Review Article

DIGITAL HEALTH

DIGITAL HEALTH
Volume 10: 1–11

DOI: 10.1177/20552076241277705
journals.sagepub.com/home/dhj

Sage

Socio-ethical challenges and opportunities for advancing diversity, equity, and inclusion in digital medicine

Ivana Paccoud[1,2], Anja K. Leist[3], Isabel Schwaninger[1,2], Robin van Kessel[4,5,6,7] and Jochen Klucken[1,2,8]

Abstract

Digitalization in medicine offers a significant opportunity to transform healthcare systems by providing novel digital tools and services to guide personalized prevention, prediction, diagnosis, treatment and disease management. This transformation raises a number of novel socio-ethical considerations for individuals and society as a whole, which need to be appropriately addressed to ensure that digital medical devices (DMDs) are widely adopted and benefit all patients as well as healthcare service providers. In this narrative review, based on a broad literature search in PubMed, Web of Science, Google Scholar, we outline five core socio-ethical considerations in digital medicine that intersect with the notions of equity and digital inclusion: (i) access, use and engagement with DMDs, (ii) inclusiveness in DMD clinical trials, (iii) algorithm fairness, (iv) surveillance and datafication, and (v) data privacy and trust. By integrating literature from multidisciplinary fields, including social, medical, and computer sciences, we shed light on challenges and opportunities related to the development and adoption of DMDs. We begin with an overview of the different types of DMDs, followed by in-depth discussions of five socio-ethical implications associated with their deployment. Concluding our review, we provide evidence-based multilevel recommendations aimed at fostering a more inclusive digital landscape to ensure that the development and integration of DMDs in healthcare mitigate rather than cause, maintain or exacerbate health inequities.

Keywords

Socio-ethical considerations, digital health equity, digital determinants of health, diversity, equity and digital inclusion, AI fairness, datafication, privacy and trust

Submission date: 27 January 2024; Acceptance date: 8 August 2024

Introduction

Emerging patient-centered technologies in the growing field of digital medicine and health come with the promise to improve patient health outcomes and healthcare delivery by supporting personalized healthcare.[1] Digital Medical Devices (DMDs) and related health technologies, including sensors, wearables, apps, personal health records, and management platforms, have the capacity to inform, manage, diagnose, monitor, or offer treatment throughout the healthcare journey. Their use and adoption is of particular importance due to the complex healthcare interventions required for the growing number of individuals living with chronic conditions, who might be more dependent on these technologies.[2] In the wider literature, DMDs have been described as digital tools or health technologies that are undergoing clinical validation and are

[1]Digital Medicine Group, Department of Population Health, Luxembourg Institute of Health (LIH), Strassen, Luxembourg
[2]Digital Medicine, Luxembourg Centre for Systems Biomedicine (LCSB), University of Luxembourg, Esch-sur-Alzette, Luxembourg
[3]Department of Social Sciences, Institute for Research on Socio-Economic Inequality (IRSEI)), University of Luxembourg, Esch-sur-Alzette, Luxembourg
[4]LSE Health, Department of Health Policy, London School of Economics and Political Science, London, UK
[5]Mental Health Policy and Economics Group, Department of Psychiatry, University of Cambridge, Cambridge, UK
[6]Department of International Health, Care and Public Health Research Institute (CAPHRI), Maastricht University, Maastricht, Netherlands
[7]Digital Public Health Task Force, Association of Schools of Public Health in the European Region (ASPHER), Brussels, Belgium
[8]Centre Hospitalier de Luxembourg (CHL), Luxembourg, Luxembourg

Corresponding author:
Ivana Paccoud, Digital Medicine Group, Luxembourg Center for System Biomedicine, Boulevard du Jazz, L- 4370 Belvaux, Luxembourg.
Email: ivana.paccoud@uni.lu

incorporated into the healthcare ecosystem in order to inform prevention, diagnosis, and provide treatment and management of health conditions.[3] Thus, through a data-driven approach, DMDs can support the clinical decisions of healthcare professionals and can encourage and support positive health behaviors, and thus improve health and care outcomes for all members of society, including those within underserved communities.

DMDs can broadly be classified into three main categories[4]:

(i) Those designed to provide more efficiently managed healthcare services—such as electronic prescribing or triaging systems;
(ii) those that support people in the self-management of their health and wellness—such as communication channels between patients and healthcare professionals, health-promoting information or advice on self-management, electronic diaries, etc.;
(iii) those used to diagnose, monitor, and treat health conditions, as well as to inform about disease context and care options—this for example includes digital therapeutics directly treating a distinct aspect of the disease, or digital diagnostics used to support clinical decision-making.

DMDs are designed with the primary goal of enhancing the quality of patient care by enabling remote monitoring, facilitating early diagnosis and access to healthcare services, and actively engaging and empowering both patients and healthcare professionals.[5,6] However, the mode of action of DMDs raises unique societal challenges that differ from those associated with traditional pharmacological interventions.[7] As healthcare systems increasingly incorporate their use, there are growing social and ethical concerns regarding the potential risks and consequences of introducing them into society. In digital medicine, socio-ethical challenges are primarily addressed within the interdisciplinary frameworks of ELSI (Ethical, Legal, and Social Implications) and Responsible Innovation.[8,9] These approaches ensure that technological advancements are developed and implemented in ways that maximize benefits while minimizing negative consequences for individuals, particularly respecting their autonomy, privacy, and trust. By emphasizing fairness, these frameworks aim to guarantee that DMDs benefit all segments of society without exacerbating health inequities—that is, unfair and avoidable differences in health across the population and between different groups.[10] While a substantial body of literature addresses various social and ethical aspects of digital medicine, these discussions often remain confined within the silos of individual disciplines. In this narrative review, we take a multidisciplinary approach and delve into comprehensive discussions on five core socio-ethical considerations associated with the digital determinants of health: (i) equity in access, use and engagement with DMDs, (ii) inclusiveness in DMD clinical trials, (iii) algorithm fairness, (iv) surveillance and datafication, and (v) data privacy and trust. Concluding this review, we present evidence-based recommendations across multiple levels of governance that encompass the individual, organizational, and national levels, that aim to drive policy action towards addressing equity and inclusion in digital medicine.

Methods

This review draws on narrative review method, that is best suited to provide a comprehensive overview of a complex and interdisciplinary topic and to provoke further reflection on a broader subject of interest[11,12] Moreover, narrative reviews provide a valuable knowledge base used to inform policy and practice.[11] For this review, we carried out a literature search in leading academic databases: PubMed, Google Scholar, and Web of Science up to November 2023 by using phrases and keywords combining "digital" "ethical," "socio-ethical," "health," "medicine" "technologies," "medical devices," "equity," "inclusion," "diversity," "inequalities" "inequity," "divide." We searched for empirical and case studies, theoretical articles, reviews and commentaries from experts, and grey literature with full text in the English language. Following a thorough review of the articles, we synthesized five key topics of policy relevance that are identified and summarized in this review.

