The European Health Data Space as a Case Study

Edward S. Dove

ABSTRACT In May 2022, the European Commission proposed the launch of a health-specific data sharing framework called the European Health Data Space (EHDS), underpinned by legislation, for the use of electronic health data by patients and for research, innovation, policy-making, patient safety, statistics, or regulatory purposes. In this essay, I review some of its more contentious features based on the latest version of the legislative proposal. I suggest that the EHDS is a useful case study to illustrate the need for a translational bioethics approach that shines a critical analytical light on contentious aspects of large-scale research infrastructures.

KEYWORDS translational bioethics, translational research ethics, translational science, health data sharing, electronic health data, health equity

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In his inaugural essay for this column, Rothstein observed that translational bioethics is a relatively new field of bioethical inquiry that analyzes not only the more traditional ethical issues in research, such as recruitment of research participants, risk-benefit analysis, and informed consent, but also "broadens the scope of inquiry to include 'downstream' societal implications of new scientific discoveries, thereby presenting an opportunity for innovative, collaborative efforts involving the social sciences, humanities, public health, law, and other disciplines"[1] to better address fundamental societal issues such as the effects of translational science on public health, health equity, and human flourishing. In their editorial, Parsons and colleagues attribute the concept to Cribb, who in 2010 argued that bioethics might also have a "bench to bedside" process leading to practice and impact.[2] Focus on implementation and practical influence seem to be the hallmarks of translational bioethics.

While Rothstein positioned translational bioethics as asking hard questions about research undertakings from the outset of the research—indicating that it might serve as a "critical friend" within individual projects that could yield one or more scientific discoveries (or innovations)—in this essay, I consider how translational bioethics can also help shine an analytical light on large-scale infrastructure projects that are designed to enable multiple discrete research undertakings (and downstream innovations) through *secondary uses* of electronic health data, which means using already-collected data for purposes unrelated to the initial collection. Secondary use of health data is of growing importance and value for researchers in the private and public sectors alike; governments recognize that enabling infrastructure to facilitate secondary use of health data can be a significant factor contributing to economic growth. But what are the ethical issues in this form of emerging translational research? I answer this through a case study looking at the proposed European Health Data Space (EHDS) and how it generates pertinent questions relating to (among other areas) health equity and human flourishing.

THE EUROPEAN HEALTH DATA SPACE

The European Commission (the executive arm of the European Union, or EU) proposed to launch the EHDS in May 2022 through a Regulation (legislation that would be of direct effect across the EU member states).[3] The EHDS is one of nine European "data spaces"[4] identified in the European Commission's 2020 European Strategy for Data, and the first to emerge from said Strategy,[5] aiming to harness the power of digitalization and to empower patients to better control and share their health data.

Using fit-for-purpose legislation and governance, the EU envisions that data can flow within the EU and across sectors through these "data spaces." They envision that European rules and values (e.g., personal data protection, consumer protection legislation, and competition law) will be fully respected; the rules for access to and use of data will be fair, practical, and clear, and there will be clear and trustworthy data governance mechanisms in place; and there can be an open but assertive approach to international data flows, based on European values.[6] The EHDS alone is estimated to lead to a €5.5 billion savings in the EU over ten years from better access and exchange of health data in health care, and a savings of €5.4 billion in the EU over ten years from better use of health data for research, innovation, and policy-making.[7]

HOW THE PROPOSED EHDS REGULATION WORKS

The proposed EHDS Regulation is a legal, governance, data quality, and operability framework that has two principal aims: (1) to enable patients to have immediate, free, and easy access to their data in electronic form and to share these data, in a common European exchange format, with health care professionals across EU member states (for primary uses, foremost for the provision of health care, but also for relevant social, administrative, or reimbursement services);[8] and (2) to facilitate access to and reuse of electronic health data to improve health care delivery, research, and policy-making across the EU. The EHDS aims to overcome limited data interoperability, fragmented rules for access to data for research, and barriers to individuals that prevent them from access to and control of their own health data, recognizing that increasingly commercial companies operate at a global level in the realm of health data. The EHDS will do this by providing rules, common standards and practices, infrastructures, and a governance framework for both primary use and secondary use of health data.

As of the writing of this essay, the final text of the EHDS Regulation has not yet been adopted. However, in April 2024, the European Parliament and the Council reached a political agreement on the European Commission's proposal for the EHDS. What can be gleaned from this latest version of the legislation[9] is that the primary goal of the EHDS is to create a genuine single market for health data. It does not aim to regulate how health care is provided by EU member states, which is beyond the EU's area of legislative competence.

