Ethical Imperatives in Digital Health Research: Promoting Equity and Empowering Patients

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Abstract

The democratization of digital health technologies in research necessitates a steadfast commitment to the foundational principles of bioethics: autonomy, beneficence, non-maleficence, and justice. All stakeholders within the digital health ecosystem, including researchers and industry players, must actively integrate bioethical considerations such as privacy, security, data governance, and equitable distribution of benefits into the development and deployment of digital health tools. Researchers bear a responsibility to engage patient stakeholders throughout the design and testing phases of digital health interventions. This inclusive approach fosters trust and enhances participation in research studies. Just as in medical decisions, respecting patient autonomy entails facilitating active involvement in decision-making processes and providing accessible, timely, and comprehensive information in lay-friendly and multi-lingual formats. Given the dearth of evidence in established frameworks and informational strategies to enhance digital health literacy, the global digital health community must adopt a more deliberate and coordinated approach to identifying and addressing these research gaps. By doing so, we can ensure that the benefits of digital health technologies are equitably distributed and that individuals are empowered to make informed decisions about their health and well-being.

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VIEWPOINT

Ethical Imperatives in Digital Health Research: Promoting Equity and Empowering Patients

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ABSTRACT:

The democratization of digital health technologies in research necessitates a steadfast commitment to the foundational principles of bioethics: autonomy, beneficence, non-maleficence, and justice. All stakeholders within the digital health ecosystem, including researchers and industry players, must actively integrate bioethical considerations such as privacy, security, data governance, and equitable distribution of benefits into the development and deployment of digital health tools. Researchers bear a responsibility to engage patient stakeholders throughout the design and testing phases of digital health interventions. This inclusive approach fosters trust and enhances participation in research studies. Just as in medical decisions, respecting patient autonomy entails facilitating active involvement in decision-making processes and providing accessible, timely, and comprehensive information in lay-friendly and multi-lingual formats. Given the dearth of evidence in established frameworks and informational strategies to enhance digital health literacy, the global digital health community must adopt a more deliberate and coordinated approach to identifying and addressing these research gaps. By doing so, we can ensure that the benefits of digital health technologies are equitably distributed and that individuals are empowered to make informed decisions about their health and well-being.

INTRODUCTION:

The accelerated pathway adopted by digital health technologies in biomedical and behavioral research brought great hope and promise in enhancing precision medicine of health. However, it also underscores the emergence of critical bioethical concerns surrounding issues of inequality, injustice, and participant autonomy. The Health Information Technology for Economic and Clinical Health (HITECH) Act of 2009[1] catalyzed private sector investment in digital health, yet bioethical scrutiny of these technologies has lagged. The COVID-19 pandemic brought the nation’s attention to the potential role of several digital technologies including mobile health, wearable devices, remote patient monitoring, and telehealth,[2,3] in exacerbating health inequities.[4,5]

Recommendations from WHO guidelines[6,7] stress the importance of developing digital health technologies ethically, ensuring they are safe, secure, reliable, equitable, and sustainable. Transparency, accessibility, and scalability should be prioritized, with a focus on safeguarding the privacy, security, and confidentiality of users.[8] The concept of Sociotechnical ethics of digital health[9] suggests broadening the ethical focus beyond technology itself to consider broader social constructs, recognizing that technologies are embedded in social contexts. The notion of digital determinants of health (DDoH)[1] operating at the individual, interpersonal, community, and societal levels acknowledges that digital factors can operate as barriers or facilitators to health outcomes, functioning independently alongside traditional social determinants of health. Digital redlining,[10] for example, impacts access to essential digital health tools like patient portals, remote monitoring programs, and telehealth, thereby affecting health outcomes.[11]

Overall, we emphasize the dual potential and challenges posed by digital health technologies, urging for their ethical development and implementation to ensure equitable access and positive health outcomes for all individuals.

Advancing Equity and Engagement: Navigating Digital Health Literacy in Research

Expanding the National Institute on Minority Health and Health Disparities (NIMHD) research framework[12] to include a domain focusing on the digital environment and Digital Determinants of Health (DDoH)[1] marks an important step towards enhancing digital literacy and promoting participant engagement with digital health initiatives.[13,14] This framework aims to ensure equitable access to digital healthcare, equitable outcomes, and experiences with digital healthcare, and equity in the design of digital health solutions.[15]

However, barriers such as educational, cultural, or linguistic differences can hinder patients' comfort and utilization of digital health solutions. These challenges are compounded by limited health literacy, which is particularly prevalent among racial and ethnic minorities, as well as older and less educated individuals across all races.[20,21] This is concerning, as individuals with limited health literacy often experience poorer health outcomes compared to those with higher health literacy levels.[22,23]

It's worth noting that while digital literacy positively contributes to an individual's digital self-efficacy or confidence in navigating the digital world, it doesn't fully account for it.[1,24] In other words, individuals may still struggle with digital confidence even if they possess basic digital literacy skills.