Equity in access, use and engagement with digital medical devices

The inequities in the adoption of DMDs documented among social groups reflect those that exist in terms of health outcomes and quality of healthcare received. In all cases, poorer outcomes are found among the most socially disadvantaged communities.[10,13] Therefore, one of the most critical prerequisites before DMDs can have a positive impact on people's lives is that they are accepted and used by all members of society.[1,14] However, a large body of evidence has documented inequities in the access to, use of and engagement with DMDs between social groups and even between countries and regions.[14–17] Different aspects underlying the social and digital determinants of health, among which age, gender, ethnicity, socioeconomic status, cultural and linguistic background, place of residence, disease severity and digital literacy, as well as reimbursement policies, can influence the way in which DMDs are used.[1,8,13,18–20] Studies in the United States (US), United Kingdom (UK) and mainland Europe have repeatedly shown that video telehealth visits and mobile health applications were more frequently downloaded and used by those who were younger and had

higher incomes and educational levels.[18–20] This pattern is also mirrored in the use of personal health records: those with socially advantaged backgrounds tend to have higher levels of access and engagement.[21–23] In an ever-evolving digital landscape, the digital divide paradigm has shifted. Initially, its primary concern of the digital divide was access to information and communication technology (ICT) and internet penetration. The focus then moved to digital skills and effective engagement with digital technologies.[24] Indeed, in more economically developed countries in which the majority of the population owns a smartphone and has access to the internet,[25] the primary concern regarding access to DMDs often revolves around engagement and adherence. Merely having access to devices and the internet does not guarantee their meaningful use and engagement.[1,23,26] Users often find that DMDs are designed for a very particular target group—those who are able-bodied, digitally and health literate, and motivated and that they often require time-consuming and complex data entry processes.[6] For example, DMD users with chronic conditions have highlighted the psychological burden of constant reminders of their poor health, mistrust, as well as a lack of time and skills needed to navigate novel digital tools, thus pointing towards the manifestation of the digital health paradox that asserts that population groups that can most benefit from DMDs are also the ones most likely to be excluded from them.[17,27]

While it has been well noted that early adopters of digital innovations are in general those with higher economic, educational and social capital,[1,27,28] the pattern can also be seen in terms of adherence to the use of the technology, with lower engagement and higher drop off rates among those with lower income and educational levels.[20] Some of the mechanisms behind these patterns might be higher awareness, digital capabilities as well as supportive social networks, and financial affluence which enable health maintaining strategies and self-efficacy among the most advantaged.[1,29–31]

When engaging with the issue of inequities in the access to, use of and engagement with DMDs, it is vital to not only consider socioeconomic, gender, or ethnic inequities in isolation, but also to explore how inequities are mutually reinforcing or intersecting between gender and socioeconomic position,[32] as well as how they may intersect with broader social and cultural norms.[33] If these challenges are not addressed, widespread adoption of DMDs may thus exacerbate health inequities, a phenomenon known as "intervention-generated inequality."[34] It would also be a lost opportunity since socially disadvantaged individuals stand to benefit the most from these interventions.[17,29,35] Therefore, careful consideration of the needs of socially disadvantaged populations is required. On one hand, the design of the DMDs needs to be guided by people-centered approaches, such as through participatory and user-centered design, to reflect the everyday experiences of a diverse range of users.[36] On the other hand, the development and personalization of health interventions addressing health inequities need to take into account the needs of socially disadvantaged members of society.[1,17] Building on the capability approach,[1] if conversion factors such as socioeconomic status, digital skills or disease severity are taken into account, DMDs can have the potential to provide choices and opportunities to increase people's capabilities to function and attain a good state of health and well-being.[37] They can be leveraged to reach underserved communities by providing them with personalized and culturally appropriate information, treatment and care. This could enable improvements in health literacy and skills essential for disease management and the maintenance of good health as well as facilitate access to healthcare services especially for those living in rural areas. All of this will ultimately contribute towards creating a more inclusive and equitable healthcare environment.[1,37]

Diversity and inclusion in clinical trials in digital medicine research

Clinical trials are considered to provide the most robust evidence on the safety, effectiveness, and efficiency of (digital) health interventions. The results of these studies therefore need to be applicable and generalizable to an increasingly diverse population. However, multiple studies have now shown that racial and ethnic communities, individuals from lower socioeconomic backgrounds, undocumented migrants as well as older people have been underrepresented, misrepresented or made entirely invisible in clinical trials, health datasets, and research studies in general,[38,39] which has recently been described as "health data poverty."[40] This may be among the reasons that developments in research have not always translated into more effective treatment options for these groups.[41] As an example, the COVID-19 pandemic exposed critical flaws related to the lack of diversity in clinical trials, and diagnostic instruments being adapted to characteristics of predominantly white samples, such as Pulse Oximetry readings which led to a higher misclassification of patient oxygenation status in less represented social groups, and consequently higher rates of forgone COVID treatment for these minorities in clinical practice.[42,43]

Some of the potential mechanisms that underpin the underrepresentation of disadvantaged population groups in clinical trials and other healthcare and population health research initiatives are thought to be the lack of awareness of research initiatives by disadvantaged communities, limited opportunities for participation, logistical reasons (e.g. cost, transportation, device and internet availability, or time commitment), as well as higher levels of mistrust in science, medical professionals and the health system as a whole.[33,44] Another related issue that could

lead to an important selection bias is retention in digital health studies. Studies in the digital medicine field have shown higher attrition rates in clinical trials on the effectiveness of digital technologies among socially disadvantaged communities.[45] While both digital and non-digital trials face challenges with attrition among socially disadvantaged communities, digital trials may have additional unique barriers related to digital literacy, technology access, and cultural relevance. This shows that targeted recruitment of more disadvantaged individuals into these studies needs to be accompanied by support for the most vulnerable to continue study participation. Such support might include reminders, feedback based on collected data, and clear instructions and techical support on how to use DMDs. It is within the researcher's responsibility to design studies that ensure diversity and recruit participants from varied backgrounds, thereby reflecting the demographic diversity of the population affected by the disease. It is crucial to transparently report data on effectiveness of digital health intervention by the socioeconomic status, age, race, ethnicity, and gender of trial participants to identify and address gaps in study representation and the generalizability of findings. Additionally, researchers must engage in raising awareness about the importance of research participation and provide necessary logistical support to facilitate the involvement of diverse populations. However, we must also consider the mutually reinforcing effects between the different factors. Figure 1 shows a hypothetical directed acyclic graph (DAG) developed by authors based on the included literature that highlights how participation and attrition in clinical trials of DMDs can be influenced by the abovementioned factors.

