

A Reality Checkpoint for Mobile Health: Three Challenges to Overcome

The PLOS Medicine Editors*

The use of mobile electronic devices to support medical or public health practice, or m-health, is currently a hot topic. It has been predicted that by 2017 there will be "more mobile phones than people" on the planet [1], and currently three-quarters of the world's population have access to a mobile phone [2]. The World Health Organization (WHO) has announced [3] that m-health has the "potential to transform the face of health service delivery across the globe," and there is increasing media and consumer interest in m-health, illustrated for example by a recent panel at the US Consumer Electronics Show on "The Digital Health Revolution" [4]. Survey data illustrates that most regions of the world, including many low- and middle-income countries, are actively working on m-health pilot projects or have set up systems, for example, for managing treatment compliance, sending appointment reminders, or conducting surveys

However, amidst the interest (and, possibly, a bit of hype) it is worth considering whether m-health needs a reality check. Recently in PLOS Medicine, an Essay by Mark Tomlinson and colleagues [5] highlighted the proliferation of m-health pilots in many countries. However, in the Essay, Tomlinson and colleagues comment that few pilots move forward to scale-up, and there is little evidence to inform whether, when, and how, pilots might expand countrywide. Tomlinson and colleagues also raise concerns regarding the increasing interest in m-health from industry, which is likely to have very different motivations than would patients or those responsible for safeguarding public health.

At a WHO forum on data standards for e-health (defined as the use of electronic processes and communication to support health care), held in December 2012 [6] (where one of us, EV, participated), countries reported that a panoply of proliferating standards exists, many of which are closed standards, with high barriers to access; barriers include not just cost, but also the technical complexity of systems and standards and language differences. Consequently, in the rush to develop new applications, many countries

end up with a fragmented patchwork of systems, which do not talk to each other. Although these concerns were raised in the context of e-health, the same issues also apply to m-health. With this in mind, we set out three key challenges that advocates will need to overcome to fulfill the promise of m-health.

Reality Check 1: Are Your Systems Interoperable?

Interoperability refers to those properties of systems (whether software, communications, or other systems), that enable the exchange of data among systems in common formats, the use of common protocols, and ultimately the ability to work together. Interoperability is a critical issue for m-health (and for e-health more generally), because patients may have multiple clinical needs and conditions at one time, and will interact with the health systems via multiple points, providers, and professionals [7]. Although many m-health applications may appear simple (e.g., a system sending texts to patients reminding them of their next appointment), such systems will have greatest potential for wider use if they can easily and accurately exchange information with other systems-for example, microscopy images taken using a mobile phone can be securely imported back into the electronic health record.

A vision for interoperability [8] has set out what should live inside the interoperable "core" of m-health systems: standards that govern health data concepts, patient identity, data processing protocols, and mechanisms for secure sharing of patient data that preserve confidentiality. However, while common standards for all these uses do not yet exist, there is light at the end of the tunnel. As Estrin and Sim have emphasized [8], there are critical differences between the e-health and m-health fields. M-health has fewer entrenched systems than does e-health, and therefore potentially fewer legacy barriers to overcome in order to establish a new shared architecture.

Reality Check 2: Are You Using Open Standards?

Open standards and interoperability go hand in hand, although these terms refer to different properties of a system [8]. There is no single definition of "open standard," but generally this term is taken to imply that the standard is publicly available, information about its use and application is available, there are no fees for use of the standard, and the standard was developed using a consensus process [9]. Multiple "standards" exist in e- and m-health—for example, Health Level Seven (HL7) refers to a set of rules that govern how health-care systems exchange information with each other. SNOMED CT is a coded taxonomy which is used to define healthcare information concepts (e.g., to define diseases, findings, procedures, and so on. However, although both examples have been developed by nonprofit organizations, neither is yet freely available for use (although HL7 hopes to

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* E-mail: medicine_editors@plos.org

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soon make its standards free [10]). Development of open standards is particularly critical for equity in e- and m-health. Contributors to the WHO forum on data standards [6] emphasized that closed standards create a knowledge barrier for systems developers in low- and middleincome countries. Without access to the standard, programmers and policy makers cannot understand how the systems or standards work, cannot develop technical capacity, and ultimately cannot make good decisions for their country about what systems they need to develop and how. There is a need for a governing body-for example, WHO-to certify open standards and enable countries access to standards that meet key criteria.

Reality Check 3: How Will You Evaluate?

Finally, a key challenge for the m-health field relates to evaluation—not just the need for better and more evaluation, but also the challenge of knowing how to evaluate. In January 2013 PLOS Medicine published two systematic reviews of randomized trials in m-health addressing the use of such interventions to improve health behaviors, improve disease self-management, and facilitate health-care delivery processes [11,12]. Caroline Free and

5. Tomlinson M, Rotheram-Borus MJ, Swartz L, Tsai AC (2013) Scaling Up mHealth: Where is the evidence? PLoS Med 10(2): e1001382.

colleagues found that while many studies

have been conducted, many are of poor

quality, few have low risk of bias, and very

few have found clinically significant ben-

efits of the interventions. However, anal-

yses do highlight some evidence suggesting

benefits from specific m-health applica-

tions, such as those helping patients quit

smoking, improving HIV medication ad-

herence, and modestly improving aspects

of clinical diagnosis and management. The

authors emphasize, crucially, that high-

quality trials are needed to provide a much

more rigorous evidence base to inform

scale-up of m-health applications. Further-

more, the authors found very few studies

that had been conducted in low- and

middle-income countries, which are need-

ed to evaluate feasibility and efficacy of m-

health in such settings, including compar-

ing interventions with control groups that

reflect real-world conditions. However,

some viewpoints suggest that focusing

exclusively on randomized trials as the

"gold standard" for evaluating interven-

tions is too restrictive for m-health [13].

After all, m-health applications can best be

thought of as complex interventions-

because to be effective, such interventions

will entail changes to the behavior of

health-care professionals or patients who

will use them, and potentially may also

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- 11. Free C, Phillips G, Watson L, Galli L, Felix L, et al. (2013) The Effectiveness of Mobile-Health

involve changes to systems or processes involved in delivery of care. Some researchers [13,14,15] have suggested that complex interventions require a broader definition of what constitutes evidencefor example, suggesting that theoretical and qualitative approaches are necessary to help policy makers go beyond evaluating whether an m-health application works to understand why, what, and under what conditions it works (or does not work). Standards are currently being developed [15] for such approaches, termed "realist" or "meta-narrative" methods. M-health aficionados would do well to follow the emerging debate in this area and avoid taking too narrow a view of what constitutes "evidence" in this fast-moving field.

Given the challenges for m-health, cooperation and coordination between very different stakeholders will be necessary to deliver on its potential.

Author Contributions

Wrote the first draft of the manuscript: EV. Contributed to the writing of the manuscript: VB JC PS MW LC AR. ICMJE criteria for authorship read and met: VB JC PS MW LC AR. Agree with manuscript results and conclusions: VB JC PS MW LC AR.

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