As one of the recitals of the proposed EHDS Regulation states, "electronic health data already exists and is being collected by healthcare providers, professional associations, public institutions, regulators, researchers, insurers etc. in the course of their activities. These data should also be made available for secondary use. However, much of the existing health-related data is not made available for purposes other than that for which they were collected. This limits the ability of researchers, innovators, policy-makers, regulators and doctors to use those data for different purposes, including research, innovation, policy-making, regulatory purposes, patient safety or personalised medicine. In order to fully unleash the benefits of the secondary use of electronic health data, all health data holders should contribute to this effort in making different categories of electronic health data they are holding available for secondary use provided that such effort is always made through effective and secured processes, with due respect for professional duties, such as confidentiality duties. In justified cases, such as in the case of a complex and burdensome request, the health data access body may extend the time period for health data holders to make the requested electronic health data available to the health data access body."[10]

In an EHDS question and answer web page, the European Commission provides an example of how secondary use could function: "A health tech company is developing a new AI-based medical decision support tool that assists doctors to make diagnostic and treatment decisions following a review of the patient's laboratory images. The AI compares the patient's im-

ages with those of many previous patients. Through the EHDS, the company is able to efficiently and securely access a large number of medical images to train the AI algorithm, which in turn optimises its accuracy and effectiveness, before seeking market approval."[11]

To make this happen, EU member states are expected to designate or create national contact points for secondary use of electronic health data, called Health Data Access Bodies (HDABs). National contact points of non-EU countries and systems established at an international level could also become authorized participants in the EHDS, provided that they are compliant with the requirements in the proposed EHDS Regulation.

Any natural or legal person (called a "health data user") can apply for access to their electronic health data (which is defined broadly to cover both personal and nonpersonal electronic health data, and likely will comprise data that has been collected in the context of clinical care or research) from a "health data holder" (defined as "any natural or legal person, which is an entity or a body in the health or care sector, or performing research in relation to these sectors"), on the basis of an access application (the details of which are set out under Article 45[12]).

Under Article 34 of the proposed Regulation, the EHDS intends to facilitate secondary use of health data for several purposes, including public health, education, and research. The EHDS proposes a *legal obligation* on electronic "health data holders" to share such data for secondary purposes if certain conditions are met; indeed, their failure to adhere to this legal obligation may lead them to being fined (Article 43). Access will be granted only if the requested data is used for specific purposes, in closed, secure environments, and without revealing the identity of individuals. Under Article 44, HDABs must provide electronic health data in an anonymized format where the purpose of processing by a health data user can be achieved with such data. Where the purpose of processing cannot be achieved with anonymized data, HDABs must provide access to electronic health data in pseudonymized format (the keycode remains with the HDAB).[13]

While the EHDS will be coregulated by other national and European legislation, such as the General Data Protection Regulation (GDPR),[14] the Data Governance Act,[15] and the Data Act,[16] it remains to be seen what final form the EHDS Regulation itself will take. But already a fair number of ethical concerns have been raised about the infrastructure.

THE EHDS: ENABLING ETHICAL TRANSLATIONAL RESEARCH?

Few would discount the ostensible benefits that could arise from enhanced health data sharing, including through more effective and efficient secondary use of health data. Siloed or unused data hinders medical treatment, public health protection, and scientific innovation. Translational research, in other words, would be stymied. But greater access to and distribution of health data is not an unalloyed good. Taking a cue from Rothstein, who recommends that "[t]ranslational bioethics should not merely operate at the margins or tinker with small issues," but should also "address big issues, including critiquing promising research initiatives,"[17] let us consider a couple of the big unanswered questions regarding the secondary use proposal within the EHDS.

Ultimately, the translational research that can accrue from a vast, groundbreaking infrastructure like the EHDS will only be as successful as the translational bioethics analysis complementing it to help identify and address these core ethical issues.

First, despite the rhetoric of giving citizens more "control" of "their" health data, the EHDS's mechanisms may in fact erode individual control in favor of broader secondary use for different purposes. As Staunton and colleagues have pointed out,[18] the EHDS, as with any large-scale infrastructure designed to enable enhanced data sharing and not operating on the basis of an opt-in consent regime, ought to operate within an environment where a "social license" has been granted by the

public, providing assurance of compliance with applicable laws as well as uses that are in accordance with the reasonable expectations of society.

