EUROPEAN
HEALTH PARLIAMENT
EUROPE'S NEXT GENERATION OF HEALTH

COMMITTEE ON DATA FOR HEALTHY SOCIETIES

CONNECT – SHARE – PROTECT
Three Priorities for an EU Health Data Ecosystem

#WeRun4Health

2018–2019

COMMITTEE ON DATA FOR HEALTHY SOCIETIES

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ENDORSEMENTS

Roberto Bertollini
President of Health First Europe
Former WHO representative to the EU

"Health data exchange and digital health have the potential to promote a philosophy where citizens are put first through innovation. In order to move towards a system what matters most to patients, the EU has to strike the right balance between fostering innovation and protecting patients' privacy and safety. More investments allocated to health are needed in order to build on the existing Digital Services Infrastructures and foster the crucial role of health settings in the uptake of digital solutions and modern data infrastructures. I believe the recommendations from the European Health Parliament's Committee on Data for Healthy Societies provide valuable guidelines for the next Commissions and upcoming European Parliament to shape an effective and trustworthy data ecosystem, focused on what matters most to a society: citizens' health and safety!"

Antonio Tajani
President of the European Parliament (EPP, Italy)

"The European Health Parliament tackles the next challenge coming from digital health which has become an integral part of our daily lives: digital infrastructure, advanced telemedicine, robotics and artificial intelligence are the new frontier of healthcare. The key is improving the exchange of data and prevention to make healthcare systems more effective and accessible. The Committee on Data for Healthy Societies has proposed an important contribution to this debate with its policy recommendations highlighting the importance of integration and patient empowerment as the centre of the healthcare systems for a new health plan in all the European Union."

Alojz Peterle
Member of the European Parliament (EPP, Slovenia)

"Digital and data revolution in care can support more integrated services, better patient safety, improved quality and access to care everywhere, as well as strengthen relationships with health carers. If European policymakers play their cards right, we can strike the right balance between patients' privacy and open data for better research and improved healthcare outcomes. I am happy to support the recommendations of the European Health Parliament on Data for Healthy Societies since I believe that they provide a suitable roadmap for the health data challenges that European countries have to face together."

Johan Prévot
Executive Director – IPOPI – International Patient Organisation for Primary Immunodeficiencies

"I welcome the initiative of the European Health Parliament, and in particular the policy recommendations presented by the Committee on Data for Healthy Societies, which are very relevant for building a European data ecosystem beneficial for all our citizens. I appreciate the attention given to data-driven research and expertise exchange to improve patients' outcomes. European Reference Networks (ERNs) on rare diseases provide an excellent success story of EU cooperation, where patients and clinicians work together for better care. For the benefit of research and diagnosis of complex conditions such as primary immunodeficiencies, ERNs should be expanded and consolidated at national level to facilitate discussion on rare conditions."

Sirpa Pietikäinen
Member of the European Parliament (S&D, Finland)

"We need EU-regulation to ensure the interoperability of patient and health data systems. The data ownership has to be with the patients, with only European insurers, or those that the patient specifically grants permission to, having access to their data. A pin-number-secured insurance health card, with a chip, that works like a credit card, could be the means to create a safeguard for this data."

José Inácio Faria
Member of the European Parliament (EPP, Portugal)

"As digitalisation of healthcare matures, we understand the potential of ICT and the need for high-quality data. These recommendations develop this idea further by acknowledging the responsibility of stakeholders in trust, transparency and value communication of the systems. For interoperability to become a reality, data models need to converge, and for that to happen there is an urgent need for broad European consensus on data taxonomy. Also, ICT literacy needs to bind to health literacy as patient involvement will be paramount in the development of eHealth and mHealth. These tools are the window for actual continuity of care: anytime, anywhere, in the palm of our hand."

