# Explorar o Excepcionalismo Digital nos Cuidados de Saúde: Navegar pela Confiança, Eficácia, Equidade e Potenciais Danos

# Exploring Digital Exceptionalism in Healthcare: Navigating Trust, Efficacy, Equity and Potential Harms

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In the ever-evolving landscape of healthcare, the integration of digital technologies has emerged as a transformative force, promising to revolutionize patient care, clinical-based research, and healthcare delivery. However, as we navigate this (our!) digital age, it becomes imperative to critically examine the concept of digital exceptionalism – the notion that digital health solutions inherently possess unique qualities and benefits that set them apart from traditional (clinical and scientific) approaches. They (indeed) might; however, it is crucial to set the bar high, ensuring that the standards for innovation are scientifically rigorous.[1]

Central to the adoption of digital health solutions is the establishment of trust between patients (including carers and relatives), healthcare providers, researchers and/or technology developers. Transparency in data usage, adherence to ethical guidelines, and clear communication regarding the benefits and limitations of digital (health) tools or solutions are paramount. Moreover, fostering a culture of shared decision-making, where patients actively participate in their care, strengthens trust, and promotes patient engagement. Collaborative efforts among stakeholders, from the clinician to the lab researcher, to co-create needed solutions, further enhances trust, and ensures the relevance and effectiveness of digital interventions.

This is, nonetheless, not sufficient. In fact, it is also imperative that studies involving digital health solutions adhere to fundamental scientific principles, and follow rigorous design and methodology, ensuring integrity in research practices, without forceful justification of ethical lapses, amongst all partners or shareholders. Amidst the proliferation of digital health solutions, discerning what truly and justly delivers meaningful and equitable clinical outcomes is essential.[2,3] In essence, that which is valid, effective, implementable, safe, and cost-effective, as well as aligned with privacy measures and core ethical values (autonomy, beneficence, non-maleficence, and justice), as we would expect from any other clinical (and/or pharmacological) solution, treatment, or practice. Conducting rigorous evaluations, including well-designed randomized, clinical trials, and/or comparative effectiveness studies, augmented by real-world evidence generation,[4] is crucial for assessing the efficacy and safety of digital interventions (notably, the perceived low-level of risk associated with digital products or solutions can be conducive to a lack of clinical trials). More so, utilizing robust methodologies and outcome measures, on-target with clinical relevance, ensures the validity and generalizability of study findings. Leveraging technologies, such as artificial intelligence and machine learning, to analyze large datasets can uncover insights into disease management and treatment optimization, driving evidence-based decision-making in healthcare. But, to validate the effectiveness and safety of digital health interventions, reproducible and large-scale studies are indispensable.[5] Embracing principles of open science, including transparent reporting, data sharing, and replication studies, enhances the credibility and reliability of research findings. Collaborative initiatives such as multi-center trials and data consortia facilitate the aggregation of diverse datasets, enabling robust analyses and generalizability of results. Furthermore, leveraging real-world evidence from electronic health records and wearables offers insights into intervention outcomes in diverse patient populations and healthcare settings, driving evidence-based practice and policy formulation. Regarding this, it is also of note that the same expectations should prevail regarding the digital transformation of clinical trials themselves, where digital solutions are increasingly used for improving trial efficiency, effectiveness, and accessibility.[6,7]

Despite the benefits of digital health, it is neither without risks nor without the (inherent it can be argued) potential for exacerbating inequalities. Regarding the former, from data breaches and cybersecurity threats to unintended consequences such as algorithmic bias and overreliance on technology, various factors can pose harm to patients and healthcare systems.[8] Proactive risk assessment, ongoing monitoring, and mitigation strategies are essential to reduce these risks and ensure patient safety. Additionally, fostering a culture of transparency, accountability, and continuous learning promotes responsible innovation and enables timely identification and mitigation of potential harms. Concerning the latter, while digital health holds promise for improving healthcare access and

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outcomes, it also can exacerbate (pre)existing disparities if not implemented equitably.[9] Addressing barriers such as digital literacy, access to technology, and socioeconomic factors is essential to ensure inclusive adoption of digital health solutions (on this, a word of caution on the nefarious consequences of "cherry picking" study populations/patients and data, see example provided in[1]). Tailoring interventions to diverse populations' needs and preferences, providing, for example, educational resources and fostering partnerships with community organizations, can enhance digital health literacy and bridge the digital divide.

Finally, a note on privacy. As digital health platforms collect and analyze vast amounts of sensitive health data, safeguarding patient privacy, while promoting trust and evidencing that the success of health information technologies positively influences patient care outcomes, becomes a critical concern.[10] Robust data encryption, adherence to data protection regulations, and stringent security measures are essential to mitigate privacy risks. Additionally, empowering individuals with control over their data through informed consent mechanisms and transparent data-sharing practices fosters a sense of autonomy and reinforces trust in digital healthcare systems. Continuous monitoring and adaptation of privacy policies to address evolving threats and technological advancements are imperative to maintain patient confidentiality and uphold ethical standards.

In conclusion, the integration of digital technologies in healthcare offers unprecedented opportunities to improve patient outcomes, enhance efficiency, and advance medical knowledge – as we can see in this Special Issue. Nonetheless, realizing the full potential of digital health requires addressing critical considerations related to trust, efficacy, equity, privacy, and potential harms. By embracing evidence-based practices, promoting transparency and inclusivity, and prioritizing patient-centered care, we can harness the power of digital innovation to transform healthcare delivery all the while steadfastly upholding ethical principles, scientific integrity, and best practices. ■

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