EPF’s Response & Accompanying Statement

Public Consultation on the European Strategy on Data

31 May 2020

The European Patients’ Forum (EPF) is an umbrella organisation of patients’ organisations across Europe and across disease-areas. EPF represents the interests of over 150 million patients with chronic conditions across the EU who expect and rely on European cooperation to improve healthcare delivery and quality for all. In concert with its 75 members, EPF ensures the patient perspective in European key health debates, including digital health and health data. To achieve this goal, over the past years EPF has been particularly active in these fields through both its policy work[1] and several projects[2].

This statement is an addition to the European Patients’ Forum’s response to the European Commission’s European Strategy for Data Public Consultation, submitted through the EU Consultation portal. The response and this statement have been developed in a consultative process together with our members and our EPF Digital Health Working Group. In this accompanying statement we further elaborate some the key elements of the Strategy and data in the field of health that we deem crucial for the patient community.

Introduction

Health is an area where Europe can undoubtedly benefit from the data revolution. Proper use of health data can improve health systems’ sustainability, increase the quality, safety and patient-centredness of healthcare, decrease costs and transform care into a more participatory process.[3] Health data can support the work of regulatory bodies, facilitating the assessment of medical products and demonstration of their safety and efficacy. Furthermore, the COVID-19 pandemic has demonstrated how accurate and quickly accessible data is also fundamental in the management of cross-border public health emergencies. Nevertheless, the road to fully exploit the potential benefits of data in health is only partially built, still extremely fragmented and not yet developed with the patients’ views at the centre.

The EU can set the global standards when it comes to technological development, but it must do so while ensuring inclusivity, empowerment and respect of everyone’s fundamental rights.

Priority no.3 of the **EPF Manifesto for the 2019 European elections**, *Driving the development of digital health*, states: “the EU should ensure that Europe’s future digital health tools and systems start from patients’ priorities and are co-developed with patients.” This is particularly important for data in healthcare: patients should be in control of their data, and the EU must guarantee adequate

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[1] EPF policy and advocacy work related to digital health and data includes our position paper on eHealth (2016), GDPR guide for patients and patients’ organisations (2016), Data and Artificial Intelligence EU Policy Briefing for Patient Organisations (2020) and a brief summary of our recent EPF survey on Electronic Healthcare Records (2020)

[2] EPF recent projects related to digital health and data include: Digital Health Europe, EHDEN – The European Health Data and Evidence Network, and Data Saves Lives.

[3] Europe for patients Manifesto, https://www.europeforpatients.eu/

frameworks to ensure their empowerment, participation, safety and protection. All patients must have access to their own health data in accessible and easily understandable formats. The EU must also work on an enabling environment and infrastructures that will ease cross-border coordination, interoperability and data flow to fully exploit health data in all its potential uses, including Artificial Intelligence, in a secure and ethical manner.

EPF welcomes the European Commission's Data strategy and the importance given to the development of a European Health Data Space as positive steps in this direction. The EU now have to lead the change, building on existing regulatory frameworks and best practices, and **involving patient organisations alongside other key stakeholders in shaping the strategy and ensuring its inclusive and coherent implementation**.

EPF's recommendations

A DATA STRATEGY FOR HEALTH DEVELOPED WITH PATIENTS AND FOR PATIENTS

To achieve its goals, the overarching data strategy on health should focus on access to health data, equitable and connected infrastructures and platforms to facilitate movement of patients' and their data across the EU. Participatory governance and fit-for-purpose legal ecosystems for health data, built on trust, ethical standards and inclusion of patient organisations as partners, will be crucial.

1. Patients need to be in control of their data

Patients must be in control of their data. They should be able to freely access it, decide who to share it with, and on what conditions. This is currently far from the case. It should be possible for those individuals who wish to do so, to give wider access to the data held about them (e.g. through so-called data altruism or data donation), as long as the implications of doing so are fully transparent and clear. Patients want to know and have some control over what purposes their data is used for and track its use when possible, and they often want to know about the results of research using their data.[4] Furthermore, more clarity and harmonisation are needed on the concept of data ownership. Depending on the different systems, for example, identifying who owns the data – the individuals or the organisations providing care (e.g. hospitals) – can still prove challenging and not transparent.

Data management should follow the FAIR Principles: data should be findable, accessible, interoperable and reusable.[5] Access and trackability should be facilitated, for example, through development of user-friendly tools and platforms, clear guidelines and information tailored to patients and the public.

Increased investments in new technologies and infrastructures enhancing data access and use are also welcome. Through investments and frameworks, the EU should also ensure that all patients have full and equal access to their health data within and across countries.

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[4] EPF, Electronic Health Records survey – Summary of results (2020), https://www.eu-patient.eu/globalassets/policy/ehr-survey-2020_summary_final.pdf

[5] FAIR Guiding Principles for scientific data management and stewardship, https://www.go-fair.org/fair-principles/

2. Meaningful informed consent mechanisms

Informed consent is a fundamental patient's right and a principle of medical ethics, enshrined in various international conventions and regulations. Informed consent is not simply about providing information to the patient, or obtaining a signature on a form. Meaningful informed consent enables a person to make an "enlightened decision"[6] about whether or not to participate in a study. EPF has called for greater harmonisation of the core elements of informed consent (in the context of clinical research) and the process, to ensure that all patients across the EU can be empowered through meaningful informed consent.[7] Meaningful informed consent is also a concern when patients are making decisions on whether or not to allow use of their data.