Heinz K. Becker
Member of the European Parliament (EPP, Austria)

"In my political work in the European Parliament I am putting a special focus on representing the interests of senior citizens and I am, at the same time, consequently following the demand of generations justice for the youngers and the elders in our society. I actively work in the Parliamentarian Intergroup of Active Ageing and fight to make one principle the leading paradigm in health policies: Life Time Healthy Ageing – beginning in early child ages and uninterrupted until highest ages. Believing that this concept must be accompanied by making prevention and early diagnosis a political priority in Europe it is evident that we need – data! Therefore, I support the three pillars concept of CONNECTING + SHARING + PROTECTING presented by the European Health Parliament."

Dipak Kalra
President, The European Institute for Innovation through Health Data (i~HD)
Professor of Health Informatics, UCL

"I would like to warmly congratulate the European Health Parliament for prioritising this call to action on creating a strong European health data ecosystem. Its analysis covers the most important challenges that urgently need to be addressed in order to scale up the availability of high-quality health data and its trustworthy use to improve healthcare, accelerate research and empower citizens. I would like to personally endorse these recommendations and add my backing to this call to action. Policy makers and decision makers at EU and national levels must now work alongside all other health stakeholders to define the concrete steps needed, per recommendation, to realise this vision."

EXECUTIVE SUMMARY

Health data is essential to trigger digital innovation and foster disease prevention and care. This comes with unprecedented challenges and opportunities. We call for the EU and its countries to build a data ecosystem able to promote healthy societies by:

1. **CONNECTING** data infrastructures and fostering digital skills
2. **SHARING** data for research
3. **PROTECTING** citizens' data and promoting data fairness

Two ingredients are essential for making those three pillars steady: EU leadership and coordination and a patient-centric approach.

INTRODUCTION

The digital era is rapidly reshaping the ways we perform, receive and perceive health and healthcare. Commonplace consumer technologies, such as smartphones and watches, are being equipped to continuously measure and analyse our health, enabling a revolutionary quantification of our health. The amount of health information generated digitally across socio-cultural domains is unprecedented. Despite the self-evident public health potential of analysing such information, a fast and uncontrolled emergence of health data carries risks that require careful consideration. Lacking interoperability, inadequate infrastructures and risk of misuse are just a few of the challenges that digital societies have to face and solve.

Despite challenges, health data can be utilised for many beneficial purposes: they can be used by individuals to get insights about their health, reduce harm and prevent diseases; they can be used by physicians to fill health record gaps and conduct informed consultations; they can be used by research institutes to enable scientific discoveries; and they can be used by health providers to offer personalised services. To allow this potential to be reached, it is essential to foster data-driven innovation, while ensuring adequate mitigation against privacy risks and misuse.

While the EU has always been at the forefront of breaking down barriers and enabling cooperation and innovation[1], the era of digitalisation and "big data" requires an ecosystem that is not only open, but most importantly, trustworthy and beneficial for all. We need an environment of:

› **adequate data infrastructures and digital skills;**
› **responsible data sharing for research;**
› **ethical safeguarding and appropriate data security**.

We believe that the EU needs to show leadership in coordinating actions on eHealth, whereby data-driven innovation is the first crucial step towards ensuring that our health data is actually used to improve the health of our societies.

> *"The amount of health information generated digitally across socio-cultural domains is unprecedented."*

RECOMMENDATIONS

I. DATA INVOLVES INFRASTRUCTURE; IT IS WORTH CONNECTING AND UPSKILLING

The European digital health ecosystem is a fragmented one. It involves a large variety of stakeholders, data and IT infrastructures. Patients' data is siloed in different systems and heterogenous formats. The health workforce across Europe and beyond generally lacks the digital skills to implement the changes needed to support the move toward interoperability of health systems. Overall, the digital divide across Europe has been substantially reduced over the last decade, however, the gap remains far from closed. In order to tackle this fragmentation and give citizens greater access to and control over their health data, policymakers should focus on: interoperability, common standards, digital skills and new tools to gain insights from emerging types of data. Therefore, building on the existing policy framework, the European Commission, the Member States and the European Parliament should:

Refine the European Digital Health Interoperability Framework

- **Broadening the scope of cross-border exchange of health data and fostering the role of the eHealth Network:** building on the EU actions on electronic health records (EHR) and the related standard formats[2], new datasets should be promoted by the eHealth Network for cross-border electronic exchange of patients' data. Furthermore, the role of the eHealth Network in coordinating national approaches to the use of cloud computing in healthcare systems should be enhanced.[3]
- **Harmonising EHR data models:** much has been done for the standardisation of health data exchanges, but the way this data is stored varies greatly across EU countries. Promoting the harmonisation of data models for EHR (meaning the way data is structured and stored) would lead to a more competitive and unified market for EHR software and ultimately foster cross-border exchange of data.
- **Create a Single Healthcare Identifier for professionals:** all healthcare transactions found in EHRs and all ePrescriptions should be linked to a single identifier of healthcare professionals, along with their institution. This single identifier, when combined with EHRs, should help to better follow patients' pathways by allowing to see *who* (which provider) provided the care at which *point in time*, and also by facilitating communication exchange among healthcare professionals for a particular patient. A Single Healthcare Identifier repository should be openly accessible to patients and other healthcare providers, as well as paying and regulatory bodies. The identifier should include detailed information, such as the medical specialities or the languages spoken by the provider.[4] The Commission should consider how this identifier can build on existing initiatives aiming at creating healthcare professional databases (e.g. European Professional Card).[5]
- **Rethinking healthcare financial model for the digital age:** healthcare systems should address data infrastructure challenges and costs by translating digital benefits and connectivity into value for money; at the same time, they should assess which investments will do the most to save lives, reduce costs, improve quality and enhance equity.

Foster the healthcare workforce’s digital and data skills through regular training and the integration of new professional profiles

It is crucial that healthcare stakeholders possess sufficient skills and knowledge to make the health data ecosystem a reality. By improving the digital skills of those involved (e.g. physicians, nurses, social workers, health managers), we can enable them to identify better ways to collect and share health data to deliver better outcomes, leaving more to the care of the patients rather than to data input, and ensuring solutions meet their needs.[6] Fostering digital and data skills can be achieved by:

- promoting training to foster data and artificial intelligence literacy, both in medical curricula at universities and at a professional level
- integrating digital health specialists into healthcare systems and hospital management (e.g. medical scribes, coders, clinical documentation specialists, data scientists, app developers).[7]

Promote the use of open standards

As the number of mobile health applications and wearable solutions increases, practices to support open data standards are already being implemented. By removing barriers between innovators, open source promotes a free exchange of ideas within a community to drive creative, scientific and technological advancement. HL7 FHIR interoperability protocol is a good example of this, by allowing start-up companies with little resources to connect with existing infrastructures.[8] The EU should encourage healthcare stakeholders to use standards that are publicly accessible.

Revamp the EU taskforce on eHealth to address emerging types of data in healthcare and ultimately support forward-thinking solutions

A taskforce between relevant Directorates-General in the European Commission should continue[9] to pool efforts on digital health while exploring the emergence of new types of data, such as Patient-Generated Health Data (PGHD). The initiative should gather resources to bridge digital, research and health domains, while promoting existing forward-thinking solutions to use emerging types of data. These solutions should include interoperability protocols and mobile kits designed to house health and wellbeing apps, to collate their data and be connected to a healthcare setting. By covering allergies, immunisations, lab results, medications and vitals, health data and mobile kits can help people live better while supporting healthcare systems in tackling the growing demand for care.

II. DATA SAVES LIVES; IT IS WORTH SHARING

As digitalisation penetrates all levels and domains of daily living, the amount of health-relevant information collected and stored across sectors is beyond comprehension. While the benefits of using such data for advancing research are significant (e.g. from finding new cures to delivering personalised medicine), much of this information remains unused, fragmented and within inaccessible infrastructures. Changing this requires a multi-level and multi-stakeholder approach that facilitates the creation of trustworthy and mutually beneficial data exchange for research. The following recommendations target the incentivisation of data flows between research institutes and three key data-holder groups:

- the private sector
- the public sector
- individuals (whether these are patients or care providers).

