

Key Issues in Mobile Health

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Abstract

mHealth or mobile health describes the use of mobile communications devices for health-related purposes. There is much interest in mHealth internationally at this time; including interest in interventions developed in New Zealand/by New Zealanders. A recent research project examined the key issues in the implementation of mHealth and the current opportunities to address those issues in the U.S. The key mHealth issues are outlined here under the themes of policy and regulation, the wireless environment, the health system, current mHealth initiatives in practice and research. This paper examines how these issues may apply in New Zealand and the current opportunities to address them. This information may be useful to those embarking on mHealth developments in New Zealand and may help to inform the inclusion of mobile capabilities within the NZ Health IT infrastructure.

1. Introduction

mHealth, or mobile health, has variously been described as ‘the provision of health-related services via mobile communications’ [1], and ‘medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices [2]. Internationally there is great interest in mHealth. In the United States alone, US\$93million is estimated to have been invested in mHealth start-up companies in the past six months [3]. Many innovative mHealth initiatives have been developed in New Zealand, including the first published randomized controlled trial of a text messaging intervention [4]. The trial conducted by the Clinical Trials Research Unit, the University of Auckland, found that the text messaging smoking cessation intervention successfully doubled short-term quit rates in comparison with a control group. This intervention was also the first to be implemented as a free national stand-alone text messaging cessation intervention [5, txt2quit, www.quit.org.nz/txt2quit] and has since been adapted for a United Kingdom population and delivered to participants there from New Zealand. A large RCT was conducted by the London School of Hygiene & Tropical Medicine, confirming and extending the doubling of quit rates out to six months [6]. Researchers at the University of Auckland were also the first to publish research on interventions using video messaging by mobile phone [7,8], and developed the first multimedia mobile phone cognitive behavioural therapy intervention [9].

A list of key issues for the implementation of mHealth initiatives in the United States was developed as part of a research project (described below) - this paper describes how these issues may apply to New Zealand. The two countries have vastly different health systems, with the U.S. a complex system of public (Medicare and Medicaid) and private insurers and both federal and state government level involvement. The current health reform there includes a huge investment in health information technology (IT) via the Health Information Technology for Economic and Clinical Health (HITECH) Act, predominantly in the national implementation of electronic health records (EHRs) and health information exchange. Other HITECH funded initiatives include 17 Beacon communities funded to demonstrate the transformative ability of health IT with respect to quality, cost-efficiency and population health. The U.S. mobile communications, or wireless, environment is also somewhat different from that in New Zealand. There are a large number of wireless networks (18+) that are represented by a not-for-profit member organisation (CTIA-The Wireless Association). Smartphones and data plans are more common than in most other countries, while text messaging has been slower to gain popularity. This is probably related to differences in consumer plans and prices, for example U.S. mobile phone users are charged to receive text messages as well as to send them.

2. Methods

During 2010-2011, I undertook a mHealth research project as part of a Commonwealth Fund Harkness fellowship in HealthCare Policy and Practice based in the United States (U.S.). This project included an environmental scan of

mHealth in the U.S., a case study of a national text messaging health information service (text4baby) supported by a large public private partnership (submitted for publication), and key informant interviews. Informants (n=27) included representatives from the federal government (Department of Health and Human Services agencies and the Department of Defense), integrated health systems, academic institutions, mHealth companies, wireless industry and sponsors of mHealth developments. Informants were identified by the environmental scan and by recommendations from people in the mHealth field and in the HHS. Semi-structured interviews were undertaken, with some themes and questions pre-specified and other themes allowed to emerge. Interviews were recorded and transcribed, and a general thematic analysis performed. Findings from these interviews included the benefits of mHealth, the priority of mHealth currently within the health system, and the key issues and barriers in the implementation of mHealth. The key issues have been summarised and opportunities for addressing these in the U.S. outlined elsewhere. This paper describes these issues as they are potentially useful for, and applicable to, New Zealand developers, health services and academics. Implications and potential opportunities for mHealth in New Zealand from the author's perspective are then outlined.

3. Results

3.1. The added value of mHealth

The main benefits of mHealth over other forms of health intervention delivery have variously been described as: the enhancement of relationships and persistent interactivity; scalability; personalisation and engagement; ability to access and transmit information anytime anywhere; alleviating some of the burden on the health system; at the same time removing geography from the equation (in terms of being able to reach almost everybody) and being able to provide 'time and place' services with location aware technology. Many see mHealth as potentially transformative, enabling a different delivery system (patient-centred rather than provider or facility focused) that will allow better care at significantly lower cost and create efficiencies within the health system.