The EU data strategy should be taken as an opportunity to set up mechanisms to ensure clear and understandable informed consent for individuals to share control of their data, for example by developing dynamic consent models, in compliance with the GDPR and to facilitate effective and ethical data use for research. This needs the close involvement of patients as well as researchers. More reflection is needed on how "broad consent" should be defined and implemented. Patients may, for example, be happy to grant blanket permission for use of their data in specific types of research, or for a specific purpose, or by a specific type of organisation; or they may wish to opt out of specific types of research. The parameters of broad consent should therefore be flexible to take into account individual patients' preferences and values. Improved and harmonised techniques of pseudonymisation and anonymisation also play a central role to ensure data safety, avoid data misuse and increase users' trust.

3. Data for better healthcare and the public interest

Data can play a crucial role in improving healthcare. However, discussions on health data, its ownership and use, require more reflection. Governance frameworks for data sharing, built on trust and ethical standards, will be indispensable. EU actions on new technological developments should always involve patients as true partners to guarantee that they can benefit directly from sharing their data or indirectly in that the public health societal benefit is ensured.

Re-use of routinely collected data for the public interest is fundamental. The recent EPF survey on patients' views regarding electronic health records[8] identified several purposes for which patients would be willing to share their data, including: collection of real-world data on a specific medicine's safety and efficacy after authorisation, on patient-reported outcomes (PROMs), on adherence to treatment, on lifestyle and demographics, collecting information on the patient journey in order to develop measures for patient experience (PREMs), and linking clinical data to registries for more information on specific diseases for research.

However, data protection rights need to be fully ensured, clearly understandable by patients and adapted to the rapid evolution of technology in healthcare. EU legislation, on top of ensuring adequate

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[6] Words used in the Nuremberg Code, the 1947 precedent of the Declaration of Helsinki.

[7] EPF, Clinical Trials Regulation: Informed Consent and Information to Patients, https://www.eu-patient.eu/globalassets/policy/clinicaltrials/epf_informed_consent_position_statement_may16.pdf

[8] EPF, Electronic Health Records survey – Summary of results (2020), https://www.eu-patient.eu/globalassets/policy/ehr-survey-2020_summary_final.pdf

protection and safety, should be designed to ensure that the exercise of rights is simple and not overly burdensome.

EPF also calls for more clarity on the definition of data use for public interest. Research and innovation using public data must be driven by public health and societal needs. The investment to facilitate use of publicly generated data, for example for the development of new technologies through public-private partnerships, should be reflected in the output of the innovation process in terms of accessibility and affordability for all.[9]

4. Health literacy and patients' empowerment as crucial elements to realise data-driven innovation in healthcare

Health literacy is a key component of patient empowerment[10] and a major priority for patients.[11] **Enhancing digital health literacy and data literacy levels is crucial to support patients' control of their data and enable them to understand and exercise their rights while realising the societal benefits of data-driven innovation in healthcare**.

EPF welcomes the importance given to skills and literacy within the data strategy and stresses the need for active patients' involvement in shaping future skills, educational and training policies for data and health. We would like to emphasise that health literacy is not only about the skills of individuals, but a relational concept that requires healthcare professionals, organisations and systems to become more easily understandable and navigable to all individuals, whatever their health literacy levels. Health literacy – including digital and data literacy – is therefore an important strategy for health equity and avoiding exacerbation of the digital divide.[12]

Building health literacy involves people being informed how their data is to be used, which in turn requires governments and/or healthcare providers to be fully transparent about how health and patient data is being used and shared – especially if with third party (private) organisations. Trust and transparency go hand in hand; there are examples where poor government communication and lack of transparency created considerable issues, with initiatives ultimately scrapped due to a lack of trust and patient buy-in.[13]

We strongly advise the Commission to develop a patient empowerment strategy encompassing (digital) health literacy as part of its strategy on data, and further address the surrounding issues around user awareness and acceptance of digital health services. This should be done in consultation

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[9] EPF statement, Core Principles from the Patients' Perspective on the Value and Pricing of Innovative Medicines (2016), p.12. https://www.eu-patient.eu/globalassets/policy/epf_pricing_statement_160616.pdf

[10] EMPATHiE Project, https://www.eu-patient.eu/whatwedo/Projects/completed-projects/EMPATHiE/

[11] EPF, Charter on Patient Empowerment (2016), https://www.eu-patient.eu/whatwedo/campaign/PatientsprescribE/charter-on-patient-empowerment/; EPF, Campaign on Patient Empowerment: Roadmap for Action (2017), https://www.eu-patient.eu/whatwedo/campaign/PatientsprescribE/roadmap-for-action/; EPF, Europe for Patients Manifesto (2019), https://www.europeforpatients.eu/

[12] Roediger A et al. (2019) "Nothing about me without me: why an EU health literacy strategy embracing the role of citizens and patients is needed", Archives of Public Health vol.77, no: 17. https://archpublichealth.biomedcentral.com/articles/10.1186/s13690-019-0342-4; EPF, Consensus paper: Making health literacy a priority for in EU policy, https://www.eu-patient.eu/globalassets/policy/healthliteracy/health-literacy-consensus-paper_2016.pdf

[13] Fiona Goodlee, "What can we salvage from care.data?" *BMJ* 2016;354:i3907 https://www.bmj.com/content/354/bmj.i3907

with civil society organisations including those representing patients. The EU should also support health literacy improvement through dedicated funds, enabling new projects and supporting initiatives already carried out at national and local level. Specific strategies should be developed to ensure that underrepresented and marginalised groups are included.

