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HOPE Position on the European Health Data Space

The European Commission's proposal for a Regulation on a European Health Data Space (EHDS) envisages the development and implementation of a digital health ecosystem in the European Union (EU) as a key step for shaping more patient-centric, integrated and resilient health systems. The envisioned primary uses of electronic health data contribute to improved patient health outcomes by facilitating easy access to, sharing and portability of electronic health data, while supporting healthcare professionals' tasks and administration. In parallel, the secondary uses are meant to advance health research, decision-making and innovation, while strengthening public health.

Hospitals and healthcare institutions being critically important settings in which data-driven technologies shape all spheres of activity, a prerequisite for the successful realisation of the EHDS will be good governance and transparency. Dialogue is crucial to ensure that the EHDS becomes an accessible, inclusive space that respects different structures of healthcare provision, safeguards patient safety and fundamental rights, and meets the needs of the beneficiaries it aims to empower.

This paper draws attention to provisions of the legislative proposal where HOPE considers that further clarification, discussion and elaboration is required for the EHDS to attain its objectives.

Ownership and co-creation

Given the growing importance of electronic data as part of health service provision, the legal basis of the Regulation (article 114 TFEU) does not take into account the specific health policy effects of the proposed data exchanges, which should be clearly articulated by way of reference to article 168 TFEU. The EHDS should, first and foremost, benefit patients, healthcare providers and professionals rather than the IT and data industry. It is also vital to ensure that the EHDS does not inadvertently create data monopolies held by conglomerates whose primary goal is to reap profits. In the United States, many of the biggest brands are moving into healthcare and integrating data including from electronic health record (EHR) systems. Moreover, EHR solutions offered by global private companies often do not satisfy the specific needs of healthcare environments in another country.

The inclusion of artificial intelligence (AI) as a segment to be developed in the digital single market further entails strong responsibilities to ensure the proper application of agreed European ethical principles[1], define the limits of its application, and inform about AI's purpose and logic.

[1] https://presidence-francaise.consilium.europa.eu/media/zp2jt3up/european-ethical-principles-for-digital-health_fr_eng.pdf

The language of the proposal, while emphasising individual rights coupled with protection of fundamental rights, does not offset this bias. Healthcare providers and patients would, at any rate, expect to exercise many of the rights outlined as health systems are integrating digital technologies.

HOPE is a partner in digital health projects that promote co-creation by involving end users from start to finish[2]. Although several articles (10, 36/37/39, 64/65, 66) of the proposal require national digital health authorities and health data access bodies, the EHDS Board and joint controllership groups to engage with and consult stakeholders, the EHDS will only succeed if informed by real-life experiences. Stakeholder dialogue and public communication are essential as the desired cultural shift cannot occur as a 'top down' exercise, neglecting the emotional dimension of change.

The EHDS Board outlined in Chapter VI of the proposal, responsible for the oversight, coordination and exchanges of best practices relevant to the implementation of primary and secondary uses of electronic health data, should be linked to a mandatory mechanism enabling stakeholders - including hospital and health provider representatives - to co-shape the development and implementation of the EHDS, including its many implementing and delegated acts. An example is the HTA Network Stakeholder Pool comprised of four separate stakeholder groups that meet regularly.

Resource constraints

The scope of the proposal is highly ambitious given the different starting positions national and regional health systems occupy. Focusing on what is feasible will be important for overcoming technical, legal, administrative and political obstacles and establishing the right balance between care, research and economic objectives.

The Commission expects the EHDS to generate significant savings amounting to approximately 11 billion EUR over ten years. That estimate reflects the potential longer-term gains of a functioning EHDS against which the immediate and continuous costs involved in enabling hospitals and healthcare services to purchase, upgrade, adapt, programme and operationalise the necessary infrastructure, systems and data-processing tools required must be wagered.

In many member states, our sector has, for decades, witnessed severe budget cuts, resource and staff shortages, amplified by the COVID-19 pandemic. For example, in France sustained cuts to hospital budgets have led to the formation of medical deserts in certain regions[3], and in many countries, healthcare operating budgets – and health expenditure per capita - have not kept up with increased demand, economic pressures and technological change.[4] Digital innovation and cybersecurity typically represent only a fraction of public hospital budgets, the majority of which is allocated to human

[2] At time of writing, these include Hosmart AI (see https://hope.be/EU_Projects/hostmartai/), RE-SAMPLE (https://hope.be/EU_Projects/re-sample/) and TeNDER (https://hope.be/EU_Projects/tender/)
[3] https://www.rfi.fr/en/france/20220622-hospitals-warn-france-s-healthcare-system-is-at-the-breaking-point
[4] For an overview of member states' multifaceted health system challenges, see the 2021 State of Health in the EU Companion Report: file:///C:/Users/Intern/Downloads/2021_companion_en.pdf

resources, procuring medicines and medical devices.[5] The EHDS set-up, transformation and implementation costs are expected to be significant for hospitals and healthcare facilities whose funding is subject to inflexible economic criteria and commonly project-based. In the context of the war in Ukraine, energy costs, inflation and supply shortages must also be considered.