The use of real-world evidence from routine healthcare procedures offers a great opportunity as it comes with fewer limitations compared to the challenges in the recruitment and retention of diverse populations in clinical trials.[46,47] Electronic health records, claims data, or disease registers can gather valuable information from large and diverse populations, thus providing useful information on inequities in healthcare access and outcomes, quality of care or treatment effects for disadvantaged communities.[27] However, they also come with limitations in terms of data quality and by definition exclude populations who might not have access to personal health records, or fall in between the cracks of the healthcare system.[27] Thus, bridging the gap between science and health improvement requires a substantial effort to ensure the representation and engagement of diverse populations in clinical trials and research within the digital medicine field.

Fairness in artificial intelligence and machine learning

One of the biggest concerns in implementing DMDs is the socio-ethical implications of their application of artificial intelligence (AI) and machine learning (ML) methods and consequently, their potential to have a negative effect on underserved populations.[48] While advancements in AI can offer vast opportunities to support healthcare practices and to deliver personalized care at lower cost, particularly through increasing predictive accuracy to support patients care pathways, diagnostics, and treatment decisions,[49,50] recent studies have highlighted that AI and ML approaches can in fact introduce and reproduce inequities in the way patients are diagnosed, given treatment and billed for healthcare or even provided with welfare benefits.[51,52]

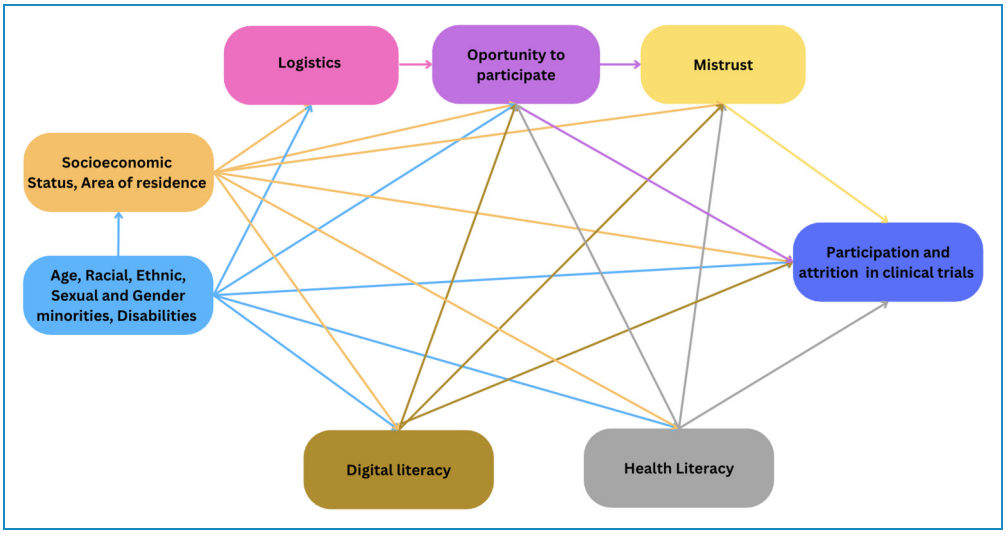

Figure 1. A hypothetical DAG that highlights the interconnectedness of factors influencing participation and attrition rates of socially disadvantaged communities in clinical trials of DMDs.

Algorithmic bias might emerge from data collection through incomplete or unrepresentative data. In some countries, such as France and Germany, data on racial and ethnic minorities is not recorded.[48] Likewise, bias might also arise from outcome definitions, labeling and deciding on threshold values.[48,53] For instance, scholars have argued that the oversimplification of racial categories as well as the fact that the sex and gender dimensions have been ignored in the design of algorithms, have contributed to poor results and discriminatory outcomes.[54,55] As an example, some studies find that women have a higher prevalence of depression than men, however, these results might be influenced by the validity of the measuring instruments, since the expression of depression and emotional vulnerability in men and women differs, partly due to the societal gender roles related to masculinity.[56] Another example emerges from one of the goals of AI, which is to identify patients at higher risk of disease. Predictive models require accurate labeling for patients with a particular disease, as well as for those without, and the establishment of cutoff points for category boundaries across different disease stages.[53] The question is then when, by whom, and how this labelling occurs. Considering the development of algorithms that are not solely developed from mathematical concepts but rather incorporate intersectional theories and knowledge on the determinants of health is of paramount importance.

On the other hand, AI bias might arise during model development such as through inaccurate assumptions about the causal relationships between different parameters included in the model.[48] As observed differences in health outcomes based on race, gender or sex are strongly intertwined with historical, socio-cultural and institutional contexts, with healthcare settings frequently adding to racialized experiences and discrimination,[57] biases related to confounding factors are becoming increasingly important. With the increasing deployment of algorithms, biases may prevent adequate diagnosis, treatment and care for already underserved populations and increase health inequities. A pragmatic approach would involve recognizing that only a few scenarios exist wherein the health disparity between majority and minority social groups significantly diminishes.[58] Instead, it would be more prudent to systematically examine stratified analyses to assess potential benefits for both majority and minority populations, deeming these benefits sufficient to justify the use of the new device.[59]

A large body of evidence has now reported gender and racial biases as a consequence of AI applications across a range of health conditions, such as cardiovascular diseases, cancer, as well as mental and maternal health.[60,61] For example, several healthcare algorithms used in clinical practice include a race category to arrive at treatment or referral decisions with possibly problematic outcomes for minority groups. As an example, one algorithm calculates a heart failure risk score in order to predict the risk of death for hospitalized patients. Because of a race-based adjustment algorithm, patients identified as "Black" were categorized as having a lower mortality risk, resulting in lower rates of referral to specialized care.[60] As race is a social rather than a biological construct, controlling for race might lead to an estimation bias resulting in unintended consequences, such as the under-treatment or over-treatment of racial minorities and perpetuating the discrimination of minorities.[60,62]

