ECONOMIST IMPACT

The effects of non-evidence-based technologies entering the health sector

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IN SHORT

- **Not all technologies entering the health sector have the clinical validation or empirical data to support claims of their medical effectiveness and successful health outcomes.**
- **Mobile health and artificial intelligence are two components of the health technology ecosystem that have limited and mixed evidence proving their impacts, despite their exponential growth and widespread investment in these technologies.**
- **Future technologies entering the health sector must have accountability mechanisms in place to ensure quantifiable health impacts and evidence-based solutions to improve population health. Achieving this accountability will depend on stakeholders' ability to come together to refine regulatory frameworks and set ethical industry norms.**
- **It is imperative to tailor more advanced evidence-generating mechanisms specifically for digital health technology assessment to allow for a nuanced understanding of their value and help the health sector keep up with the pace of innovation.**

Introduction

Unlike new medical devices and pharmaceutical interventions, not all healthcare technologies undergo a rigorous clinical approval process. As a result, certain technological interventions may not be grounded in scientific evidence, potentially leading to harmful effects and costly interventions without benefit for those who use them. These new digital and other health technologies offer opportunities for clinical research and treatment,[1] but their use in the healthcare space raises data quality, privacy and regulatory concerns.[2] Creators must provide credible evidence for new health technologies in order to support widespread adoption. Conventional evaluative methodologies, such as clinical trials, have seldom been applied, and more pragmatic approaches are needed.[3]

The technological literacy necessary for evaluation and regulation can also pose a challenge: members of existing regulatory bodies may not have the experience or knowledge required to conduct holistic risk assessments and evaluations.[4]

The article below examines some of the impacts of evidence- and non-evidence-based technologies that are currently entering the health sector and reviews the ongoing efforts to improve evidence-based assessments of such technologies.

The challenging current landscape

Since 2011, investments in and funding of health startup companies have grown by a factor of 17, from $1.2b in 2011 to $29.1b in 2021.[5] This rapid acceleration towards digital health

solutions has increased opportunities for direct-to-consumer solutions in markets worldwide, and many companies have promised to offer niche health products and interventions to diagnose and treat diseases and to monitor and manage health data, among other services. But as these startups continue to push products in the health market, their solutions are not always supported by evidence of clinical effectiveness. A study published in the Journal of Medical Internet Research reported that many health technology companies have limited – if any – clinical validation when making claims for products related to the prevention, diagnosis and treatment of disease.[6] In fact, on a scale of one to ten, 80% of the 224 companies evaluated had a clinical robustness score under five, of which nearly half had a score of zero.[6] Theranos, in a well-known example, is a biotechnology company that touted breakthroughs in biomedical technology without peer-reviewed research to back up various media claims.[7] It is clear that health technology companies' claims of product effectiveness and success may not always be backed by evidence, which is a source of significant concern for consumers.

Mobile health (mHealth), defined as "the practice of medicine supported by portable diagnostic devices," aims to provide health consumers with opportunities for patient-centric health engagement with better outcomes at a lower cost.[8] While certain mHealth interventions targeting specific health outcomes show promise, such as improving the management of musculoskeletal conditions or increasing medication adherence for certain conditions, overall evidence correlating use to successful health outcomes continues to be limited—mixed at best.[8,9,10,11] Challenges continue to plague this pursuit of evidence, ranging from obstacles in seeking clinical trial validation to the fundamental agreement on terminology when discussing mHealth.[12]

Moving away from consumer-interactive health technology solutions, health system–oriented products involving artificial intelligence (AI) have impacted data management and analytics, system integration and the development of other decision-making assistive technologies. With data at its core, AI has piqued the interest of consumers and decision-makers alike, accounting for an expected healthcare market growth from $5b in 2022 to $70b by 2032.[13] AI-enabled tools have demonstrated some success in medical settings, particularly in the use of electronic health records for suicide prevention and in supporting clinical efficiency for physician's performance in thoracic pathologies.[14,15] However, while AI has been successful for predictive models, active monitoring and decision-making support in clinical settings, more research is needed to fill gaps in the academic literature. One study published in the Health Informatics Journal investigated data-driven AI in supporting decision-making in health and social care settings.[16] The study found not only a low quality of existing published studies but also a lack of randomized controlled trials (RCTs) to substantiate any findings. The dearth of evidence was largely due to limited access to data and limited adoption of this technology —a few of many issues found in similar studies.[17,18,19] Therefore, there is much to be done within the scope of mHealth, AI, and other digital health technologies to ensure that solutions stem from evidence-based approaches and best practices.