5. More inclusive and user-friendly data-based applications and products

In order to enhance health literacy, **the development of easy-to-use and more understandable data-based applications and products is equally important**. Simple products, interfaces and data platforms can partially bridge health literacy gaps, increase trust levels and enable people with low health literacy levels to still benefit from data innovation. This calls for a more inclusive and co-designed development process for health data-based solutions putting patients at the centre.

The data strategy and European Health Data Space should take into account existing initiatives, for example the European Medicines Agency's activities to develop electronic product information. There is considerable potential in digitalising information on medicines, not only by providing standard information online, but for example though development of much more interactive tools whereby patients could receive updates in real time (for example concerning new safety information on the medicines they take) but also to be able to give feedback themselves (for example on symptoms or reporting potential adverse reactions).[14]

Respondents to the EPF survey on electronic health records showed interest in comprehensive patient portals, where patients could not only access their own health data but also contribute to their health records, correct wrong information, and connect with healthcare providers and the system in an easier way.[15]

6. A patient-centred European Health Data Space

Considering the peculiarity of the health sector and its specific challenges, adopting a sector-specific approach on healthcare and data is fundamental. EPF therefore welcomes the European Commission intention to develop a sector-specific European Health Data Space (EHDS), as included in the Data Strategy and in the Mission Letter to Stella Kyriakides.[16] A connected and interoperable data space could prove invaluable for future research, as previously demonstrated on a smaller scale, by a number of EU programs such as the European Reference Networks, IMI projects[17] and the Data Saves Lives Initiative[18]

Given the challenges of adopting such complex initiative at European level, there is an urgent need for more information on how the EHDS will work in practice, for example on whether it should operate

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[14] https://www.ema.europa.eu/en/documents/presentation/presentation-opportunities-expanding-access-produce-information-medicines-patient-perspective-k_en.pdf Such information should be provided by trusted public authorities.

[15] EPF, Electronic Health Records survey – Summary of results (2020), https://www.eu-patient.eu/globalassets/policy/ehr-survey-2020_summary_final.pdf

[16] European Commission, Mission letter – Stella Kyriakides (2019), https://ec.europa.eu/commission/sites/beta-political/files/mission-letter-stella-kyriakides_en.pdf

[17] For example, the EMIF project (https://www.imi.europa.eu/projects-results/project-factsheets/emif)

[18] Data Saves Lives is a collaborative initiative to create a "health data community" that can function as a safe space where all stakeholders can openly discuss views and ideas on data and policy at European and national level. It will also develop an informative web platform for lay-friendly information for patients and citizens, https://datasaveslives.eu/

as a federated structure or more centrally controlled.[19] This may ultimately determine the approach which needs to be taken on several key elements, including data ownership and control, access, tracking and data literacy. Implementation and enforcement options, including the necessary updates to the current regulatory framework and infrastructural investments, should be therefore carefully scoped out by the EU and thoroughly discussed with all the stakeholders involved.

In particular, the EHDS must be based on an appropriate framework ensuring data ownership, health literacy, empowerment and specific data protection provision for patients, including a dedicated code of conduct for health data. The EHDS will also have to be based on strengthened and harmonised infrastructures and enhanced interoperability to allow secure health data flow across the EU. Learning from national and European best practices and projects will be fundamental to swiftly achieve the EHDS. Furthermore, the EHDS will also have to address the risks of potentially exacerbating inequalities within and across Member States, taking into consideration the digital divide.

The EHDS should ensure synergies with relevant initiatives in all areas, such as in the medicines regulatory field the recommendations of the European Medicines Agency's task force on big data and the call to develop a platform for accessing and analysing health data as well as a network of stakeholders on implementation.

Finally, despite the strong consensus on the need for patient-centredness, trust and ethics, there is a demonstrable lack of practical tools or suggestions to make the concept a reality.[20] This requires a broad systematic approach that should be at the centre of the EHDS discussions. The EHDS should therefore include the necessary mechanisms to ensure a meaningful involvement of patients' from the very beginning, such as inclusive governance structures and appropriate capacity-building. In doing so, the EU will be able to build a health data space engaging with the unique experience and knowledge of patients.

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[19] The outcome of projects such as EHDEN will be vital in setting out what works and what the barriers to this being established are.

[20] EPF, EPF Congress 2019 – Report, https://www.eu-patient.eu/News/News/epf-congress-2019-theres-nothing-for-patients-without-patients/