Yet, to date, the proposed draft text appears more laser-focused on compliance with data protection legislation such as the GDPR than recognition of and respect for broader, vaguer, but arguably more socially penetrant rights and interests. This includes one's right to autonomous decision-making, namely decisions on what will be done with one's own data, and protection against discrimination and stigmatization that can occur on both individual and group levels. For a rather vast piece of legislation, the ethico-legal tool of consent features surprisingly rarely in the text.

These omissions raise questions about the extent to which the EHDS fully respects the autonomous decision-making of individuals. Unlike the initial version proposed in May 2022, the latest version of the EHDS Regulation includes an "opt-out" provision (Article 48a) for those individuals who do not wish to have their data shared in certain contexts. But two points are worth observing here. First, the opt-out may be overridden for certain important public interests and under strict safeguards, including transparency requirements.[19] Second, any ethical opt-out regime (be it for organ donation or secondary data use) requires a robust information campaign by the government to enable individuals to make reasoned, autonomous decisions concerning whether they agree to any proposed uses of their electronic health data; those decisions should be entirely up to them, no matter how irrational or inconsistent they may be. But to make an informed decision does require access to information. It is unclear the extent to which Europeans will be well-versed in the EHDS and the HDABs to know that they can opt out—and the basis and means for so doing—and this uncertainty can lead to inequitable stratification along educational and socio-economic lines, not to mention disharmonized approaches across the EU member states.[20] As Marelli and colleagues note, given "what we know from studies of public opinions about health data reuse, the aim of stimulating the European economy by granting free access to citizens' health data can backfire and have detrimental effects on public trust in and support for medical research."[21]

Second, there are questions regarding the strength of privacy, security, antidiscrimination, and antistigmatization protections of health data and the potential for commercial companies to misuse health data. The proposed EHDS Regulation intends to prohibit the use of health data for commercial advertising, creating harmful products, or raising insurance premiums (Article 35), and prohibit re-identification of individuals in the electronic health data provided (Articles 41a and 43a), but commentary on the robustness and fairness of the EHDS, its relationship with existing privacy and data protection laws, and demonstration to the public of trustworthiness, suggests, as of now, a mixed projection of success.[22] As Staunton and colleagues caution, "Even if data [provided by HDABs to health data users] is anonymized, the data can be misused, used beyond what an individual consented to or reasonably expected the data to be used for, and lead to group discrimination and stigmatization."[23] Data protection law does not resolve this and the EHDS Regulation contains little text on how HDABs in their assessment of access applications are to navigate these complex ethical issues, other than leaving it up to individual EU member states to consider ethical assessments and make reference to "ethical provisions pursuant to national law" rather than broader (nonlegal) ethical norms.[24] This can lead to potential deadlock with conflict between national ethical rules and the EHDS, in turn leading to underutilization of data and diminished public trust.

Finally, there are open questions about the downstream benefits of the EHDS. While enabling more efficient and effective secondary use of electronic health data—potentially involving every European—is something many would support, many would also likely have questions about how they are to benefit individually, collectively, and equitably from this massive data sharing initiative. HDABs and the European legislators cannot prescribe in detail how benefits from secondary use ought to accrue to the people who have made available their data in the first place, but the absence of consideration of this downstream effect in the text leaves something to be desired. As Marelli and colleagues note, "As it stands, the Proposal does not sufficiently ensure that any profits, services or intellectual property generated through non-public institutions by access to the EHDS are translated back to EU citizens."[25] The gover-

nance model espoused in the EHDS Regulation, and as reflected in the form and function of the HDABs, suggests some stakeholder involvement,[26] and the Regulation does envisage a "stakeholder forum," composed of representatives of patients, consumers, health professionals, industry, scientific researchers, and academia, being set up to advise the EHDS board in the fulfillment of its tasks by providing stakeholder input on matters pertaining to the Regulation.[27] But this is distinct from active public engagement and deliberative exercises that feed into the design of the EHDS itself (e.g., what the public's reasonable expectations are with respect to data uses) and the measures adopted to create access to and distribution of people's electronic health data, with due consideration for how benefits (in various modalities) can be returned to Europeans in ways that are equitable and ethical. The level of public engagement has been very limited to date,[28] and there is no indication that it will improve over the remaining duration of the legislative process.

