

privilege can advance the rights of migrant communities. The current toll of the COVID-19 pandemic on racialised migrants represents an urgent call for action to prioritise dismantling structural racism within and beyond the health-care sector.

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Value from health data: European opportunity to catalyse progress in digital health

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Innovations in digital health are expected to transform health care, health research, and public health in the years ahead. WHO's digital health strategy emphasises the potential for digital health to transform global health and improve the health of all people.¹ During the COVID-19 pandemic expectations for data and artificial intelligence (AI) have been high, with applications in epidemic modelling, diagnostics, triage and patient outcomes, vaccine and drug development, detection of misinformation, and identification of regions of greatest

need.² In the laboratory, open sharing of viral genomes has led to rapid development of diagnostics; in the community, countries have introduced digital contact tracing systems and QR code scanning of travel histories, helping to facilitate effective public health surveillance.³ Yet there are still challenges to overcome before the widespread benefits from data, AI, and digital health can be realised.^{4,5} Three of these challenges are crucially important.

First, technical and governance standards must be harmonised. Despite increased use of electronic health records (EHRs), gaps remain in the ability of computer systems and software to exchange and use information, defined as interoperability. Data are collected in ways not universally recognised, with conceptually different values recorded under the same term. Although there has been steady progress towards the development of universal standards, adoption of these standards by health-care systems lags behind.⁶ Similarly, inconsistent regulatory and governance approaches hinder progress, because legal requirements differ across data types, purpose of use, and jurisdictions. In 2018, the EU introduced the General Data Protection Regulation (GDPR), but the regulatory landscape for health data processing is not cohesive. Health data governance should ensure the ethical use of data and development of trustworthy digital



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health applications, yet it has received comparably little attention.

Second, there is insufficient clarity over what constitutes evidence of impact and demonstrable benefit for the many digital tools with a patient interface and which entities have authority to assess the evidence.⁷ Experimental AI studies provide inadequate insight into the challenges and impact of heterogeneous real-world care settings. There is, therefore, a need for innovative health technology assessment methods to be adopted in a systematic way.

Third, in the complex ecosystem of digital health, stakeholders are driven by diverging incentives.⁸ Patients, regulators, pharmaceutical and other commercial companies, health-care providers, researchers, policy makers, and investors have different targets, while often using the same health datasets—eg, EHR or research data. Commercial goals, competition, and attribution all contribute to a splintered digital health landscape, slowing progress in data use.

Political will and decisive action are needed to increase health data access and usability.⁹ In November, 2020, at the virtual High-Level Conference Digital Health 2020—EU on the Move, organised by the German Government, the European Commission declared its commitment to the establishment of the European Health Data Space (EHDS), with the aim of facilitating access and use of European health data—eg, EHR, genomic, public health, registry data.⁹ This initiative's overall goal is to generate value for European health-care systems, policy, health research, and innovation.

A decisive factor for moving digital health forward is governance. Along with a strong legal foundation in the GDPR, the EHDS will require effective governance and ethical oversight.¹⁰ With this initiative, Europe has the opportunity to recall its fundamental values¹¹ and set an example of a data governance approach grounded in human rights that promotes dignity, fairness, transparency, inclusion, and accountability. Conditions for data access and use must be clearly articulated, as should conditions for distribution of benefits, with patients and citizens included in negotiations. Both upstream and downstream conditions must be guided by the demands of health equity. Accountability should not be mechanical checks in an opaque digital ecosystem, rather an opportunity for all stakeholders to embrace responsibility and exercise good judgment. The legal protections afforded to privacy are not intended to be

antithetical to the common good of public health, despite how it is often portrayed. The legal basis of public interest for secondary uses of data is an ethically defensible option when robust oversight of data initiatives is in place and transparency is guaranteed. Good governance can strike the right balance between individual protections and promotion of the common good of health.¹²

For international data initiatives such as the EHDS to be trustworthy, they must be infused with our shared values. Failure to achieve this will perpetuate underuse and misuse of health data, and poor-performing digital health tools, ultimately depriving us of much needed health benefits and causing harms. The COVID-19 pandemic has seen some actors present binary conceptions of our challenges: privacy versus health, health versus the economy, or we versus they. These binaries lock societies into narrow options. The same binaries could propel our choices in digital health down a similarly narrow path. The EHDS should avoid this path by clearly defining the best practices for fair benefit sharing, transparent and accountable governance of public and private sector data, true commitment to public dialogue, and global cooperation.

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