a patient, or change the world"*. Extracting this knowledge is, according to him, the *"fastest, least costly, most effective path to improving people's health"*. Indeed, while the growth of information technologies and digital tools have transformed industries from banking to transport, the age-old foundations of the healthcare sector have yet to be shaken. It is high time the healthcare sector wakes from its slumber and takes steps to modernise and improve its functioning, for the benefit of patients, health practitioners and European countries alike.

The explosion of personal health data is a direct consequence of this evolution. New technologies (whether specifically designed for healthcare or not) progressively enable patients to easily access specific health parameters (e.g. their vital functions, medication intake, or response to their treatment) and to better connect with physicians, other health practitioners, and researchers. While much of this data remains insulated and fragmented along different paper-based and digital platforms, it has been widely recognised that the combination and mining of these datasets – Big Data for healthcare – could be used to achieve improvements in diagnosis, quality of care and, more generally, patient satisfaction.

Since the millennium, the European Union has recognised the importance of accompanying its member states in these transformations, and has increased its efforts and resources aimed at connecting European healthcare. The first European eHealth Action Plan adopted in 2004, and the many initiatives, regulations and policies that have since followed, embody the commitment of the European Union to make eHealth more than an ambition . Examples include the creation of the eHealth Network, the adoption of the 2011 Directive on the Application of Patient's rights in cross border healthcare, the 2012-2020 eHealth action plan, and pilot projects such as Antilope, e-SENS, PALANTE, PARENT, and SALUS.

However, it is easy to drown in the endless sea of datasets and possibilities to combine them. In 2010, Google's Eric Schmidt drew attention to the fact that *"there were five exabytes of information created between the dawn of civilization through 2003, but that much information is now created every two days"*. In healthcare, there are typically three broad categories of data sets available, all with their own associated array of challenges:

(a) Electronic Health Records ("EHRs"), providing real-time medical and treatment history of a patient;

(b) biological footprints, such as personal genomic information derived from single-nucleotide polymorphism analysis or whole-genome sequencing; and (c) "quantified self" data, the measure of an individual's daily life (physical activity, food intake, sleep patterns, etc.). This paper is devoted to the first category, EHRs, since it is the area where a policy solution is the most relevant for society at large and where the benefits of data mining and analysis can be best exploited, ultimately leading to an improvement in health and cost savings. Nonetheless, ideas raised in this paper would also apply to biological footprints and "quantified self" data.

It is not yet possible to provide truly connected European healthcare or ensure the effective collection and usage of data to improve the quality of healthcare for all European citizens. Big Data is noton the digital and health agenda of all EU member states. Some have recognised its potential and are working intensively on it, but others have struggled to incorporate it into their policies and healthcare delivery. This is another example of the challenges presented by fragmentation.

This paper aims at introducing the European Health Records Organisation (EHRO), an innovative tool to develop Electronic Health Records (EHRs) across Europe, with a view to making them available to all EU citizens. After a review of the benefits that offer such tools, and the challenges currently preventing implementation, the proposal will cover seven points essential to implementation of EHRO. This project is discussed in the wider perspective of Big Data, considering in particular its impact on European healthcare and the patient community.

What are the potential benefits of using Electronic Health Records?

Focusing on EHRs at EU level could create value for patients, health practitioners and governments. Here, the main short- to mid-term benefits are outlined.

Patients would be able to receive appropriate treatment across member states, in particular by sharing personal health information with any physician in the EU (conditional on the patient's consent) and avoiding unnecessary medical fees and administrative burdens (such as duplication of medical analyses). They would possess a centralised, up-to-date and easily accessible health "database", while retaining ownership and ensuring appropriate use of their data.

Healthcare practitioners would have a comprehensive view of the patient's medical background and history over time, thereby enabling them to offer the most appropriate treatment. This would avoid misunderstandings with patients over their health condition (e.g. due to differences in languages, or in national names of drugs), and would save time and improve their ability to provide service to patients. It would also promote the development of telemedicine, by attracting patients from abroad through diagnoses and monitoring services *via* remote systems.

Member states would be able to develop a single electronic health platform that could be rolled out across all national administrative units. It would achieve a better balance of costs and benefits in healthcare budgets through improvement of treatment and avoidance of duplicate medical tests. More importantly, it make it possible to obtain better health data and insights into the state of health of the population, along with the ability to tailor specific prevention programmes, improve reimbursement systems, or increase focus on areas of unmet need.

These opportunities are only the short- to mid-term opportunities. Further benefits stemming from the large-scale analysis of European EHRs are highlighted below under "Future prospects for Big Data applications".