Despite the increase in the awareness of such biases in AI and ML, more work is needed to bring transparency to AI algorithms in order to make possible the effective scrutiny of the assumptions at the heart of the models.[63] For now, AI and ML models for health applications have largely been developed post-data collection.[50] Ethics and governance need to be addressed and reevaluated also after the deployment of the algorithms.[63–65] It is important to understand how personalized predictions and clinical decision support algorithms may vary for individuals of different groups, and to assess the extent to which these variations can be linked to validated research findings. Another way forward is to adapt the FAIR principles[2] of AI development and deployment in order to promote the transparency, reproducibility, and responsible use of AI technologies.[66] While AI and ML are increasingly employed in diagnostic prediction, monitoring, and healthcare decision-making, it is crucial to raise awareness among healthcare professionals and patients regarding the risks, consequences, and opportunities associated with AI in relation to equity. A recent article by Chen (2020) argues that if AI is used purposefully, it could identify and correct inequities, through the development of "fair risk prediction models" to account and adjust for the underrepresentation of socially disadvantaged groups in clinical trials.[67]

Addressing datafication and the continuous surveillance of health behaviors and outcomes

The growing availability and use of digital tools, such as wearables, and monitoring systems enable the collection of a wide range of data via GPS tracking, Bluetooth, cameras and voice recording. This provides a novel opportunity to gather, store, share, and analyze vast amounts of health data across an individual's lifespan. It allows for continuously collect valuable patient information on health behaviors such as diet, heart rate, movement or sleep patterns, which could benefit different healthcare actors such as healthcare professionals, patients and healthcare commissioners. Importantly, these tools offer the potential to reduce health disparities by providing underserved populations with greater access to healthcare services and by offering personalized interventions via AI-driven risk stratification.[68]

Data collected through digital tools and their metadata can provide quick and objective information about human

behaviors and interactions: where the individuals are located, with whom they are interacting, and for how long.[69] This gives rise to the risk of so-called patient "datafication"—a term coined by Cukier and Mayer-Schoenberger (2013) for the transformation of people's daily activities into quantified data flows captured through continuous surveillance and self-tracking.[70] This emphasis on self-monitoring and self-management through continuous surveillance, although beneficial in understanding health conditions and behaviors, can come with important socio-ethical concerns related to the concept of equity. Indeed, while these tools can provide patients with greater autonomy in the management of their condition, the emphasis on patient empowerment, lifestyle intervention and self-care through personal responsibility fails to recognize the broader digital, political, social and economic determinants of health.[71,72] Limited digital literacy or socioeconomic circumstances make it hard for individuals to adopt and comply with behavioral health interventions.[73] Moreover, many patients, particularly those from socially disadvantaged backgrounds, may struggle to understand the complex medical data generated by continuous monitoring.[74] This difficulty can exacerbate feelings of anxiety and stress and can negatively impact the ability of those with lower health literacy to make informed health choices. Datafication could also introduce a disciplining effect and even be used to restrict entitlement to healthcare resources for individuals in greater need. Indeed, scholars have highlighted the emerging trend in the USA of encouraging employees to engage in self-monitoring activities aimed at behavioral change such as exercising, keeping a healthy diet, or smoking cessation in return for financial gains or healthcare insurance discounts.[75–77]

In the healthcare context, the data available through the linkage of a wide range of DMDs could be used to stratify patients based on certain risk scores using data from medical or even non-medical contexts (patients' social connectedness, socioeconomic position, etc.). Using these risk scores, healthcare providers could then decide whether to offer further treatment or prevention programs. Hogle (2016), for instance, gives a real-world example of a health insurance company that uses a "drug adherence index" to identify noncompliant patients (or those at risk of noncompliance) based on the behavior within a given prescribed medicine protocol. Since a patient's socioeconomic circumstances is determinant of non-adherence to medication,[78] this could lead to the classification of certain patients with socially disadvantaged backgrounds as "higher cost," with potentially lasting implications for their healthcare trajectory and further exacerbation of health inequities. In a value-driven healthcare system, in which providers are rewarded based on improving patient health outcomes, there is an incentive to flag "problematic" patients.[76] This is explained by "surveillance capitalism" rooted in political economy in which data is commodified by private companies and big corporations and used to shape people's actions and behaviors, ultimately leading to profit.[79] That said, it is worth noting that all these risks depend on the way in which the information collected through continuous surveillance is used and regulated. Indeed, identifying the types of patients struggling with adherence could provide important information to healthcare professionals and serve, for example, to facilitate targeted additional health and social care services to help patients in need.

As outlined above, the datafication of health can present both opportunities and challenges. Further research is required to better comprehend how individuals from socially advantaged and disadvantaged backgrounds can equally benefit from the data collected through continuous surveillance. Data from the DMDs should be user-friendly, offering easy-to-read information to prevent information overload or misinterpretation. Risk-benefit analyses need to be complemented with research on individual attitudes and preferences for the treatment and usage of their health data from multiple sources. Additionally, using privacy-preserving techniques and well-built data infrastructures, researchers may be able to leverage health information contained within health data without the need to access personal data.[80] Data would continue to be stored in secure environments, thus ensuring their safety, while researchers are enabled to perform analyses using aggregate information.[81] Current efforts to develop so-called synthetic data, which mimics real-world health data without containing actual patient information, as well as reliance on federated data networks such as the European Health Data Space (EHDS) have a great potential to mitigate some of the risks related to datafication in the European context.[81] However, technical advancement related to health data needs to be followed by developing easy-to-read information on the risks and benefits of DMDs that are meaningful for patients and citizens and adapted to their language and health literacy proficiency levels. On an individual and societal level, it has been argued that people are often willing to accept risks if the benefits significantly outweigh the potential drawbacks.[82] These considerations must therefore be guided by clear benefits and policy decisions justified within a relevant ethical framework.

Addressing privacy and trust in digital medicine

Privacy, confidentiality and trust are fundamental values defined by the oath of Hippocrates and comprise an essential part of medical ethics and professional regulations. The issue of privacy due to the digitalization of medicine is complex and multi-faceted and entails respecting the individual's right to manage the collection, use, and sharing of their personal information.[83] It considers data stewardship, data protection, security and data transparency as well as

data governance. In the context of this review, the emphasis will be placed on the way in which privacy intersects with the notion of equity. This means engaging with the issue of how trustworthy DMDs are perceived by the users in terms of data privacy. Given that these devices generate vast amounts of personal health data, trust and privacy are both critical and closely intertwined concepts when it comes to assessing their socio-ethical considerations in digital medicine.