Moreover, healthcare digitalisation poses a tremendous capacity and education challenge. Digital deficits are felt across the entire health spectre and the costs involved in training and upskilling personnel to increase data competence and use digital tools with confidence must not be underestimated. Likewise, healthcare is unable to compete with other industries in the struggle to attract IT specialists to oversee and perform data tasks. Further costs will be incurred for linking up data silos (health, social, etc.) of value to research, public health and policymaking.

Critically, the EHDS should be clearly linked to strategic systemic and institutional goals. It must not trigger a detrimental ripple effect by creating a hierarchy based exclusively on data competence, eradicating less digitally advanced hospitals and healthcare services whose strengths lie elsewhere.

Respecting national, regional and local needs and practices

The EHDS will be implemented at national, regional and local levels bound by specific legal mandates. Digital fragmentation has resulted in different national regulations difficult to harmonise, e.g. regarding data access and authorisation to make changes, of particular relevance to article 3.

Moreover, where large-scale investments in digital infrastructures have already taken place, it will be important to ensure the continued and efficient functioning of national and regional digital systems and data registries designed for specific purposes, without EU objectives in mind. Allowing room for national specificities and practices will be important as it is unlikely that 'one size fits all'.

This is equally important in the context of national procedures pertaining to ethical aspects governing access to health data, such as involving ethics committees and existing laws on obtaining informed patient consent.

The EHDS holds potential to improve healthcare services both cross-border and within countries. However, at present, the number of patients able to take advantage of cross-border healthcare services is very low[6] and it must be avoided that, in a European Health Union based on solidarity, the enormous effort required will benefit a minority of mobile citizens only.

Hospital telemedicine services at present being subject to many different rules across the EU, with high fragmentation of use within and between countries, the relevant provisions contained in article 8 should be removed from the proposal.

[5] See this French example: https://www.pourleco.com/politique-economique/dans-les-entrailles-budgetaires-de-lhopital-public

[6] https://www.euractiv.com/section/health-consumers/news/health-brief-cross-border-healthcare-rights-are-still-unknown/

Technical challenges, data and responsibilities

The EHDS proposal foresees that the MyHealth@EU platform will facilitate the smooth exchange of electronic health data across the EU via national contact points. In practice, technical and semantic interoperability is problematic at all levels (national, regional and even within health institutions). The seamless exchange of health data depends on unambiguous technical guidelines, clearly defined standards and flexible funding to overcome complex challenges.

The timelines for implementing important parts of the Regulation such as EHR systems are short and unrealistic given the need to restructure key aspects of national and regional health systems, build up technical capacity and warrant that all data-related functions can be performed correctly and securely.

Clarification will be needed regarding the responsibilities of hospitals and healthcare institutions potentially required to handle data requests as single data holders (art 49) and provide access in secure processing environments, possibly in exchange for a fee. This could be impractical, burdensome and disruptive for health providers not classified as micro enterprises. Hospital and healthcare operations should not be compromised by disproportionate and/or unjustified EHDS obligations.

The proposed deadlines are also problematic. For example, following the granting of a data permit for secondary use, data holders have only two months to comply with the request and make the data available. In the absence of a clear structure for handling such requests, this poses a real challenge for already strained healthcare providers. Such requests could instead be handled by research data centres where data intended for secondary uses could be pooled and securely stored. Similarly, tacit approvals should not occur if data access bodies are unable to reach a decision within the stipulated time limit.

Regarding data quality, the EHDS foresees incorporating data from wellness and other digital applications subject to a voluntary labelling scheme if interoperable with EHR systems (art 31). Mandatory registration in an EU database will be necessary, in addition to the requirements set out for EHR-interoperable medical devices and high-risk AI systems established under the relevant EU laws. While there is much emphasis on the conformity of systems, the accuracy, completeness and size, quality and granularity, comparability and meaningfulness of datasets raises concerns. For certain wellness apps that could be considered as an integral part of healthcare provision, certification combined with adherence to common standards and CE marking, would ensure better compliance with quality criteria and offer more legal clarity than labelling.