Main challenges

In order to fully unlock these sources of value, three key challenges remain at EU level: **standardisation** (the creation of common tools and norms to ensure interoperability), **access control** (the definition of the relevant level of access for each group of stakeholders, as well as of data ownership) and **communication** (the development of a relevant outreach to patients and healthcare providers).

The first challenge is to ensure that the European Union creates and guarantees a mature and interoperable environment for health records for all its member states and citizens. For example, a Portuguese woman who wants a second opinion for a cataract surgery from a renowned Spanish expert should be able to effortlessly carry with her all the relevant medical data and the results from her previous ophthalmological tests conducted in Portugal. A Belgian patient who would like to avoid a 6-month waiting time to attend a consultation with his orthopaedic doctor, and who decides to seek treatment in the Netherlands, should be easily able to make the Dutch doctor aware of his entire medical background. Theoretically, each European citizen possesses their own EHR, which is a repository of their lifetime health data and treatment journey. Therefore, in practice, European citizens should have access to the regularly updated version of their medical data, in a secure electronic format, whenever and wherever in the European Union.

This is currently far from being the case. The deployment of EHRs within the EU remains fragmented. The member states are at differing stages in organising the way health data is recorded and stored in their healthcare systems. Moreover, not only are there differences between them, but also in many cases they do not have uniform systems within their different national administrative levels. Thus, a general practitioner in the countryside may still use paper records, while public hospitals in the capital may solely rely on electronic records. Similarly, individual regions may have had positive experiences with a local version of connected EHR systems, bringing forward a smart analysis of the data collected and successfully implementing changes in their health care provision, while others have not reached such level of maturity.

The challenges of access control and communication stem from the fact that not only are EU citizens and patients little aware of the existence of central recording and storage systems, but they also chiefly mistrust them. Following recent scandals, such as the revelations about the U.S. National Security Agency's practices, Europeans are very conscious that their data could be in the hands of unexpected actors. Indeed, 43% of the respondents to the most recent Eurobarometer survey on cyber security *"are concerned about someone misusing personal data"*, a number that has risen by six percentage points since the last survey of its kind in 2013 (European Commission, 2015). Hence, clear and strict rules would have to be established in regards to data access, while communication plans should insist on reinforcing the citizens' right to (health) data protection.

II. PROPOSAL: THE EUROPEAN HEALTH RECORD ORGANISATION

The proposal

Our objective is to reinvent Electronic Health Records in order to offer each European citizen the ability to build throughout their lifespan a comprehensive, easy-to-use and secure personal health record, constantly accessible and portable within any other member states of the EU. This is in line with the aim of further empowering patients during the care process, while making them aware of their options to access and make use of their own medical data according to their individual needs. At the same time, this is an opportunity for the European Union to stand as a defender of citizens' rights and privacy by ensuring the comprehensive security and confidentiality of health data.

In order to achieve this goal, the creation of EHRO, a permanent body dedicated to the design and rollout of Electronic Health Records at European and member state level, is an important step forward. EHRO could integrate or otherwise benefit from the assets and participation of existing structures such as the eHealth Network or IHE-Europe. The goal of this centralised body would however not be the storage of health data, which would remain at national level.

While the exact structure, participants and sources of funding of EHRO remain beyond the scope of this paper, we describe the key features of its implementation.

Implementation of the EHRO

1. BUILD ON PILLARS OF SUCCESS

The original capabilities and structure of epSOS (Smart Open Services for European Patients), see e.g. (Lindén, 2014), and EXPAND (Expanding Health Data Interoperability Services), see e.g. (Marques, et al., 2015), can be leveraged by building on their successes. The goal of the EXPAND project is to progress towards an environment of sustainable cross border eHealth services established at EU level. EpSOS has already developed a legal draft framework relating to the roll-out of electronic prescriptions, which could be further expanded to incorporate EHRs. Our recommendation is to use the same processes and structure that the epSOS and EXPAND projects have already created, tried and successfully tested, for the purpose of scaling up to a large project such as the evisaged EHRO. One of the early take-aways from both initiatives is the necessity to ensure mature infrastructures for producing and using the content. As such, ensuring national points of contact in each EU member state, such as a national agency to oversee Electronic Health Records and a neutral body with a strong mandate to facilitate the interaction between agencies, is critical for long-term sustainability and success.