Trust in DMDs typically refers to the level of beliefs and confidence that individuals have in the technical aspects of data usage in terms of accuracy, reliability or data security, as well as the assurance that the system will provide benefits without causing harm.[83,84] While in the European context, the technical aspects of data privacy and data security are outlined in the General Data Protection Regulation (GDPR)—data encryptions, anonymisation and access control, when considering socio-ethical concerns of DMDs—trust can be established through such data privacy on a regulatory level (such as through GDPR), and it is intertwined with how data privacy is ultimately perceived by end users (trustworthiness of DMDs).[17,36] Trust plays a central role in the acceptance and use of these devices, and it also hinges on the issue of transparency.[36] Regarding equity, evidence indicates that people from lower socioeconomic groups, older demographic groups - a dominant user group in digital medicine, and ethnic minorities might be more vulnerable to security breaches due to the lack of linguistically and culturally appropriate information on cybersecurity, and also may have less trust in healthcare services and the security of their personal health information.[33,85] One key issue in relation to the establishment of trust in DMDs is the fact that these innovations fall under the general umbrella of medical devices, which may inadequately address the unique complexities brought forward by DMDs.[1,7] Without clear perceived health benefits, the assurance of transparency and robust privacy measures, some populations might be reluctant to engage with these health technologies. On the flip side, some populations might be hesitant to provide information about technologies developed by public institutions due to prior negative experiences with public healthcare providers or a lack of trust in public institutions in general. For example, it has been shown in the context of the USA that there is a higher likelihood of distrust in the healthcare system for African Americans than whites, as well as higher rates of reported racism and concerns about privacy arising from patient electronic health records.[33,86]

Another closely related issue affecting trust in DMDs concerns the extent to which the users are privacy literate and know how to effectively understand and protect the privacy of the digital information they allow these technologies to collect. Although distinct, digital literacy and privacy literacy go hand in hand and as such might disproportionally affect socially disadvantaged populations.[87,88] Those with higher digital privacy literacy in the context of a digital world can more successfully protect themselves from security threats and therefore be more confident when engaging with DMDs.[89] This can in turn empower and enable them to leverage their health data during health visits. Conversely, individuals with limited digital privacy literacy may be hesitant to engage with new health technologies potentially due to concerns of exposing their health information and therefore hinder the opportunity to actively engage in their health. Given that health information is a particularly sensitive issue, the development of innovative privacy-preserving data infrastructures and increasing awareness of their existence, particularly among socially disadvantaged individuals, is an essential requirement for addressing the issues of trust and privacy in digital medicine.

Multilevel recommendations to advance equity, diversity and inclusion

Depending on how DMDs are designed, deployed and integrated into the healthcare systems, they can exacerbate or potentially alleviate health inequities by reaching and serving underserved communities. To achieve the latter, we suggest a range of individual, organizational (e.g. academia, healthcare, industry) and national level recommendations, summarized in Figure 2, and further elaborated in Appendix 1.

Individual level

To ensure equitable access, use, and adherence to DMDs, efforts should be made to create an inclusive digital health ecosystem by providing internet access, and affordable equipment, complemented by financial, technical, and social support for those in need.To raise awareness about clinical trials through culturally appropriate outreach and incentives like transportation costs and childcare should be offered to research participants. Additionally, efforts should be made to identify and address algorithm bias in AI and to enhance literacy related to data privacy and security.

Organizational level

Organizations should adopt participatory design approaches in developing DMDs, focusing on the inclusion of diverse populations. They should continuously monitor disparities in DMD access and use and ensure that trials include and retain participants from diverse cultural and socioeconomic backgrounds, providing necessary instructions on the use of digital technologies and user-friendly feedback on the collected data. In addition, oversampling of underrepresented populations and transparency in data reporting should be rigorously implemented. Collaborations between AI researchers and social scientists should be fostered to ensure fairness and transparency in AI applications.

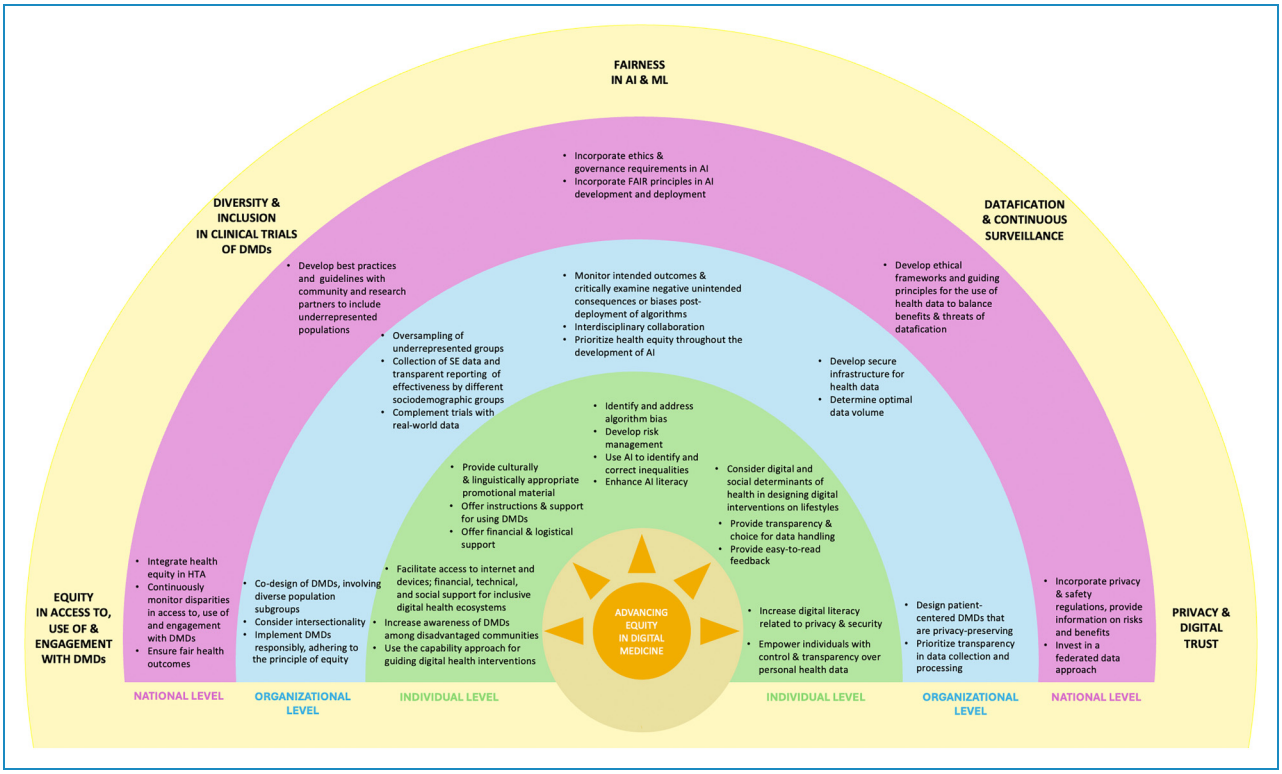

Figure 2. Multilevel recommendations for the advancement of equity across different socio-ethical challenges in digital medicine.