As part of this, the EU and its Member States should encourage the flow of data between key stakeholders and academia or research institutions by targeting three principles: trust, transparency and value communication (i.e. those who share data for health research purposes should have access to easy-to-understand feedback on the output/impact of resulting research). At the same time, patients’ privacy, preferences and inputs should be placed at the very heart of data collection and use for research.[10] Therefore, building on the existing policy framework, the European Commission, the Member States and the European Parliament should:

> *"The EU and its Member States should encourage the flow of data between key stakeholders and academia or research institutions by targeting three principles: trust, transparency and value communication."*

Encourage industry to participate in data sharing by promoting trust and transparency measures while unifying research data repositories

In the context of health research, pharmaceutical companies or health technology producers generate a large amount of clinical data to underpin learnings related to clinical conditions. Hesitancy in sharing this data remains, both among industry stakeholders themselves, as well as between them and academic research centres. Building on the European Open Science Cloud (EOSC)[11] and successful public-private partnerships such as the Innovative Medicines Initiative, scepticism in sharing should be addressed by fostering trust and transparency. Data access should be provided to the researchers for the agreed upon project only, while progress reports on the research should circulate among relevant data providers. Each industry stakeholder may have only a fragmented data set due to limited resources; facilitating data access upon agreement among members of the repository should avoid duplication of resources invested and create reimbursement value propositions from the research institutes.[12]

Clarify and upgrade GDPR framework for health data, going beyond consent and focusing on patients' involvement

Uncertainty over data sharing and use can hinder the research potential of health information. The public sector should engage in setting a new agenda to better safeguard public trust to enable the sharing of health data with researchers. While the General Data Protection Regulation (GDPR) is already an achievement in the protection of health data, further clarifications on its implementation in the healthcare sector are needed. There is still confusion around the current rules for secondary use of data and patients' consent, as well as a lack of detailed definitions for some key concepts, creating the potential for differences in implementation.[13] Last but not least, consent is not enough for building trust and understanding around data sharing and its advantages. Patients' participation in data sharing should be expanded: patients should be involved across all points of the data cycle, not only through dynamic consent, but also in the curation and governance of health data platforms.

Develop new European Reference Networks (ERNs) and consolidate their model to overcome geographical differences and gaps in expertise

ERNs on rare diseases provide an excellent ecosystem where patients and clinicians work together for better care and research. To foster exchange of expertise across borders, and for the benefit of research, European Reference Networks (ERNs) should be expanded and consolidated at national level to facilitate discussion on complex conditions.[14] The newly established European Platform on Rare Diseases Registration[15] will be valuable for ERN development, allowing them to make use of anonymised information from a large pool of patients and offer better treatment to those in need.

Facilitate the sharing of patients' data by building a European framework for health data donation and by promoting value feedback loops

- The EU, together with its Member States, should create a **European framework for post-mortem health data donation** to allow patients to share data comfortably (meaning respecting their preferences and protecting their privacy) after death. Citizens willing to donate their health data should be able to 'opt-in', making their information available post-mortality within health data repositories accessible for research purposes. This patient data should be pseudonymised and protected under GDPR. Within this framework, individuals could provide informed consent for their data to be used, while personalising their data sharing.[16] Just as for organ donation, people should be able to indicate which data can be shared (e.g. removing sensitive data on mental health issues or sexually transmitted diseases), for how long, for which research purposes, and to choose between one-off use or limited multiple uses.
- The creation of a European framework for health data donation should be accompanied by the creation of **common standards on anonymity in data**, while ensuring a limited impact on the scientific value of the data.
- All major health research communication channels (e.g. scientific journals) should be incentivised to introduce free-to-access "**lay summaries" of published research, addressed to patients**, as well as caregivers that are not necessarily acquainted with scientific terminology and complex methodologies. Beyond that, those summaries should be additionally published in the languages of the

regions in which the research was conducted. This is an essential step for building trust and transparency, while enabling patients to appraise the value of their data for society, hopefully creating a more engaged data flow environment between European citizens and research institutes.[17]

Launch an awareness campaign to explain the benefits of data sharing

EU Member States should tackle the lack of awareness and limited interest in data sharing through public campaigns; these would explain the advantages of safe data sharing for public and population health, digital health engagement, and net new knowledge discovery, while putting the challenges of privacy and cybersecurity into an appropriate perspective.