2. SCALABILITY APPROACH

To manage the complexity of EU-wide implementation, a start could be made with a software and infrastructure prototype in one pilot-country or a small number of like-minded countries. This would allow the complete structure of the system to be built from the ground up, with constant improvements in light of actual experience. This would, subsequently, make possible the expansion of the system to more countries, as the complexity and requirements become better known.New opt-in countries will be able to adapt more easily. To help this scalability process, it is essential to have national contact points in all EU member states, even in those which do not have an immediate intention to opt in Regular meetings between national contact points will encourage sharing experiences and discussing the main obstacles ahead, so as to better address them when they arise. The European Health Records project might benefit from the well established EXPAND and existing e-Health Network.

3. AN OPEN AND TRANSPARENT APPROACH TO PLATFORM CREATION

For the software platform creation, it would be helpful to adopt an open source software architecture approach. The use of a web collaborative approach would allow for more efficiency as well as more transparency.

The project team will lead the development of the platform with its own developers, but the use of open source software will permit external software designers, healthcare practitioners and other experts to actively participate. The proactive involvement of such actors in the discussion and the design of the prototype through an interactive platform can lead to greater efficiency: this is a way of ensuring that the platform will include all the relevant information for practitioners, organised in the most practical manner. The software has to be designed so that all practitioners can intuitively make the best use of it, without any delay. In addition, the open source approach and its collaborative implications will reduce the costs of design.

Besides the potential gains in terms of efficiency, an open source mechanism also makes the process more transparent, reinforcing trust in the system. Healthcare practitioners and patients will be more confident about such a platform if they have been able to voice their concerns and suggestions during the design process, ensuring it does not appear as a "black box".

The use of open source software will also allow for more flexibility: it makes the platform more adaptable to national specificities - an important factor, since each member state depends on different health software architecture at hospital level. Open software architecture also makes it simpler for private software vendors to adapt their software to feed into the EHRO system. For example a vendor of ultrasound imaging systems could load the patients' scans and related data directly into the system, allowing healthcare professionals comprehensive access directly within EHRO to patient information from a variety of systems operated by different vendors.

Open software, rather than a closed system, has advantages illustrated by the experience with the UK's care. data. After contracting the development to multiple private vendors, the initiative was left with no access to the source code when multiple vendors walked out on contracts. An open source software platform can avoid such a scenario, by ensuring the software becomes a public good rather than a private commodity.

For all these reasons, an open and transparent approach to platform creation seems to be the best way to achieve the main objectives, which are building trust in the whole system and maximising practicality and efficiency.

4. PLATFORM SECURITY

To ensure universal access across member states, a single secured cloud-based platform with rigorous privacy and access controls is needed. An OrBAC-based multilevel security policy could be assigned to prevent users from accessing information for which they lack authorisation (Cuppens & Cuppens-Boulahia, 2011). This platform would be based on the patients' ultimate decision to selectively share information according to their wishes or concerns. The patient would retain full control over which information to share whether for medical or research purposes. Only health professionals working for the exclusive interest of the patient would have access to the data, only with the explicit consent of the patient. For access to data for research purposes, an independent supervisory board would ensure that future access would be allowed only for legitimate scientific research purposes.

Ensuring the privacy and confidentiality of all European patients is a priority. Basic principles would govern access to a patient's medical records via their EHR. The overarching principle will be to apply the European legislation regarding data protection and e-privacy (as well as future amendments)[1]. More specifically, access should be prohibited to a patient's records in situations not directly related to delivering or supporting healthcare. A healthcare professional should access only the patient records required for work and only during the period required for execution (time-limited access rights), and everyone accessing patient records should be bound by rules of non-disclosure (professional secrecy). No data should be communicated to third parties in any form without explicit consent of the patient. Access to patient records must always be subject to the consent of the patient.

When properly designed, security of computerised medical records is better than for paper records. The destruction or loss of a unique paper file is irreversible, and viewing of a paper file is not logged. Computerised records permit backup copies at remote locations, and all accesses can be logged. Scrupulous safeguards, security measures and data protection requirements are necessary to ensure the safety and security of all patient data collected and stored on computers and to ensure operability in practice. As security conditions still vary between member states, alignment of minimum standards between member states is needed to ensure equal levels of security safeguards are in place across all member states.

5. OPT-IN PRINCIPLE

The key to user acceptance lies in empowering current and possible future patients and healthcare practitioners to select their degree of participation in EHRO. Using an opt-in process will give users full control over their own health records, while allowing those individuals reluctant to participate - because of privacy, technology or other concerns - to remain with the current paper-based system.