Organizations must implement security infrastructure to protect health data and design privacy-preserving DMDs by principle.

National level

National policies should integrate equity considerations in health technology assessments, promote sustainable digital health business models, and ensure continuous monitoring of DMD inequities in access to, use of, and engagement with DMDs as well as fair health outcomes associated with their use. Standards for including underrepresented populations in research should be developed, along with guidelines for addressing algorithm bias in AI. A clear ethical framework for health data use should be established, with investments in federated data approaches to enhance transparency and trust in digital health systems.

Limitations

While some critics of the narrative review argue that it might lead to the selective use of evidence to support a particular point, this is balanced by the fact that the selection of literature was guided by how pertinent the evidence was to important policy questions that aid decision-makers.[11] This process was aided by the multidisciplinary expertise of the authors (coming from social medicine, social psychology, medical and computer science as well as health policy), which allowed for the careful selection and review of key topics across a wide range of disciplines relevant to equity in digital medicine. Although we recognize the importance of country-specific contexts, most of the recommendations in this narrative review are not tailored to any single country but will apply to most countries within the Global North. Instead, they aim to provide researchers and policymakers with tools to analyze specific interventions within their unique contexts. Lastly, In this review, we focused our discussion on DMDs used in healthcare, acknowledging the slow yet growing trend of their integration into the healthcare systems.

Conclusion

Equity as a lens can shed light on a range of socio-ethical challenges and opportunities linked to the development and deployment of DMDs in the healthcare system and in the wider society. Although not exhaustive, the five socio-ethical considerations discussed in this article underscore the importance of a critical examination and reflection, prompting consideration of potential socio-ethical challenges that may emerge in the current trend of developing data-driven innovations. While digital medicine offers a promising new avenue to optimize healthcare outcomes through the development of robust evidenced-based

interventions—and thus improving clinical decision-making, addressing the socio-ethical implications of their use is essential to advance health equity.

Contributorship: I.P. and J.K. conceptualized the manuscript. I.P. drafted the manuscript. All authors (I.P., A.L., R.V.K., I.S., J.K.) contributed to the conception, critically reviewed the manuscript, and approved it.

Declaration of conflicting interests: The authors declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: J.K. declares an unpaid role in the European Taskforce for Harmonized Evaluation of Digital Medical Devices. A.L. has served on advisory boards with Roche (remunerated). None of the other authors report conflicts of interest.

Ethical approval: Not applicable.

Funding: The authors disclosed receipt of the following financial support for the research, authorship, and/or publication of this article: the Luxembourg National Research Fund: (dHealthPD: 14146272).

Guarantor: JK.

Informed consent: Informed consent was not required as no personal data were processed in this study.

ORCID iDs: Ivana Paccoud https://orcid.org/0000-0002-1526-8013

Supplemental material: Supplemental material for this article is available online.

Notes

1. The capability approach was developed in 1979 by Nobel laureate Amartya Sen and focuses on the freedom individuals have to achieve well-being, emphasizing what people are able to do (capabilities) and be (functionings) rather than focusing solely on economic wealth. In the health field, this approach underscores the importance of providing individuals with the resources and opportunities needed to attain good health, considering social, economic, and personal factors that influence their ability to lead healthy lives
2. The FAIR principles are a set of guidelines for making data Findable, Accessible, Interoperable, and Reusable. These principles advocate for the identification and rectification of bias throughout AI development stages, implementation of effective risk management strategies, leveraging AI to address inequties, and promoting awareness among healthcare professionals and the public about AI's role in healthcare.

References

1. van Kessel R, Roman-Urrestarazu A, Anderson M, et al. Mapping factors that affect the uptake of digital therapeutics within health systems: scoping review. *J Med Internet Res* 2023; 25: e48000.
2. Strong K, Mathers C, Leeder S, et al. Preventing chronic diseases: how many lives can we save? *Lancet* 2005; 366: 1578–1582.
3. Elenko E, Underwood L and Zohar D. Defining digital medicine. *Nat Biotechnol* 2015; 33: 456–461.
4. The NICE Evidence Standards Framework for digital health and care technologies—Developing and maintaining an innovative evidence framework with global impact—Harriet Unsworth, Bernice Dillon, Lucie Collinson, Helen Powell, Mark Salmon, Tosin Oladapo, Lynda Ayiku, Gary Shield, Joanne Holden, Neelam Patel, Mark Campbell, Felix Greaves, Indra Joshi, John Powell, Alexia Tonnel, https://journals.sagepub.com/doi/full/10.1177/20552076211018617 (2021).
5. Lyles CR, Wachter RM and Sarkar U. Focusing on digital health equity. *JAMA* 2021; 326: 1795.
6. Grundy Q. A review of the quality and impact of mobile health apps. *Annu Rev Public Health* 2022; 43: 117–134.
7. Fahy N, Williams GA, Habicht T, et al. *Use of digital health tools in Europe: before, during and after COVID-19*. (European Observatory on Health Systems and Policies, Copenhagen (Denmark), 2021).
8. Rudschies C and Schneider I. Ethical, legal, and social implications (ELSI) of virtual agents and virtual reality in healthcare. *Soc Sci Med* 2024; 340: 116483.
9. van den Hoven J. Value sensitive design and responsible innovation. In: *Responsible innovation*. John Wiley & Sons, Ltd, Hoboken, New Jersey, U.S, 2013, pp.75–83. doi:10.1002/9781118551424.ch4
10. Braveman P, Egerter S and Williams DR. The social determinants of health: coming of age. *Annu Rev Public Health* 2011; 32: 381–398.
11. Greenhalgh T, Thorne S and Malterud K. Time to challenge the spurious hierarchy of systematic over narrative reviews? *Eur J Clin Invest* 2018; 48: e12931.
12. Collins JA and Fauser BCJM. Balancing the strengths of systematic and narrative reviews. *Hum Reprod Update* 2005; 11: 103–104.
13. Marmot M. Social justice, epidemiology and health inequalities. *Eur J Epidemiol* 2017; 32: 537–546.
14. Honeyman M, Maguire D, Evans H, et al. *Digital technology and health inequalities: a scoping review*. 44, https://phw.nhs.wales/publications/publications1/digital-technology-and-health-inequalities-a-scoping-review/ (2020).
15. Palzes VA, Chi FW, Metz VE, et al. Overall and telehealth addiction treatment utilization by age, race, ethnicity, and socioeconomic status in California after COVID-19 policy changes. *JAMA Health Forum* 2023; 4: e231018.
16. Zhai Y, Carney JV and Hazler RJ. Policy effects of the expansion of telehealth under 1135 waivers on intentions to seek counseling services: difference-in-difference (DiD) analysis. *J Couns Dev* 2023; 101: 277–292.
17. van Kessel R, Hrzic R, O'Nuallain E, et al. Digital health paradox: international policy perspectives to address increased health inequalities for people living with disabilities. *J Med Internet Res* 2022; 24: e33819.
18. Adepoju OE, Chae M, Ojinnaka CO, et al. Utilization gaps during the COVID-19 pandemic: racial and ethnic disparities in telemedicine uptake in federally qualified health center clinics. *J Gen Intern Med* 2022; 37: 1191–1197.

