

Moving forward with the European health data space: the need to restore trust in European health systems

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The European institutions reached an agreement on the regulation of European Health Data Space (EHDS) on March 15th, 2024, after three months of intense negotiations that prolonged beyond the original deadline. Harmonizing the needs and priorities of all stakeholders takes time; yet, we critically argue that heated negotiations and fragmentation of the solutions unquestionably shake the cornerstone of the project: Trust.

In May 2022, the European Commission (EC) presented the EHDS as a framework that would revolutionize European health systems. This space was meant to upgrade the primary use of health data, providing citizens with immediate access to their electronic health records and enabling data sharing with health professionals cross-border. Moreover, the EHDS was set to create a robust legal framework for the secondary use of health data (i.e., the use of health records for research, innovation and policymaking). This promising proposal soon encountered its sticking point: Under a framework that aimed to “empower individuals to have control over their health data”,¹ what should be the most appropriate consent scheme? In December 2023 the European Parliament amended the original EC’s proposal to include the right to opt-out of the processing health data for secondary use, and stipulated that an opt-in mechanism should be put in place for particularly sensitive health data, including genetic information. Also in December 2023, the Council of the EU reached its position, introducing that members states (MS) should retain control over the decision to implement an opt-out mechanism. The aftermath? The provisional agreement states that MS will be able to allow patients to opt-out their health data being accessed (both for primary and secondary use) and to implement stricter procedures to access sensitive data.²

According to the EC “Trust is a fundamental enabler for the success of the European Health Data Space”.¹ Notably, differences in ethical values and interpretations of the law have already hindered data sharing across EU countries³ The negotiations should

have reassured citizens and all relevant stakeholders that the final regulation will warrant a robust and reliable system. Hence we wonder, have the conversations around consent mechanisms strengthened trust? We fear they have not.

Take the suggestion to include an opt-in mechanism for genetic data: If particular datasets need special layers of protection, are other types of less-sensitive data not fully secured in the system? And how do we effectively set a threshold to the sensitiveness of health information that stands for 448M people? Sensitiveness is often based on the level of constraint to fully deidentify health data,⁴ but as technology and precision medicine progress, more and more types of data will become laborious to anonymize (i.e., medical imaging),^{5,6} so the EHDS should be rightfully equipped to withstand the challenge. To others sensitiveness is closely linked to stigma and risk of discrimination or victimization,⁷ even in primary use. Therefore, an integrative and holistic solution is required, where additional measures tackle and mitigate the risks that accompany the implementation of such an ambitious and disruptive regulation.

On the opposite side of the spectrum, closer to the initial position of the EC, multiple stakeholders worry that consent mechanisms add extra layers of complexity that introduce massive biases in the data collected,⁸ inevitably defeating the purpose of the system. For them, an opt-out (for the secondary use of data exclusively) already represents a compromise⁹; having 28 different consent mechanisms is not acceptable neither manageable. In response, the provisional agreement considers a few exceptions to opt-outs: Purposes of public interest and situations of vital interest.²

While there are valid insights in all the positions that diverse stakeholders have taken over the last two years, one thing is clear: Fear-based communication hampers trust in healthcare services, both in their current form and in the promised new landscape. If patients hesitate to seek for medical advice due to lack of reassurance in data protection, the system fails. As formulated by Bak et al., trust bridges the privacy-solidarity debate⁹; and trust increases with clarity about who benefits from data access.¹⁰ Transparency, security and equity should be at the bases of the design of the EHDS and at the core of the current conversations. Empowering citizens goes beyond enabling consent, it implies guaranteeing sufficient levels



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of digital health literacy and facilitating equitable access to healthcare and innovative treatments. The burden of responsibility should not be simply transferred from the institutions to patients. Neither should it fall on healthcare professionals. Adequate funding provisions are crucial to avoid fragmentation and warrant workability and transparency across all MS.

Contributors

JdFL and HTH worked together on the conceptualisation of the comment. JdFL took care of writing the original draft, and both JdFL and HTH contributed to reviewing and editing the manuscript.

Declaration of interests

The contributors have no conflict of interest to declare.

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