Most people see the potential for mHealth to reach into disadvantaged and traditionally under-served populations, due to the ubiquity of mobile phone use, as one of the greatest benefits of mHealth. Indeed in the U.S. approximately one-quarter of households surveyed are wireless-only (no fixed lines) and these households are more likely to be those living in poverty, uninsured, with no usual place for healthcare [10]. Higher proportions of minority populations own mobile phones and use them for functions such as text messaging and searching for health information online [11]. However, there are as yet limited available data to demonstrate the increase in access to services or any improved health outcomes for such disadvantaged populations as a result of mHealth initiatives. It is important that mHealth developers ensure they are working to reduce barriers to care, not just efficiently managing those who are already in the system, and that reach into such populations is measured, so we can ensure that they do not widen health disparities further.

3.2. Current priority of implementing mHealth

mHealth is not widely seen as a high priority in health care systems at this time. This is mainly seen to be due to competing urgent priorities around the affordability of health care and competing health IT priorities such as the implementation of EHRs and health information exchange processes. The recent large private investments in mHealth companies in the U.S. [3] possibly reflect a move towards increasing priority that may soon be seen in the broader health care environment.

3.3. Key issues in the implementation of mHealth

The most commonly discussed issues in mHealth currently are around privacy and data security, followed by the need to prove that it works and provide some understanding of the value of mHealth to decision makers. All key issues have been categorised under the following headings.

3.3.1. Policy and regulation

A perceived lack of clarity on issues of health information privacy and data security over mobile communications technology has been seen as stifling innovation by some. However, the rules are fairly clear according to the Health Insurance Portability and Accountability Act (HIPAA) Privacy, Security and Breach Notification Rules in the U.S. and the Health Information Privacy Code 1994 in New Zealand. What is considered to be 'reasonable security safeguards' may involve new technological solutions for mobile phones or wireless networks. Some points to be aware of are that lists of mobile phone numbers alone are considered to be personal information and if held by a health agency may have personal health information implications (individuals have received a particular health service) and therefore should be

protected certainly from misuse or unauthorised disclosure. In the U.S. at least, an application or health information that is solely held on the mobile phone is considered to be the individual's responsibility.

Regulation of mHealth tools and interventions by the U.S. Food and Drug Administration (FDA) is seen as a major issue and several U.S.-based companies have applied for and received approval for mHealth tools. The FDA has issued draft guidance on the regulation of mHealth for consultation purposes, that indicates what is likely to require regulation and what may not - such as 'general health and wellness applications' and those 'not intended for curing, treating, seeking treatment for mitigating, or diagnosing a specific disease, disorder, patient state or any specific identifiable health condition' [12].

Other policy level issues that affect mHealth and other forms of telemedicine include regulations around medical practice, e.g. practicing medicine across states and across countries, and clinical role accountabilities.

3.3.2. Wireless environment

Some of the issues regarding the wireless environment with respect to mHealth include: fragmentation of the industry with multiple platforms and multiple networks; possible barriers to better solutions due to proprietary systems, patents, platforms etc; the potential cost to the public of mHealth services; a lack of clarity around the wireless networks' position in terms of issues such as health information privacy and data security; and coverage issues in some remote areas. While the U.S. may have a larger and more complex wireless network environment, the CTIA (as described above) was recently able to facilitate an industry-wide agreement to support a national health information text message service (text4baby) to ensure it would be free to the end user [13]. The two major New Zealand networks have also supported mHealth projects. For some mHealth services, such as the national quit smoking text messaging service fully funded by the Ministry of Health, ensuring they remain free to the end user is likely to be important in their uptake and continued engagement. For more expensive mHealth services, it is unclear whether this is achievable. In the U.S., networks are choosing from a variety of models including implementing mHealth solutions themselves, partnering with others to develop and implement mHealth solutions, and solely providing the services to allow health systems to implement mHealth solutions [14].

3.3.3. The Health system

The overarching issue for the U.S. health system regarding mHealth is who should fund mHealth initiatives. The potential answers to this question will be different in New Zealand but the fundamental issue is still the same. The issue of upfront costs to be covered with the promise of savings by keeping people out of clinics and hospitals is similar in many e-health and prevention services. Many decision makers feel that the tangible value of mHealth still needs to be proven in order for it to be reimbursed or funded. One point of contention is whether there is likely to be a sustainable direct-to-consumer business model.

Potential governance issues and the need for a strategic framework for the implementation of mHealth have been raised by some. This aligns with an interest in an open approach similar to the Internet, with open architecture and common standards and interfaces to allow interoperability and greater integration [15]. Integration with electronic health records (EHRs) is also seen as an important issue for clinical applications. Several concerns have been raised about the potential for mHealth initiatives to overwhelm clinicians with communications or with real-time monitoring data without an understanding of what variations will need to be acted on.