19. Jaworski BK, Webb Hooper M, Aklin WM, et al. Advancing digital health equity: directions for behavioral and social science research. *Transl Behav Med* 2023; 13: 132–139.
20. Ernsting C, Dombrowski SU, Oedekoven M, et al. Using smartphones and health apps to change and manage health behaviors: a population-based survey. *J Med Internet Res* 2017; 19: e101.
21. Paccoud I, Baumann M, Le Bihan E, et al. Socioeconomic and behavioural factors associated with access to and use of patient electronic health records: a cross-sectional analysis of four European countries; 2020.
22. Sinha S, Garriga M, Naik N, et al. Disparities in electronic health record patient portal enrollment among oncology patients. *JAMA Oncol* 2021; 7: 935–937.
23. Greenhalgh T, Wherton J, Papoutsi C, et al. Beyond adoption: a new framework for theorizing and evaluating nonadoption, abandonment, and challenges to the scale-up, spread, and sustainability of health and care technologies. *J Med Internet Res* 2017; 19: e8775.
24. Lythreatis S, Singh SK and El-Kassar A-N. The digital divide: a review and future research agenda. *Technol Forecast Soc Change* 2022; 175: 121359.
25. Eurostat. Digital economy and society statistics—households and individuals. https://ec.europa.eu/eurostat/statisticsexplained/index.php?title=Digital_economy_and_society_statistics_-_households_and_individuals#Internet_usage.
26. World Health Organization. Equity within digital health technology within the WHO European Region: a scoping review. *Equity Digit. Health Technol. WHO Eur. Reg. Scoping Rev.* (2022).
27. van Kessel R, Wong BLH, Forman R, et al. The European Health Data Space fails to bridge digital divides. *Br Med J* 2022; 378: e071913.
28. van Kessel R, Wong BLH, Rubinić I, et al. Is Europe prepared to go digital? Making the case for developing digital capacity: an exploratory analysis of Eurostat survey data. *PLOS Digit Health* 2022; 1: e0000013.
29. Fast N, van Kessel R, Humphreys K, et al. The evolution of telepsychiatry for substance use disorders during COVID-19: a narrative review. *Curr Addict Rep* 2023; 10: 187–197.
30. Ancker JS, Nosal S, Hauser D, et al. Access policy and the digital divide in patient access to medical records. *Health Policy Technol* 2017; 6: 3–11.
31. Veinot TC, Mitchell H and Ancker JS. Good intentions are not enough: how informatics interventions can worsen inequality. *J Am Med Inform Assoc* 2018; 25: 1080–1088.
32. Figueroa CA, Luo T, Aguilera A, et al. The need for feminist intersectionality in digital health. *Lancet Digit Health* 2021; 3: e526–e533.
33. Richardson S, Lawrence K, Schoenthaler AM, et al. A framework for digital health equity. *Npj Digit Med* 2022; 5: 1–6.
34. Lorenc T, Petticrew M, Welch V, et al. What types of interventions generate inequalities? Evidence from systematic reviews. *J Epidemiol Community Health* 2013; 67: 190–193.
35. Wong BLH, Maaß L, Vodden A, et al. The dawn of digital public health in Europe: implications for public health policy and practice. *Lancet Reg Health Eur* 2022; 14: 100316.
36. Schwaninger I, Güldenpfennig F, Weiss A, et al. What do you mean by trust? Establishing shared meaning in interdisciplinary design for assistive technology. *Int J Soc Robot* 2021; 13: 1879–1897.
37. Alkire S. Why the capability approach? *J Hum Dev* 2005; 6: 115–135.
38. Simon MA, de la Riva EE, Bergan R, et al. Improving diversity in cancer research trials: the story of the cancer disparities research network. *J Cancer Educ* 2014; 29: 366–374.
39. Chen IY, Szolovits P and Ghassemi M. Can AI help reduce disparities in general medical and mental health care? *AMA J Ethics* 2019; 21: 167–179.
40. Ibrahim H, Liu X, Zariffa N, et al. Health data poverty: an assailable barrier to equitable digital health care. *Lancet Digit Health* 2021; 3: e260–e265.
41. Advancing equity in medical device performance—The Lancet Global Health, https://www.thelancet.com/journals/langlo/article/PIIS2214-109X(24)00141-4/fulltext?dgcid=raven_jbs_etoc_email.
42. Bangash MN, Hodson J, Evison F, et al. Impact of ethnicity on the accuracy of measurements of oxygen saturations: a retrospective observational cohort study. *eClinicalMedicine* 2022; 48: 101428.
43. Fawzy A, Wu TD, Wang K, et al. Racial and ethnic discrepancy in pulse oximetry and delayed identification of treatment eligibility among patients with COVID-19. *JAMA Intern Med* 2022; 182: 730–738.
44. Ford JG, Howerton MW, Lai GY, et al. Barriers to recruiting underrepresented populations to cancer clinical trials: a systematic review. *Cancer* 2008; 112: 228–242.
45. Pratap A, Neto EC, Snyder P, et al. Indicators of retention in remote digital health studies: a cross-study evaluation of 100,000 participants. *NPJ Digit Med* 2020; 3: 21.
46. Rudrapatna VA and Butte AJ. Opportunities and challenges in using real-world data for health care; 2020. doi:10.1172/JCI129197. https://www.jci.org/articles/view/129197/pdf
47. Stern AD, Brönneke J, Debatin JF, et al. Advancing digital health applications: priorities for innovation in real-world evidence generation. *Lancet Digit Health* 2022; 4: e200–e206.
48. Chen IY, Pierson E, Rose S, et al. Ethical machine learning in healthcare. *Annu Rev Biomed Data Sci* 2021; 4: 123–144.
49. Klucken J, Krüger R, Schmidt P, et al. Management of Parkinson's disease 20 years from now: towards digital health pathways. *J Park Dis* 2018; 8: S85–S94.
50. Leist AK, Klee M, Kim JH, et al. Mapping of machine learning approaches for description, prediction, and causal inference in the social and health sciences. *Sci Adv* 2022; 8: eabk1942.
51. Obermeyer Z, Powers B, Vogeli C, et al. Dissecting racial bias in an algorithm used to manage the health of populations. *Science* 2019; 366: 447–453.
52. Chen RJ, Chen TY, Lipkova J, et al. Algorithm fairness in AI for medicine and healthcare. *ArXiv Prepr. ArXiv211000603* (2021).
53. Manly JJ, Jones RN, Langa KM, et al. Estimating the prevalence of dementia and mild cognitive impairment in the US: the 2016 health and retirement study harmonized cognitive assessment protocol project. *JAMA Neurol* 2022; 79: 1242–1249.
54. Flanagin A, Frey T and Christiansen SL and AMA Manual of Style Committee. Updated guidance on the reporting of race and ethnicity in medical and science journals. *JAMA* 2021; 326: 621–627.