Relatedly, the EHDS may exacerbate already existent digital divides in Europe, reinforcing inequitable discrepancies in digital access across member states. Those who may be more vulnerable, such as older people, those from disadvantaged socio-economic backgrounds, those with chronic conditions, and ethnic minority communities may face more challenges to obtaining the digital literacy or resources needed to fully partake in, and benefit from, the EHDS. As Marelli and colleagues put it, "this would lead to the unfortunate outcome of excluding those who could benefit most from the envisaged benefits of the EHDS."[29]

WHAT TRANSLATIONAL BIOETHICS CAN OFFER

The concerns mentioned above are not intended as a critique of the EHDS per se as a proposed endeavor, but rather as a call for continuing, and indeed much deeper, engagement by the legislative body with the bioethics community to provide input on some of the more controversial elements. They should encourage a much wider public engagement and dialogue, in particular with traditionally overlooked communities, to listen and learn what their expectations are with secondary uses of their electronic health data, and to query whether a social license for the EHDS is feasible. If public engagement and dialogue indicates skepticism, uncertainty, and confusion, it may be necessary to pause the proposal and consider alternatives, or maintain the status quo framework across the EU.

Ultimately, the translational research that can accrue from a vast, groundbreaking infrastructure like the EHDS will only be as successful as the translational bioethics analysis complementing it to help identify and address these core ethical issues. Similar to large-scale projects launched in the United States, such as the All of Us Research Program,[30] which aims to enroll over one million participants to contribute their health data over a number of years, but which has experienced aspects of controversy,[31] ethics expertise can be especially beneficial when applied to practical projects, both before and during the translational stages of those projects. Ideally, this should be done in as much of the upstream stage as possible to maximize influence by urging critical reflection and practical intervention on legislative choices made in the EHDS (or another piece of legislation for a health-related infrastructure) that can feed into redesign and in changes in practice. In the U.S. and in Europe (and around the globe), then, translational bioethics has a crucial role to play in influencing health policy and practice. While the "translational" aspect suggests that the most decisive role is at the penultimate stage of the research pipeline, on how to translate findings from bioethics research into real-world practice, I would also highlight that practically focused bioethics work matters just as much at the earlier design stage, as this can strongly influence what practical outputs are delivered.

The EHDS is a worthy case study to demonstrate the value of translational bioethics at the upstream design stage (and subsequent downstream stages). The EHDS is, in my view, a worthy endeavor that, with the right ethical design, could generate significant benefit for Europeans; time will tell, though, whether the final text of the Regulation will address these big issues and garner the necessary social license and public trust for its fruitful implementation—and whether translational bioethics can help steer the EHDS toward ethically desirable outcomes. ♦

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7. European Commission, "European Health Data Space," factsheet, May 2024, https://ec.europa.eu/commission/presscorner/detail/en/FS_24_1347.

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9. See European Parliament, Legislative Observatory, "2022/0140(COD): European Health Data Space." All provisions cited in this article pertain to the consolidated text version from April 24, 2024, https://www.europarl.europa.eu/doceo/document/TA-9-2024-0331_EN.html.

10. Ibid., recital 38 (as proposed).

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12. European Parliament, Legislative Observatory, "2022/0140(COD)."

13. As recital 37b of the EHDS Regulation (as proposed) notes, the secondary use of electronic health data is based on pseudonymized or anonymized data in order to preclude the identification of individuals.

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20. Ibid., Article 37a(2), EHDS Regulation (as proposed), states: "If a Member State has provided for the right to opt out pursuant to Article 48a to be exercised at [HDABs], the relevant [HDABs] shall provide public information about the procedure to opt out and facilitate the exercise of this right."

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23. Staunton, C., et al., "Ethical and Social Reflections on the Proposed European Health Data Space," 500.

24. European Parliament, Legislative Observatory, "2022/0140(COD)," Article 35(eb) of EHDS Regulation (as proposed) prohibits secondary use of electronic health data where they involve "activities in conflict with ethical provisions pursuant to national law."

25. Marelli et al., "The European Health Data Space."

26. European Parliament, Legislative Observatory, "2022/0140(COD)," see Articles 10(5a), 36(3), 37(2)(c), 39(1)(g), EHDS Regulation (as proposed).

27. Ibid., Article 64a, EHDS Regulation (as proposed).

28. The European Commission ran a brief public consultation on the EHDS from May 3 until July 26, 2021; there was a total of 385 valid feedback instances received, of which only 99 were EU citizens and seven were non-EU citizens. The rest comprised bodies or organizations, such as NGOs, trade unions, public authorities, research institutions, and companies. See "Digital Health Data and Services—the European Health Data Space," European Commission, https://ec.europa.eu/info/law/better-regulation/have-your-say/

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