III. DATA NEEDS TRUST; IT IS WORTH TACKLING MISUSE AND PROMOTING DATA FAIRNESS

The amount of data currently generated is fuelling a new era of technologies which, in the wake of recent data scandals, can only succeed by enhancing users' trust and by applying targeted policy solutions to tackle the real problems. While cybersecurity and privacy breaches are recognised as critical barriers to making health data more accessible, transformative technologies like cloud computing and artificial intelligence (AI) continue to evolve and are inherently fuelled by data. To make this into a success story, it is important that we work towards creating partnerships that embrace a common vision of the future of data-driven healthcare systems, tackling data misuses and fostering ethical behaviour. Therefore, the European Commission, the Member States and the European Parliament should:

Boost stakeholder dialogue and cooperation to develop secure tools against data breaches and cyberattacks

Public awareness of the rights and opportunities of sharing data should be complemented with a transparent and visible partnership to promote health-related cybersecurity standards. There should be full transparency around access and use of patients' data through the implementation of appropriate safe and innovative technologies (e.g. blockchain). Voluntary and real-time sharing of actionable cyber threat information between governments, businesses and academia should be in place to collaboratively prevent and mitigate cyberattacks.

Release EU guidelines on the ethics of data access and use in healthcare, also including an assessment of the ethical implications of big data and AI applications

European citizens and businesses need guidelines governing the ethical implications of AI, the purposes of research and access to patient data. In light of the AI Ethics Guidelines presented by the European Commission's High Level Expert Group on AI[18], the EU should go beyond a one-size-fits-all approach. The Commission should tailor its ethical guidelines to the sensitivities of different AI applications, which is especially important in the healthcare sector. Those tailormade guidelines should assess the risks of data misuse and algorithmic bias in the digital healthcare industry, and how that affects patients and their rights (i.e. discrimination in data-supported decision making, from recruitment to insurance services). They should also consider accountability and the ability to explain AI applications (from the data sets used for training to the end results).[19] Ultimately, those measures should ensure that data fairness is in place, meaning that personal data is handled in ways that people would reasonably expect, and not used in ways that could cause disparities or affect them adversely.[20]

Promote EU-wide codes of conduct for data-driven technologies and patient data protection

The Commission should support healthcare stakeholders in setting up principles for ethical, responsible and transparent data usage, while fostering a higher level of harmonisation and legal certainty for data rules across the EU. A self-regulatory code of conduct would be a crucial tool in ensuring that data protection of EU citizens is guaranteed when they make use of eHealth systems (especially cloud services).[21] This code of conduct should also lead the industry to responsible creation of AI solutions, ensuring fairness, inclusivity, accountability and transparency for all involved (keeping in mind the importance of lay language and algorithms to be understood or reviewed by clinicians or regulators). This would contribute to an environment of trust and create a high default level of data protection, especially in the European cloud market.

CONCLUSIONS

> *"Europe needs a Commissioner fully dedicated to health to oversee all the health-related actions across Directorates-General and to address the unique challenges of health data."*

Health and lifestyle data generated by numerous sources is rapidly expanding. The EU can and should break data siloes and create an ecosystem that connects and protects, while fostering the growth of digital health technologies and data-driven innovations. It is essential for the EU to seize the opportunity to develop data management practices and shape a common ecosystem before these become too widespread; this should be done across all Member States, even if a homogenous approach is not immediately taken. The EU cannot miss the chance to show its leadership in this field and set an example of best practice on data infrastructures, data-driven research and ethical governance. But this leadership cannot be achieved without centralisation and coordination of healthcare policies. 70% of Europeans want the EU to do more in the area of health; Europe needs a Commissioner fully dedicated to health to oversee all the health-related actions across Directorates-General and to address the unique challenges of health data.

By creating equal access to necessary healthcare for its citizens, the EU has already built an exemplary society which other parts of the world look up to. Now, again, it is time for the EU to build a data ecosystem that can stand up as an example to the world, by considering the sensitive data challenges involved in healthcare and by creating healthy societies with fair and effective use of data.

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