One step at a time: challenges in seeking evidence

Deploying evidence-based solutions in the healthcare space takes various approaches and strategies, depending on regional market regulation. The complexity of evaluative guidelines presents one significant challenge. Charles Lowe, chief executive of the Digital Health and Care Alliance in the UK, flags NICE, the government's National Institute for Health and Care Excellence, as experts in evaluating medicines and medical devices. However, while in the UK any health claim has to be backed up by evidence, Mr Lowe notes that there is still a way to go when it comes to robust and clear evaluation, noting that NICE recently produced "a fairly confusing bit of guidance on how to evaluate the benefits of medical devices."

Further complicating the evaluation of healthcare technology is the multitude of local contexts in which a single piece of technology may be used. Mark Brommeyer, Senior Lecturer in health care management at Flinders University and Fellow of the Australasian Institute of Digital Health, notes that digital tools will produce different results depending on the environment. For instance, there may be a significant difference in how information is digitally collected, and the underlying electronic decision-support knowledge bases and protocols used, by healthcare workers in a major tertiary hospital versus in a rural area, in treating heart attacks for example.

A final prominent challenge is research methodology. RCTs have long been considered the gold standard in research in terms of minimizing bias. However, RCTs may not be the best approach for all interventions. "There are some difficult thorny methodological challenges in evaluating these things [technologies] that require specialized expertise", affirms Dr Michael Howell, chief clinical officer at a major tech company. "The way that you develop software is iterative, and iterative changes in an intervention are not the way that standard individual randomized controlled trials are designed. They are designed for a fixed, static intervention. There are methods that can address this, and can rigorously evaluate interventions that change over time (the way that software typically gets built) but these approaches can require some pretty complicated things, like Bayesian complex adaptive trial design."

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The wider concerns of unevaluated technology in healthcare

Allowing unregulated models to proliferate, especially in the private sector, can pose risks. For example, at the beginning of the coronavirus pandemic, private electronic health record companies produced clinical prediction tools to help doctors decide when to move patients into intensive care.[20] An untested tool—one that has not been not independently evaluated, peer reviewed or examined critically for underlying racial or gender biases—or tools that have been tested and shown to have significant bias, also threaten the key medical concept of triage, or the holistic system by which doctors prioritize patient care.[21,22]

Additionally, there are privacy concerns and a lack of public trust in technology's role in healthcare. One scoping review on the "building blocks of trust in digital health systems" mapped out elements of personal, technological and institutional trust as essential components.[23] In particular, researchers flagged concerns about the accuracy of digital information, compounded by a lack of uniform quality control measures or standards.[24] None of these issues are prohibitive, but they all call for rigorous evidence-based reviews of technologies in healthcare.

Furthermore, complex reimbursement pathways for technologies makes it difficult for stakeholders to develop evidence-based solutions. Without clear reimbursement pathways, which are mapped to evidence requirements, there is little incentive for digital health solution developers to undertake evidence-generation activities. One study acknowledges that market maturity, the structure of health systems, digital governance and the standardization of evidence vary in Europe, leading to convoluted reimbursement mechanisms.[25] For example, while Germany has cemented its guidelines into law, the UK has put forth guidelines that aim to establish standards of evidence for assessing digital technologies.[26] In Latin America, Brazil has recently introduced its digital health strategy and has begun to take

initial steps to evaluate digital technologies, whereas other Latin American countries do not have any formal pathway to evaluate digital health technologies. Thus, variations in reimbursement mechanisms and guidelines may impact the time companies need to learn about the market before deploying their solution and seeking evidence for their product.

Conclusion: the path forward

New and emerging healthcare technologies require the same rigorous validation and review processes as medical interventions. Both mobile health and AI are examples in the wider ecosystem of health technology that have limited and mixed evidence proving their impacts, despite their growing presence in the healthcare space. A useful next step could be to create metrics to better measure how technologies like AI and mHealth are improving health outcomes and to determine the enabling environment for doing so. The future of health technologies requires accountability mechanisms to ensure quantifiable health impacts. National and international stakeholders must come together to create regulatory frameworks and set ethical industry norms. The path forward must include review and evidence standards that are equivalent to the stringent scientific standards for medical devices. These methods can help assuage the hesitancy and skepticism many in the public feel about healthcare technologies by helping to prove their benefits.

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