Interaction between EU laws

The proposal contains a vast number of references to other EU legislation relevant to digitalisation. Most prominently feature the General Data Protection Regulation, the Data Governance and Data Acts, the AI Act and the Cybersecurity Package, each containing specific provisions and mechanisms. It will be important to ensure that the relevant definitions and structures for interoperability and data

security are aligned as much as possible, also to avoid duplication of obligations where these would not add value. There are also interactions with, inter alia, the ePrivacy Directive, the eID Regulation and framework for a European Digital Identity, the Medical Devices and InVitro Medical Devices Regulations, and laws governing the functioning and security of network and information systems, in addition to member states' own laws. Legal uncertainties and ambiguities will need to be reconciled.

In a Joint Opinion, the European Data Protection Board and European Data Protection Supervisor highlighted the lack of consistency between the EHDS and GDPR regarding data subjects' rights, and consent issues pertaining to the processing of data derived from wellness apps and other digital applications as well as behaviour data in the realm of secondary use (GDPR/ePrivacy interplay).[7]

Evidence on use and benefits

The proposal cites contact tracing apps and Digital COVID Certificates as effective solutions introduced during the pandemic. However, while the Digital Certificates facilitated international mobility and are likely to remain valuable, contact tracing apps were deployed unevenly across the EU, their functionalities and quality differed, and they were quickly deactivated again, with an evaluation of their deployment and impact pending. Considering the effort expended on interoperable apps, the six priority categories of electronic health data to be included in the EHDS as a minimum for primary uses (Art 5) could be unworkable: many member states are not connected to the existing cross-border data infrastructures nor do they have sufficient data available for processing.

The recent surge in adopting digital solutions must also not be confused with general enthusiasm for data-driven care. HOPE members report that healthcare professionals are taking a cautious approach to national health data spaces given that much of the data is incomplete and cannot be sufficiently trusted. While many countries recorded digital expansion during the pandemic, German respondents to a hospital survey felt that digitalisation had stagnated or regressed.[8]

More generally, in the absence of solid clinical data, the evidence base for proving the effectiveness of most digital health technologies remains weak; the EHDS should contribute to closing this gap.

Protecting individuals and tackling health inequalities

The proposal contains no mention of vulnerable populations prone to stigma and exclusion due to their physical or mental health conditions, disability, gender, ethnicity, sexual orientation, social situation, etc. Leaking personal health and social data bears particularly severe consequences for their fundamental rights, potentially resulting in loss of insurance or welfare entitlements, employment termination, deportation, discrimination, etc. Re-identification of data subjects might be possible due to the specific combination of characteristics and small sizes of data sets, or resulting from AI

[7] https://edps.europa.eu/data-protection/our-work/publications/edps-edpb-joint-opinions/european-health-data-space_en

[8] Meyer, J. 'KHZG: Zwischen Impuls und Strohfeuer', *daskrankenhaus.de*, 04/22, pp. 206-207

deployment. As noted by the EDPB-EDPS, the data quality requirements for wellness and other digital applications do not match those of medical devices and they could reveal user characteristics.[9] It is unclear how the EHDS advances the health outcomes of millions of Europeans without access to digital technology and low digital health literacy.

For secondary uses, pseudonymisation shall only occur when the purpose of data processing cannot be achieved with anonymous data (art 44/45); however, the provision that 'data users shall not re-identify the electronic health data provided to them in pseudonymised format' and related penalties might not be sufficiently dissuasive. Similarly, it must be ensured that public sector and other entities exempted from data permits do not misuse data (art 48). Clarification is also needed regarding 'activities for reason of public interest' and 'training, testing, and evaluating of algorithms' and how such data uses contribute to public health, social security and healthcare (art 34).

Without having evaluated the data protection threats arising from the EHDS within the EU, enabling third-country actors - following a compliance check - to participate could be premature.

Finally, the provisions pertaining to supplementary services provided via MyHealth@EU (art 13) and telemedicine (see above) could widen the digital gap between countries and exacerbate inequalities.

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HOPE, the European Hospital and Healthcare Federation, is a European non-profit organisation, created in 1966. HOPE represents national public and private hospitals associations and hospitals owners either federations of local and regional authorities or national health services. Today, HOPE is made up of 36 organisations coming from the 27 Member States of the European Union, as well as from the United Kingdom, Switzerland and Serbia as observer members. HOPE mission is to promote improvements in the health of citizens throughout Europe, high standard of hospital care and to foster efficiency with humanity in the organisation and operation of hospital and healthcare services.

[9] Joint EDPB-EDPS Opinion, p. 4