Opting in will create a person-specific EHR account on the online platform, where the user will find a simple interface giving access to the growing repository of personal health information collected. Transparent user settings will allow a patient to authorise a trusted healthcare professional to access their health records. More advanced settings could enable a patient to limit the information that is shared - such as only records of the most recent 5 years, or pertaining to a certain condition. They could limit the period during which a healthcare professional may access their data. Underage citizens may have their EHR managed by their legal guardian until they come of age. Approved practitioners will be able to view the data for which they have been given permission and add new information based on their consultation with the patient.

The system will become a trustworthy and well-used service only when patients have full and dependable control over their EHR.

1   Directive 95/46/EC on the protection of individuals with regard to the processing of personal data and on the free movement of such data; Directive 2002/58/EC concerning the processing of personal data and the protection of privacy in the electronic communications sector; Council of Europe Convention 108 for the Protection of Individuals with regard to Automatic Processing of Personal Data.

6. EDUCATION CAMPAIGN

European citizens themselves can make or break any European initiative, and this is particularly true when personal health is involved and where patient engagement is essential. A recent study by Harvard Business School on the Affordable Care Act (Quelch & Norris, 2014) suggests that properly marketing structural healthcare reforms is a pivotal factor of success:

> "the sheer scope of the [Affordable Care Act], passed after more than a decade without any major healthcare legislation in the US, ensured that it would be complex and tough to sell to the public. [...] But that was just the problem: Congress and the Obama Administration didn't sell it. [...] By using a marketing-based approach, [...] government officials can ensure that the laws they spend so much time and energy crafting are utilised by the people who need them most" (Blanding, 2014).

A public marketing and education campaign is thus of crucial importance for each country's roll out and pre-roll out phase. Valuable lessons can be drawn from previously successfully deployed initiatives that faced hurdles because of inadequate consultation of the public and weak communication of the value to patients and practitioners alike. Initiatives like care.data launched by the NHS have shown limited success so far, in particular because citizens were not sufficiently informed of the programme and of its potential benefits (Triggle, 2014).

Addressing potential fears about the new technology will be crucial. Putting the empowerment of the individual in the foreground will help to overcome privacy concerns. Widespread citizen outreach by well-targeted communication channels, demonstrating in full transparency the advantages of participation in the initiative, will ensure fast acceptance and uptake.

7. ACCELERATE UPTAKE AT PRACTITIONER-LEVEL

This system can work only with wide adoption by healthcare practitioners. Although we believe that providers will appreciate the value of such an interconnected platform, a complementary incentive system will be required. The main challenges to adoption from a provider side are implementation costs and training. For this reason utilising a milestone-based payment system is recommended. At the healthcare practitioner level, important milestones could be (a) opt-in and software installation; (b) completion of the new user training; (c) first X patient records created or updated.

EHRO may provide incentive payments to eligible professionals and eligible hospitals as they adopt, implement, upgrade or demonstrate meaningful use of certified EHR technology. Similar incentive systems have been successfully implemented in the U.S. in the Medicare/Medicaid framework (CMS. gov, 2015). In order to ensure widespread adoption and use, the communication strategy should look at partnering with medical and paramedical associations such as the European Federation of Nurses Associations, the Standing Committee of European Doctors or the European Association of Senior Hospital Physicians.

Future prospects for Big Data applications

Beyond the improvement of day-to-day delivery of care, the widespread use of EHR will make it possible to generate a wealth of information on patients and the healthcare system. Public and private organisations are expected to greatly benefit from the ability to explore and analyse such data.

PRIVATE ENTITIES

In the long term, the EHRO database could allow (under specific conditions) the participation of private entities, such as life science, research, and insurance companies, thereby opening the door to benefits from data analytics, not just for these entities but for society as a whole.

Developers of medicines, vaccinations and therapies could analyse the available records on prescription and drug usage to determine hitherto unknown circumstances or problems affecting the efficacy and safety of their products throughout a heterogeneous group of patients, presenting a great number of possible varieties of the conditions in question. This would allow them to improve and advance the science and safety of their products, which should impact directly on the quality of treatment of all patients.

Similarly, insurers could reform their own compensation systems with the pharmaceutical industry, and offer incentives and rewards for products with an especially good efficacy record. This may be done in parallel with Health Technology Assessments performed by public reimbursement systems. In their direct relationship with the insured, insurers could analyse EHRO records to specifically target at-risk groups with preventive measures. Through such measures, insurance companies could save money otherwise spent on therapies, while patients would also benefit from support.

The potential benefits are numerous, but careful consideration is needed to commercial effects and the requirements of data protection. An independent supervisory board should be able to rule on access to patient data, on the one hand, and on how a private entity could act on this data. The decision criteria of the supervisory board would be made public. Information on aspects allowing identification of a person (such as address, financial details, family records) should never be available, unless the person in question has given specific consent.

