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H_pe for mHealth: More "y" or "o" on the horizon?

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Abstract

Objective—Efforts in the domain of mobile health, or mHealth, have been criticized for the unfettered proliferation of pilots and a lack of a rigorous evidence base to support these strategies. In this letter, we present the response of a group of researchers in the mHealth community to the recent calls for evidence issued by global health and funding agencies. We support our conclusions through a summary of the numerous ongoing mHealth studies listed in the US federal clinical trial registry.

Methods—We conducted a search on the US federal clinicaltrials.gov database using the keywords "mHealth", "mobile" or "cell AND phone" to obtain 1678 results of studies. We manually inspected each result to check if it fit the purview of an mHealth study. Studies that were terminated or withdrawn prior to submission were excluded.

Results—We identified 215 unique mHealth studies that were registered in the clinicaltrials.gov database, of which 8.4% (n = 18) were observational in nature while the remaining 91.6% (n = 197) were interventional. Of the 215 studies, 81.8% (n = 176) studies used a classical randomized trial design and 40 new studies were added to the database between May and November 2012 alone. Based on these results, we posit that the field is entering a new 'era' where a body of rigorous evaluation of mHealth strategies is rapidly accumulating.

Conclusions—The transition into an era of evidence-based mHealth supports our position that innovation in this domain can be evaluated with the same rigor as other public health strategies, attenuating some of the hype previously associated with mHealth.

Keywords

mHealth; Evidence; Evaluation

Author contributions

Competing interests

The authors declare no conflict of interest.

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Over the past decade, a growing 'mHealth' movement has been exploring and identifying opportunities to improve the delivery of, and access to, health services and information. There are currently 6 billion mobile phone subscriptions permeating 87% of the world's population, fueling the interest in mHealth solutions as a sea changer for global health [1]. A broad ecosystem has emerged around using mobile technologies to catalyze healthcare, across the economic spectrum, from sophisticated high-income settings to rural populations where basic health needs are often unmet. Technologies used in this space range from simple voice-only phones to highly sophisticated portable computing devices, resulting in a breadth of solutions being developed and tested globally. At the core of most mHealth strategies lies a mix of conventional approaches that optimize processes and meaningful data utilization, to novel systems that depend on emergent sensor technologies to provide diagnostic insights and personalize care. mHealth can be used to incentivize action, improve timeliness of data collection and utilization, improve access to and communication with clients, provide information on-demand, improve adherence, reduce attrition to clinical follow-up, and document system-client interactions to improve accountability by identifying and acting on missed contacts. There is widespread recognition of the *potential* inherent in these technologies, across development investors, national governments, global health agencies and the telecommunications sector.

The first 'era of mHealth' has been characterized by a global proliferation of proof-ofconcept projects. A number of foundations, government agencies and telecommunication operators (e.g., the Bill and Melinda Gates Foundation, USAID, and Vodafone, among others) have provided seed funding mechanisms to help stimulate innovation and experimentation over the past five years. Hundreds of projects, almost impossible to catalog [2] have been spurred on, leading to criticisms of 'pilotitis', or the unfettered proliferation of lightweight mHealth 'solutions' which fail to translate or scale into health systems. Over the past few years, a conversation has emerged about the need for generating evidence of improvements in health system processes and ultimately, patient outcomes, attributable to the integration of mHealth strategies [3].

This 'call for evidence' has been echoed by many groups, including the World Health Organization, culminating in 2011 by a global statement endorsed by leading research and implementation agencies - the Bellagio Call to Action on Global eHealth Evaluation [4]. This reflected an effort to acknowledge the criticized "hype" associated with innovation in the mHealth space, and to affirm, across a wide range of stake-holders, the critical role that evidence plays in promoting these strategies. The Bellagio statement calls for rigorous evaluation "to generate evidence and promote the appropriate integration and use of technologies. . .to improve health and reduce health inequalities" [4]. Other groups, such as the Robert Wood Johnson Foundation, McKesson Foundation, the National Science Foundation and the Office of Behavioral and Social Sciences Research at NIH have begun to invest in rigorous testing and evaluation of mHealth strategies; and through the UN Innovations Working Group, the Norwegian Agency for Development Cooperation (NORAD) supports mHealth implementation research. Discussions catalyzed by these stakeholders have resulted in calls for the development of robust but novel research designs for analyzing data obtained from mHealth applications [5]. Mechanisms to help policymakers assess the weight of evidence in mHealth have also been identified as a gap in this space, requiring the adaptation of existing systems such as the GRADE framework or the CONSORT-EHEALTH checklist [6,7].

Despite concerns about dearth of evidence and potential commercial pressures driving mHealth to the forefront of policy discussions, it may be reassuring to view this first era of experimental proliferation as a natural state within any new domain of disruptive technology or health systems innovation. We may, however, be entering into a second, more empirical

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era of mHealth. The landscape of mHealth evidence is changing rapidly, with an increasing number of mHealth research projects underway and the peer-reviewed literature on mHealth growing exponentially. This focus on evaluation is also reflected in now two published Cochrane reviews of text messaging interventions as strategies to improve ART adherence (n = 2 studies) and optimize smoking cessation programs (n = 5 studies) [8,9]. To further assess the state of the mHealth research landscape, we conducted a search on the US government federal clinical trials tracking system (http://clinicaltrials.gov). We used the keywords "mHealth", "mobile" or "cell AND phone" individually to search the database and identified 1678 search results. We manually inspected each result to check if it fit the purview of an mHealth project, i.e., a project where mobile or wireless communication device were used for the "provision of health services and information" [10]. We included completed and active studies, but excluded studies that were withdrawn or terminated prior to completion (n = 3). This search found, as of November 14, 2012, 215 unique registered studies of mHealth technologies on this website, many of which (81.8%, n = 176) employ classical randomized controlled trial designs. Of the 215 studies, 40 new studies were added to this database in the 6-month period between May and November 2012 alone. We are in the process of further analyzing and classifying studies based on health areas, location, mHealth strategy used, and methodology used for evaluation. The WHO has convened a new task force – the mHealth Technical Advisory Group (mTAG) – to distil this growing body of information and evidence and provide guidance to governments and implementing agencies on promising, evidence-based strategies to improve health systems and, ultimately, outcomes.

As the evidence base continues to be strengthened using both conventional and novel methods of evaluation, the gradual adoption of mHealth into mainstream health systems can be expected. The lowest-hanging fruit of success will likely be the use of mHealth strategies to improve coverage and quality of known health interventions. Identifying the least disruptive 'fit' within existing health systems may make mHealth strategies more palatable for systems that normally eschew changes to status quo. We agree that the potential for mHealth to leapfrog decades of foundational, infrastructure development is real. The astronomer Carl Sagan is quoted as saying, "Extraordinary claims require extraordinary evidence [11]." We agree, and posit that mHealth evaluation and the accompanying evidence base is beginning to catch up to the pace of innovation. The rigor of evidence will not only help legitimize mHealth as a valid strategy to optimize health systems, but also justify investments where resources are limited.

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