3.3.4. mHealth in practice

The main issue with current mHealth applications is an immature understanding of how to do mHealth well. There is a rapidly expanding body of mHealth applications available – particularly smartphone 'apps' – with little knowledge about what aspects of mHealth work successfully for whom and why. Many smartphone apps are not well used [16]. Much of the existing research evidence is on the use of text messaging [17-19]. However, even with messaging there is much as yet unknown about how to achieve mHealth's full potential, for example, how to maintain engagement, the optimal frequency of messages, whether the elderly will accept and use such initiatives, and how people process snippets of information within the context of their daily lives. It is also considered a barrier that there are so many players developing their own systems with a lack of integration that is not helpful for patients or the public.

3.3.5. Research

Randomised controlled trials are the gold standard evidence of effectiveness in health research. However there is debate over whether RCTs are required on all forms of mHealth, for example where it is merely providing access to information or effective services that the target population otherwise has little or no access to [20, 21]. Also, aspects of design, such as the appropriate comparator and measures, are up for debate. Much of the discussion has arisen due to the obvious mismatch in pace and flexibility between mHealth and mobile technology advances and traditional research practices, with the potential for platforms or tools to be out of date by the time a study has been completed. Potential alternative designs are currently being considered by the U.S. National Institutes of Health and the Robert Wood Johnson Foundation [22,23].

A summary of the issues is shown in Table 1.

4. Implications for New Zealand and opportunities to address the issues

There are vast differences between the health systems in the U.S. and New Zealand, and also differences in the wireless environments. Despite this, the issues and implications are similar. mHealth has potential global applications with local adaptations, and therefore issues in implementation may involve both global and local solutions.

The opportunities to address the issues outlined above are similar in New Zealand as those suggested for the U.S.

- New Zealand is already ahead to some degree with widespread use of electronic medical record systems in primary care and a greater acceptance of shared electronic health information. The National Health IT Plan is extending this further with a national strategic approach to the next stage of health IT developments, working towards accessible patient-centered electronic health information [24]. It is suggested that these projects consider mobile devices and capabilities in planning ahead for future service improvements, so that effective advances in mHealth can be incorporated where appropriate.

Table 1 - Summary of Key Issues in mHealth

	Issues
Policy & regulatory	Privacy and data security FDA regulation as medical devices Medical practice across states/countries Bandwidth/spectrum availability
Wireless networks	Working across multiple networks Working across multiple platforms Cost to the public/end-user
Health system	Lack of sustainable business models Lack of reimbursement Lack of understanding of value Clinical roles and accountability Integration into EHR and systems Competing health IT priorities
mHealth practice	Lack of knowledge of how to do it well Wrong focus (population, technology, or content) Governance Integration into practice and systems Lack of theory and evidence-base
Research	Need more high quality research Need to demonstrate value and cost-effectiveness Mismatch in pace and flexibility between research and technology development Measuring reach/access for underserved

- Collaborations across wireless networks, mHealth IT industry, health services and researchers to ensure an enabling environment, with shared definitions and standards, capacity for interoperability and integration, and development of mHealth initiatives that are feasible and useful for the New Zealand health system. An open and collaborative approach, particularly in a relatively small country, may help us to move forward quicker than many more complex and competitive systems. A good place to start would be within primary care, where New Zealand already leads internationally with respect to access, multidisciplinary care of the health of defined populations, and meaningful use of health IT. With the U.S. and other countries looking towards reform of primary care (e.g. the Patient Centered Medical Home [25]), integration of effective mHealth interventions and initiatives within this environment would ensure our position as a leading example of health innovation globally.
- Globalisation of mHealth and health IT solutions mean that we should be aware of and where possible adhere to international guidelines and standards, for example around health information privacy and regulation.
- Improve what we do in mHealth practice and research. This is the same in New Zealand as in the U.S. We have developed a robust process that appears to be appreciated internationally. That is, starting with the problem, using evidence and theory as a basis for developing mHealth interventions, involving end-users extensively throughout the process with early design input and pretesting, learning from previous research, and testing effectiveness in large high quality research trials. Even where such trials are not possible, it is vitally important to evaluate mHealth developments and disseminate learnings in order to build the body of knowledge and to continue to iterate and improve what we do for better health outcomes.

5. Conclusions

mHealth has the potential to be transformative in health care delivery although there are still many issues facing the successful implementation of mHealth initiatives. These issues include those relating to the regulation of mobile medical devices, policy issues such as privacy and data security, difficulties working across wireless networks and platforms, a lack of clarity around cost-effectiveness and who should fund such initiatives, integration into clinical practice and health information systems, a lack of effective demonstration projects based on good science, and issues with conducting high quality research.

New Zealand has previously led the way in many areas of health IT and in mHealth research and implementation. A collaborative and strategic approach to mHealth, and a focus on its application within primary care and integration into electronic medical records systems, could be a worthwhile priority.

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