55. Cirillo D, Catuara-Solarz S, Morey C, et al. Sex and gender differences and biases in artificial intelligence for biomedicine and healthcare. *Npj Digit Med* 2020; 3: 1–11.
56. La M, Hw N and Dm G. The experience of symptoms of depression in men vs women: analysis of the National Comorbidity Survey Replication. *JAMA Psychiatry* 2013; 70(10): 1100–1106
57. Paccoud I, Nazroo J and Leist AK. Region of birth differences in healthcare navigation and optimisation: the interplay of racial discrimination and socioeconomic position. *Int J Equity Health* 2022; 21: 106.
58. Norheim OF and Asada Y. The ideal of equal health revisited: definitions and measures of inequity in health should be better integrated with theories of distributive justice. *Int J Equity Health* 2009; 8: 40.
59. Starke G, De Clercq E and Elger BS. Towards a pragmatist dealing with algorithmic bias in medical machine learning. *Med Health Care Philos* 2021; 24: 341–349.
60. Vyas DA, Eisenstein LG and Jones DS. Hidden in plain sight —reconsidering the use of race correction in clinical algorithms. *N Engl J Med* 2020; 383: 874–882.
61. Owens K and Walker A. Those designing healthcare algorithms must become actively anti-racist. *Nat Med* 2020; 26: 1327–1328.
62. Levey AS, Tighiouart H, Titan SM, et al. Estimation of glomerular filtration rate with vs without including patient race. *JAMA Intern Med* 2020; 180: 793–795.
63. Reddy S. Explainability and artificial intelligence in medicine. *Lancet Digit Health* 2022; 4: e214–e215.
64. Ethics and governance of artificial intelligence for health, https://www.who.int/publications-detail-redirect/9789240029200.
65. Amann J, Blasimme A, Vayena E, et al. Explainability for artificial intelligence in healthcare: a multidisciplinary perspective. *BMC Med Inform Decis Mak* 2020; 20: 310.
66. Huerta EA, Blaiszik B, Brinson LC, et al. FAIR For AI: an interdisciplinary and international community building perspective. *Sci Data* 2023; 10: 487.
67. Chen IY, Joshi S and Ghassemi M. Treating health disparities with artificial intelligence. *Nat Med* 2020; 26: 16–17.
68. van Veen T, Binz S, Muminovic M, et al. Potential of mobile health technology to reduce health disparities in underserved communities. *West J Emerg Med* 2019; 20: 799–802.
69. Dijck Jv. Datafication, dataism and dataveillance: big data between scientific paradigm and ideology. *Surveill Soc* 2014; 12: 197–208.
70. Cukier K and Mayer-Schoenberger V. The rise of big data: how it's changing the way we think about the world. *Foreign Aff* 2013; 92: 28–40.
71. Lupton D. Health promotion in the digital era: a critical commentary. *Health Promot Int* 2015; 30: 174–183.
72. Kickbusch I, Piselli D, Agrawal A, et al. The lancet and Financial Times commission on governing health futures 2030: growing up in a digital world. *Lancet* 2021; 398: 1727–1776.
73. Braveman PA, Egerter SA and Mockenhaupt RE. Broadening the focus: the need to address the social determinants of health. *Am J Prev Med* 2011; 40: S4–S18.
74. Saeed SA and Masters RM. Disparities in health care and the digital divide. *Curr Psychiatry Rep* 2021; 23: 61.
75. Ruckenstein M and Schüll ND. The datafication of health. *Annu Rev Anthropol* 2017; 46: 261–278.
76. Hogle L. Data-intensive resourcing in healthcare. *BioSocieties* 2016; 11: 372–393.
77. Christophersen M, Mørck P, Langhoff TO, et al. Unforeseen challenges. In: Antona M and Stephanidis C (eds) *Universal access in human-computer interaction. Access to learning, health and well-being*. Cham: Springer International Publishing, 2015, pp.288–299. doi:10.1007/978-3-319-20684-4_28
78. Osborn CY, Kripalani S, Goggins KM, et al. Financial strain is associated with medication nonadherence and worse self-rated health among cardiovascular patients. *J Health Care Poor Underserved* 2017; 28: 499–513.
79. Zuboff S. Big other: surveillance capitalism and the prospects of an information civilization. *J Inf Technol* 2015; 30: 75–89.
80. Dwork C and Roth A. The algorithmic foundations of differential privacy. *Found Trends® Theor Comput Sci* 2014; 9: 211–407.
81. Raab R, Küderle A, Zakreuskaya A, et al. Federated electronic health records for the European Health Data Space. *Lancet Digit Health* 2023; 5: e840–e847.
82. Hale TM and Kvedar JC. Privacy and security concerns in telehealth. *AMA J Ethics* 2014; 16: 981–985.
83. Bächle TC and Wernick A. *The futures of eHealth: social, ethical and legal challenges*. Berlin, Germany: Alexander von Humboldt Institute for Internet and Society, 2019.
84. Adjekum A, Blasimme A and Vayena E. Elements of trust in digital health systems: scoping review. *J Med Internet Res* 2018; 20: e11254.
85. Rodriguez JA, Clark CR and Bates DW. Digital health equity as a necessity in the 21st century cures act era. *JAMA* 2020; 323: 2381.
86. LaVeist TA, Nickerson KJ and Bowie JV. Attitudes about racism, medical mistrust, and satisfaction with care among African American and white cardiac patients. *Med Care Res Rev* 2000; 57: 146–161.
87. Wissinger C. Privacy literacy: from theory to practice. *Commun Inf Lit* 2017; 11: 378–389.
88. van Kessel R, Wong BLH, Clemens T, et al. Digital health literacy as a super determinant of health: more than simply the sum of its parts. *Internet Interv* 2022; 27: 100500.
89. Li X. Understanding eHealth literacy from a privacy perspective: eHealth literacy and digital privacy skills in American disadvantaged communities. *Am Behav Sci* 2018; 62: 1431–1449.