Studies aiming to increase research engagement among underrepresented groups have identified awareness of research's purpose, processes, and importance as a key individual-level factor.[25-27] This is especially relevant in digital health research, where complex data outputs may be challenging for participants to understand without awareness of their significance for clinical care. This lack of understanding raises ethical concerns, particularly when working with vulnerable populations.

Trust in digital health is another crucial consideration, as disadvantaged populations may have unique concerns regarding privacy, security, data governance, and surveillance.[28,29] Addressing these concerns is essential for fostering trust and promoting equitable participation in digital health research initiatives.

Exploring the Digital Divide: Insights from Behavioral Research

In a National Institutes of Health-funded observational study (HL15331),[30] we aimed to characterize the psychological and health behavior dimensions following survival from a life-threatening cardiovascular condition, specifically cardiac arrest. Wearables such as an actigraph, a wireless heart monitor patch, and mobile health tools, including an ecological momentary mood assessment app, were utilized. These tools were administered in-person at hospital discharge and remotely at the 6-month mark.

Our study cohort encompassed a broad age range (22-88 years) and was racially/ethnically diverse, with 43% identifying as White and 39% as Hispanic/Latino. Additionally, 20% of participants did not complete high school education.

An interim examination of the usage of digital health technologies revealed a significant drop in the proportion of assigned patients providing any usable data. This ranged from 77-79% for actigraph and ambulatory heart-patch data during in-person baseline assessments to 41-47% at the 6-month follow-up when the devices were sent home with instructions available in both English and Spanish. Surprisingly, compliance with the mobile health app was low even at baseline and remained so during the 6-month follow-up visit, dropping from 51% to 43%.

Demographic differences among participants may explain some of these disparities in digital health engagement. Specifically, Spanish-speaking participants were less likely to provide any usable actigraph data, while older participants tended to lack usable survey data in the mobile health app.

These findings underscore the existence of disparities in digital health-based research studies. However, they also present a unique opportunity to address these gaps by incorporating bioethical and digital environmental considerations. Ultimately, our goal should be to enhance engagement with digital research and improve outcomes for all participants.

What strategies can be employed to increase digital health research engagement by underrepresented groups?

Fortunately, akin to genomic health,[31] the dissemination of digital health technologies for research is early enough that there is an opportunity to use our emerging understanding of the DDoH to alter the usual diffusion curve and build educational interventions that can meaningfully engage health disparity populations.[1] To truly translate bioethical concepts to research methods, it needs tight integration with actual practices of developing and implementing digital health technologies.[29] Whether the utilization of human-centered design[32] during technology development improves digital literacy and engagement needs to be known. It will require that the core principles, frameworks, and strategies of dissemination and implementation science are employed to understand root causes, people, and their context through focus groups, and then integrate those findings into journey maps to depict the ideal participant experience with the proposed digital platform. Another strategy involves creating interactive, educational methods[33,34] conveying information across cultural and linguistic barriers and in which formal assessment of comprehension is linked to repeated passes through targeted education until understanding is obtained (a process also known as ‘‘teach-to-goal’’). It may be especially important for those with limited literacy, minority status, or participants with language barriers.[35-38] Again, informed by DDoH, the user interface needs to be built on trust, self-efficacy, and usability. However, such educational materials cannot be pulled “off the shelf” from third-party providers since they should incorporate considerations of cultural awareness for the pool of potential research participants they are designed for.[39,40-42] The future goals of researcher stakeholders lie in designing an intervention that maximizes uptake and fidelity in real-world research settings by optimizing the user experience and considering practical implementation issues early in the intervention design process.

Empowering Participant Autonomy: A Cornerstone of Ethical Research

This is a commonly overlooked yet crucial ethical aspect within digital health research, emphasizing the need for both "freedom" (freedom from external control) and "capability" (the capacity for intentional action).[43,44] Research endeavors should focus on creating effective resources that support individual autonomy to enhance engagement. This is particularly relevant during the informed consent process for studies involving digital health, which often involves complex technical language that may be challenging for potential participants to understand. To uphold the principle of respecting individuals and to address information imbalances, it's essential to communicate information about the technology and the study in clear, accessible language.[45] Additional methods such as videos and in-person demonstrations can aid comprehension during the consent process.[46] Adjustments to the informed consent process may also be necessary to accommodate differences in educational literacy, cognitive abilities, and clinical conditions among potential participants. Furthermore, it's important to clarify the issue of data ownership and the potential secondary use of data within the informed consent process for the digital health research community.

Long-term Implications

As digital health technologies undergo testing and validation, they are anticipated to become integrated into more intricate closed-loop systems, allowing for autonomous interventions for therapeutic purposes, with the overarching aim of personalized disease management.[19] The widespread acceptance of these non-invasive technologies within the medical community, and their subsequent adoption by a broader audience, will necessitate collaborative efforts from the research community. This includes conducting scientifically and ethically rigorous human validation studies and comprehensive investigations into the clinical significance of data gathered through digital technologies. To ensure equal participation in digital health research, it will be imperative to address barriers at the community and societal levels, such as limited resources and competing priorities, through interventions that focus on enhancing digital infrastructure.

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