



“Big data in Healthcare – what role for the EU?”

Learnings and recommendations from the European Health Parliament

Today the European Union (EU) is faced with several changes that may affect the sustainability of its healthcare system if nothing is done. For instance, by 2025 the life expectancy is expected to further increase. This may result in more people living longer, but not necessarily in a healthy and active condition, which can put further pressure on Europe’s healthcare costs and economic productivity. Looking at these challenges ahead, the idea of launching the European Health Parliament (EHP) was born and, since November 2014, Europe’s youth has been gathering in Brussels with the intention of exploring new and fresh ideas on the solutions for the future of healthcare in Europe. The initiative is backed by Johnson&Johnson, which is the founding partner and sponsoring the project together with: Politico, Google, European Patients’ Forum, College of Europe and EU40.¹

More specifically, the EHP is a platform of 55 young European professionals and students with a mix of diverse backgrounds (political studies, biomedical science, pharmacy, medicine, economics, international relations and others) and jobs (healthcare industry, students, European institutions, patient organization, civil society...). Participants are working together over 7 months. Throughout this time, they are brainstorming as a Parliament across 5 committees to develop political solutions around specific topics ranging from digital skills for the medical profession, prevention & self-care, antimicrobial resistance and others. During the project lifespan, four plenary sessions are organized to pull in expert feedback from the EU policymaking circle. The objective is to meet with key stakeholders and share ideas with EU officials, Members of

¹ EU 40 is the network of Members of the European Parliament under 40 years old.

the European Parliament, NGOs, media and interested public, in order to deliver high-level policy-oriented recommendations. Once the papers are finalized and presented at the last plenary session, they are shared with policymakers and the healthcare community across the EU28. The ultimate goal is that the proposals can be implemented by the European Commission or any other national government as a possible legislative proposal.

So far, two EHP editions have been organized and, in October 2017, Johnson&Johnson and EHP partners will be launching the third one. The project has become a brand in itself and it sparked great interest from the policy community and the wider public thanks to the engagement of a broad spectrum of stakeholders. Further, the EHP has inspired other countries to replicate the initiative and it has already been executed also in UK, Portugal, Germany, while other markets are considering it, like South Africa, Brazil, Mexico and Australia.

The first EHP edition (2014-2015) has addressed seven issues, namely (i) Big data in healthcare, (ii) Cross-border health threats, (iii) Access to therapeutic innovation, (iv) Patient empowerment and centrality, (v) The economic dimension of healthcare, (vi) Prevention of chronic diseases, (vii) Electronic/mobile health. If we look at the various topics discussed, *Big data in healthcare* is still a sensitive issue for the EU institutions with a view to achieving a fully integrated single market on data sharing to improve evidence based health care decision making and improving outcomes for patients. This would be of utmost importance since 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.

In this context, the “Big data in healthcare committee” drawn up an interesting and ground-breaking proposal that aims at creating a European wide connected Electronic Health Records Organization (EHRO) empowering patients by enabling the effective collection and usage of patients’ health data across Member states,

revolutionizing healthcare and ultimately leading to better health outcomes for patients and payers irrespective of national borders.

According to the work done by the committee, 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. 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. The committee members claimed that a patient driven opt-in system would lead to fast adoption, while targeted education campaigns and an incentive based system at health provider level would accelerate uptake and build trust. Moreover, the system would empower patients and assist clinicians, but also provide a wealth of knowledge to advance medical science, preventing diseases and improve health for everyone.

The benefits of using Electronic Health Records would be remarkable not only because the EHRs at EU level could create value for patients, but also for health practitioners and governments. As a matter of fact, patients would be able to receive appropriate treatment across Member states 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 centralized, up-to-date and easily accessible health "database", while retaining ownership and ensuring the use of their data, even though we perfectly understand that the concept of ownership has to be better defined at this stage. In fact, does ownership mean that the patient has the right to withdraw specific data from that database if he rejects to disclose them? If so, a coherent diagnosis could be jeopardized. Patients, while doubtlessly being more active and retrieving information from digital sources, are not in state to give an expert judgment on the value of these sources. Hence, they are not apt to consider any specific data crucial or non-crucial to a reliable diagnosis and this is why it is an issue that needs further discussions and analysis.

Other benefits brought by an EHR concern healthcare practitioners that 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. In this respect, we could even wonder whether increasing application of telemedicine in EU Member States makes a centralized database worth thinking about to ensure efficient cross-border treatment. In fact, the creation of a centralized eHealth database should be created before telemedicine has been established instead of being a result of it.

Another advantage of an HER would be that Member states could develop a single electronic health platform that could be rolled out across all national administrative units achieving a better balance of costs and benefits in healthcare budgets improving treatments and avoiding duplicate medical tests. More importantly, it would make 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.

In order to fully unlock these sources of value, three key problems remain at EU level: standardization (the establishment 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). Indeed, fragmentation in the European healthcare sector and of data is a key challenge for Europe and its Member states in the coming years for achieving the 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 fulfilled 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. Since public authorities may lack of inside knowledge to achieve this objective, it is necessary that experts from relevant fields (public / legal sector, IT-sector, health care sector...) bring together their expertise and can be actively involved in the policy making process.

To conclude, the recommendation for an EU-wide coordinated action to facilitate easy access, sharing and interoperability of electronic health records and future Big Data analytics would improve healthcare in Europe in the future. This is why the setting up of a European Health Records Organization, in charge of designing and rolling out a standardized electronic platform for medical records throughout Europe, would 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 would guarantee a higher level of protection for patient data and would give them the possibility to receive medical treatment in another EU country, in the most efficient manner with the best quality treatment. Therefore, the creation of EHRO would constitute a significant step towards this revolution in medical research and healthcare improvement.

However, it is important to underline that, to attain this objective, an expansion of the high-speed internet at the EU level, especially in rural areas, is needed. Indeed, eHealth applications will make a supply of remote areas much easier and efficient, but telemedicine as well as data collection require a stable internet. The creation of an EHRO for all patients certainly depends on the digital network of Member states.

Further, using eHealth tools, patient ownership of their personal health data will lead to an increased involvement in the administration, treatment and monitoring of their health information. Hence, the relationship to doctors will change, as information will be shared digitally and permissions will be needed throughout a treatment process. The question arises as to how this generated patient information will be accessible and transferable without threatening the patient's privacy and safety. It will be important to offer patients a transparent access to their EHR and information on who can use their data. The exclusive administration of patient data by the patient is not without risk though. Providing the patient with rights to disclose only particular data bears the danger of incomplete information being available to the doctor. This might jeopardize the diagnosis' degree of reliance. Even though patients consider themselves more informed due to online access, the eventual judgment on the value of the acquired information remains in the hands of a justified healthcare professional.

Finally, health data consists of heterogenous information coming from a wide variety of sources. This makes it attractive to use Big Data technologies to match and analyze the different points of data. Nevertheless, it is important to keep in mind that Big Data needs to be of clear benefit to patients in the first place. Any other cause is secondary but sound, if it can be demonstrated. A healthcare system focused on patient needs would propose a dedicated reimbursement option for e-health and related Big data solutions. This could be a powerful investment, not only in a better healthcare system, but to incentivize inventors to create new solutions, employ skilled people and make healthcare systems more sustainable and the economy more dynamic. This will allow society to drive digitalization instead of watching it passively.

To read more about EHO recommendation on big data, please visit the website <http://www.healthparliament.eu/>.