Essentially, if access by private third parties is to be granted, a good balance must be struck between the benefits of data analysis for society and healthcare delivery, and how far to rein in commercial interests.

PUBLIC ENTITIES

With soaring healthcare costs in Europe, a primary challenge for the European healthcare sector will be finding how to curb spending. As the World Bank notes, *"public expenditure on healthcare in the EU could jump from 8% GDP in 2000 to 14% in 2030 and continue to grow beyond that date"* (The Economist Intelligence Unit, 2011). Further, Europe will soon be confronted by the health challenges of an ageing population, the rise in chronic diseases and increased costs of medical innovation and technology.

Data analytics, in particular of EHRs, offers an important contribution to meeting these challenges. EHRO would provide member states and decision makers with deeper insights into the state of health of their populations, and allow them to allocate funds to areas of highest unmet needs. A growing problem in the European healthcare sector is governments' lack of knowledge about the effectiveness of their expenditure. As the demand for spending increases and the need to balance budgets grows, sound analysis of returns on investment will be increasingly important. Currently, restrictions on access to patient data are an obstacle to advancing investment analyses. Improved access and transparency of data would permit more appropriate investments by governments in the healthcare sector, and help avoid wasteful spending - through more robust Health Technology Assessments or optimising healthcare infrastructure networks.

Patients may opt in to use of their data by public researchers after a prior approval by the independent supervisory board. Medical research typically needs long-term observation following large human and material investments, and a systematic design is required to avoid biases through all stages during these long follow-ups. For example, EHR data could help to achieve an overview of the population before sampling, including how to stratify a population in study (Moseley, Hsu, Stone, & Celi, 2014). Differentiated settings would be possible, allowing individual patients to decide whether to make their data available to science, and how: in clear, pseudonymised, or anonymised and aggregated format, for which period of time, and even for which area of research.

Disease prevention or epidemics detection authorities should also benefit from the data. They, in turn, would be able to study disease patterns (such as geographic spread or prevalence in population groups) by monitoring spikes in the appearance of specific diseases. Through this type of data analysis, counter-measures to flu epidemics or worse outbreaks could be initiated faster and thus more effectively. The ability to quantify medical information that data analytics provides can offer opportunities to enhance the understanding about patterns of diseases and their origins. It facilitates the mapping of genetic data to identify at-risk demographics for chronic diseases, cancer or heart diseases. The World Health Organisation found that *"at least 80% of all cases of heart disease, stroke and diabetes are preventable"* (The Economist Intelligence Unit, 2011), so one of the effective use of EHR databases could be earlier detection and prevention of diseases, rather than treatment at a late stage. This would provide healthcare practitioners earlier identification mechanisms, and allow them to better and more effectively treat patients, for example with more individualised or tailored treatment plans.

In the long-term, the application of big data analytics could provide an invaluable public good. The implementation of the EHRO body is a first step towards these greater benefits, because it will allow for the aggregation of standardised data at the EU level, thereby facilitating valuable analyses in the future and providing an immeasurable public good.

III. FINAL WORDS

Fragmentation in the European healthcare sector and of data will be the key challenge for Europe in the coming years in order to achieve the tremendous potential of Big Data analytics. Healthcare, as a public good and associated with many sensitive issues for patients and practitioners alike, requires the support and leadership of public authorities in the drive towards unleashing the digital revolution in this field. This can be best achieved through the establishment of a clear legal framework for collecting and accessing medical records. Unless supervised by public bodies with strong yet impartial mandates, such initiatives are unlikely to succeed in delivering the desired far-reaching positive impacts.

The recommendation for an EU-wide coordinated action to facilitate easy access, sharing and interoperability of electronic health records and future Big Data analytics aims at improving healthcare in Europe in the future. The proposal is to create a European Health Records Organisation, in charge of designing and rolling out a standardised electronic platform for medical records throughout Europe. Such a platform will greatly facilitate the aggregation of medical data at the European level for research purposes, helping notably the prevention of chronic diseases and epidemics. At the same time, it will empower patients by ensuring a higher level of protection for their data and improving their ability to receive medical treatment in another EU country, in the most efficient manner with the best quality treatment.

 With appropriate and rigorous safeguards, notably on personal data protection, the use of Big Data will be essential for improving healthcare for decades to come. The creation of EHRO constitutes a significant step towards this revolution in medical research and healthcare improvement.

Let's improve healthcare for Europeans. Let's make Europe a leader in this field.
Think Big. Think of Big Data.

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