From Blueprint to Best Practice: Gauging the Efficacy of Digital Health Solutions

Abbas ZAVAR [a1] and Razieh POORANDY [a]

[a] *Institute of Health Policy, Management and Evaluation, Dalla Lana School of Public Health, University of Toronto, Toronto, ON, Canada*
ORCiD ID: Abbas Zavar https://orcid.org/0000-0003-0639-2765

Abstract. The surge of AI-driven technologies in the digital health market demands a concurrent evolution in evaluation standards, a pace currently lagging behind innovation. This paper explores the pivotal inadequacies within existing evaluation models, highlighting the necessity for refined methodologies that align with the unique complexities of digital health. We critically examine the initiatives of key entities such as Health Canada, CADTH, and CNDHE, pinpointing the deficiencies in addressing the volatility and intricacies of AI applications. To bridge these gaps, we advocate for a nuanced evaluation paradigm, proposing the establishment of an oversight body, implementing detailed category-specific criteria, and a robust six-step evaluation framework tailored for AI health solutions. The paper culminates by underscoring the indispensable role of strategic leadership and agile policymaking in cultivating a resilient digital health environment that prioritizes patient care without compromising the ingenuity of technological advances.

Keywords. Digital health solutions, evaluation, AI-driven solutions, policymaking, standards

1. Introduction

The Digital Health sector has witnessed an exponential surge over the past two decades, introducing myriad innovations to the healthcare landscape. By 2030, projections forecast the global digital health market to reach an astounding $1.5 trillion [1]. Yet, a discernible contrast emerges as we move closer to this future. The rapid progression of these digital solutions, especially those powered by artificial intelligence, significantly outpaces the development of a standardized evaluation framework.

Historically, medical interventions have undergone rigorous evaluations, ensuring they meet stringent standards before introduction to the marketplace. However, with their unique attributes, digital health solutions present an entirely different set of challenges than their traditional counterparts. Recognizing these disparities, international regulatory bodies have made attempts to categorize these digital innovations, coining terms such as "Software as a Medical Device" (SaMD) in the US and "Medical Device Software" (MDSW) in the EU. Despite these categorizations, a substantial portion of these tools remains unsupported by tangible evidence confirming their clinical claims [2,3].

As the number of applications continues to rise, the methodologies for their timely, cost-effective, and robust evaluations lag behind. Current frameworks have failed to adapt to the diverse nature of these solutions, with each category requiring distinct

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[1] Corresponding author: Abbas Zavar, abbas.zavar@utoronto.ca

evaluation criteria [2]. This has given rise to a conspicuous gap where developers are left without standardized creation guidelines, end-users, including physicians, are devoid of comparative standards, and researchers grapple with the absence of unified efficacy evaluation criteria for these digital health tools. The resulting scenario paints a worrisome picture; an overflow of digital health solutions, with a glaring disconnect between their sheer quantity and proven quality.

Artificial Intelligence (AI) rapidly transforms the healthcare industry by offering innovative solutions to complex problems. AI solutions in healthcare are increasingly vital for their capacity to address current challenges and their role in shaping the future of medicine and public health. The intersection of AI with healthcare promises revolutionary breakthroughs, but the absence of a coherent evaluation system threatens this potential. Without clear, universally accepted standards, there lies an inherent risk of compromising the efficacy of these Digital Health Solutions (DHS). Stakeholders, whether patients, healthcare providers, or developers, require transparent and standardized evaluation mechanisms to navigate this burgeoning digital landscape. Without these mechanisms, they remain at risk of sifting through myriad solutions, many of which might be unverified or ineffective, making the pressing need for a comprehensive evaluation system for digital health, particularly AI-enabled solutions, undeniable.

The following sections of this paper will delve into the current state of evaluation mechanisms, identifying their limitations and proposing a focused framework specifically tailored to address the complexities inherent in AI-driven digital health solutions.

2.   Discussion

2.1 Health Canada

A leading health institution in the nation launched its "Guidance Document: Software as a Medical Device (SaMD): Definition and Classification" in 2019, focusing on the intricate digital health realm. This guidance delivers a clear categorization system based on SaMD's purpose and employs a risk-based approach, effectively evaluating higher-risk software and including AI-integrated SaMDs [4].

The guidance may seem limited in scope, overlooking emerging digital health tech. It might be perceived as leaning heavily towards established medical models, possibly neglecting patient-centric innovations and data management advancements. The lack of emphasis on data privacy, system interoperability, and user interface is also concerning. Issues arise in the AI context. The dynamic behaviour of AI is not addressed, nor are transparency concerns, data bias, or continuous AI validation. Furthermore, the guidance does not cater to AI's vulnerability to adversarial attacks, interactions with other AI systems, or the challenge of generalizing AI models across varied datasets or populations. Thus, while valuable, the guidance requires a more in-depth perspective on AI's challenges in healthcare [4].

2.2. Canadian Agency for Drugs and Technologies in Health (CADTH)

CADTH is an esteemed organization in Canada focusing on evaluating health technologies. One of its core sectors entails appraising digital health solutions (DHS).

Emphasizing this mission, CADTH pioneered the establishment of Canada's First Digital Health Evaluation Network, aiming to thoroughly examine digital health interventions' safety, efficacy, and value. By offering evidence-based insights into digital health, CADTH ensures that stakeholders and policymakers are updated with the latest digital health advancements and methodologies [5].

Critically, while CADTH recognizes the importance of DHS, it lacks specificity regarding its approaches or guidelines, especially concerning AI-enabled solutions. This paucity of detailed information makes it difficult to thoroughly critique their role in the digital health domain. Although CADTH has shown signs of acknowledging the rapidly progressing field of AI in clinical applications, the exact ways in which they assess or endorse AI-powered solutions remain somewhat veiled. Additionally, their "Rapid Response Service" suggests a possible avenue for addressing pressing health technology inquiries, but its application to DHS or AI-specific concerns seems uncertain. In light of policy perspectives on health technologies becoming obsolete, CADTH does seem to indirectly grasp the need for perpetually refreshed evaluation standards in healthcare, yet concrete plans for DHS are still wanting.

2.3. Canadian Network for Digital Health Evaluation (CNDHE) and Centre for Digital Health Evaluation (CDHE)

CNDHE and CDHE are organizations driving the evaluation of digital health interventions across Canada. Positioned under Health Canada's jurisdiction, they aim to form a comprehensive strategy for digital health evaluation. This effort's main objective is the creation of the Pan-Canadian Digital Health Evaluation Framework. This framework aims to give researchers a unified blueprint for evaluations, grounded in significant research and collaboration, and is captured in a Conceptual Model with stages of Planning, Implementing, and Impact, aiming to foster a Learning Health System [6].

However, the model's broader scope may be its downfall. It lacks detailed instructions for varied digital health solutions, making practical application challenging. Concerns arise around its flexibility to accommodate emergent themes and clarity about stakeholder involvement. For AI solutions, the model must emphasize Explainable AI (XAI) for transparency, integrate ethical guidelines considering fairness, biases, and privacy, and consider interaction dynamics between humans and AI. It should also consider the continuous learning nature of AI, the importance of diverse training datasets, and the educational impact on health professionals [6].

3.   Recommendations

To navigate the complex interplay between standardization and innovation in AI-enabled digital health solutions, our recommendations advocate for a balanced, multi-faceted approach to evaluation. Recognizing the necessity for rigorous standards while also allowing for the dynamic nature of technological advancement, the following structured yet adaptable recommendations are proposed.

3.1. Establishment of a Dedicated Oversight Body

It is imperative to institute an independent oversight body to unify the evaluation standards. This entity will be responsible for establishing and updating uniform criteria tailored to the distinct categories of Digital Health Solutions (DHS), with special attention to the unique characteristics of AI-driven technologies. This approach ensures that each category is evaluated against relevant and stringent standards, thereby balancing rigorous evaluation and encouraging innovative development practices.

3.2. Adoption of Detailed and Category-Specific Standards

Categorical specificity ensures uniformity in development, leading to easier comparison and evaluation of products. Encourage developers and providers to adapt their production strategies according to meticulous criteria specific to each category. This not only standardizes the development process but also assists end-users in comparing and evaluating similar products within the same category.

3.3. Introduction of Burnout Evaluation

Considering the critical issue of physician burnout, we recommend the inclusion of evaluation criteria that specifically address the impact of DHS on healthcare providers. By assessing whether a tool alleviates or exacerbates burnout, we can better gauge its overall benefit to the healthcare system and its providers, thereby ensuring that the well-being of clinicians is a factor in the utility assessment of digital health innovations [7].

3.4. Implementation of a Comprehensive Six-Step Evaluation for AI Solutions

To assess AI solutions comprehensively, we endorse a structured six-step evaluation process that considers the following dimensions: (1) Initial alignment with healthcare needs, (2) Technical robustness, (3) Clinical outcome relevance, (4) User experience efficiency, (5) System integration capability, and (6) Ethical and privacy safeguards. This framework guarantees comprehensive assessments, covering practicality, clinical efficacy, and alignment with recognized benchmarks. [8] This methodology does not intend to create redundancies with Health Technology Assessment (HTA) but rather to serve as a specific, actionable framework within the broader HTA context, addressing the unique demands of AI in healthcare.

3.5. Development of an Adaptive Evaluation Ecosystem

Acknowledging the fast-paced evolution of digital health, it is crucial to establish systematic and capable evaluation mechanisms to adjust to new developments. By implementing structures that are designed to be organized yet flexible, the evaluation process can remain up-to-date with the latest advancements, ensuring both the reliability and relevance of evaluations [9].

3.6 Integration of Health Technology Assessment (HTA) in Evaluation

HTA's well-established, comprehensive methodology for assessing the various impacts of health technologies is invaluable. By incorporating HTA into the broader evaluation framework, we ensure a thorough understanding of a technology's potential impacts. This integration allows for informed policy and decision-making that fully accounts for health technology's medical, social, economic, and ethical dimensions [10].

4.   Conclusion

Fueled by the digital revolution, the evolution toward a proactive healthcare framework marks a critical juncture in health service delivery. It brings to the fore the essential requirement for robust evaluation methods that are specifically designed for AI-driven digital health solutions. While there are concerted efforts to devise comprehensive evaluation systems, the heterogeneity of digital health solutions demands nuanced, category-specific assessment tools.

Evaluation now transcends clinical efficacy, including user engagement, ethical data management, and technological congruence within healthcare systems. Therefore, an effective evaluation framework must marry traditional healthcare assessment with the novel complexities introduced by AI technologies.

As we transition to a proactive healthcare model, our evaluative practices must also evolve, incorporating both established and emerging research methods that reflect the agility of digital health advancements. This integrated approach ensures relevance and drives innovation within the sector.

Leadership and policymaking play pivotal roles in this shift. Visionaries championing adaptive evaluation models and policymakers supporting their widespread implementation are indispensable for establishing a robust digital health ecosystem.

Provided recommendations advocate for an evaluation environment that judiciously combines rigor and flexibility. This approach seeks to uphold the integrity and utility of digital health innovations, paving the way for a healthcare landscape where safety, efficacy, and innovation are harmoniously balanced for the betterment of patient care.

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