Mobile Health Information Technology: US Public Policy Considerations

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CERTIFICATE OF APPROVAL

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US Public Policy Considerations for Mobile Health Information Technology

Abstract

There are increasing reports of the benefits of the adoption of mobile health (mHealth) technology such as PDAs and smart phones for health services, data collection, treatment support, and information dissemination in the practice and delivery of health and prevention services and public health. Mobile health information technology (HIT) is rapidly growing and has potential to improve care processes, expand access to care, augment other technologies, and reduce the costs of care. Increasingly, individuals around the world are using mobile technologies/devices to access health services. In addition, health care and public health professionals are integrating mobile technologies into public health practice and clinical care activities. The "reach" of such technological advancements has yet to be fully realized. The definitions of mHealth vary but generally all relate to the delivery of health-related services to patients, consumers, clinicians and caregivers through mobile technology platforms on cellular or wireless networks. Mobile technologies include tablets, cell phones (hardware and software), smart phones, mobile-enabled diagnostic devices, or devices with mobile alert systems.

Objectives. The purpose of this paper is to review the evolving US public policy environment related to the use of mobile health information technology with a focus on cell and smart phones for health and wellness

Methods

With the assistance of a librarian from OHSU, the author searched the Pubmed database and Google Scholar using the following terms: wireless health, mobile health, mHealth, mobile phones, smart phones, cellular phone, and mobile devices. The author also reviewed the reference lists of identified studies and relevant articles. Inclusion criteria were publications that related to the importance and challenges of mHealth technologies and applications, their potential impact on care delivery in the US and related public policy issues. The searches were limited to articles published in English during the period between 2000-2011 that focused on the use of smart and cell phone in the US. The searches were performed in June 2011.[1] Leveraging the review of the original sets of papers as well as additional sources that became available since

2011, the author describes the evolving "state of the use of mHealth" and provides suggestions for future US public policy considerations.

Conclusions

Devices such as cell phones and smart phones are likely to continue to proliferate with increasingly sophisticated functionality and practicality. The numbers and variety of applications for mHealth devices are increasing. The rapid and evolving technologies are outpacing current US health policy abut mHealth applications and their use. US public policy efforts that are inclusive and that consider various types of technology would help assure safe, effective and efficient adoption and use of mobile health information technology (HIT) solutions in the US.

Despite the ongoing and growing interest in mHealth, in-depth examination and synthesis of what works and does not work has yet to be rigorously assessed and established in the US. The extent to which the use and adoption of mHealth contributes to the effectiveness in informing action and impacting health outcomes in not clear. It appears that the literature on the use of mobile technologies for information support for health professionals and service delivery in the US is growing but at present remains mostly anecdotal and fragmented.

Furthermore, there is a need for a more strategic approach in order to implement mHealth interventions on a broader scale and to study how the technology can improve health outcomes. While there is a growing literature base that documents the promise of mHealth the current evidence base does not seem to be sufficient. While mHealth has great potential, current research does not clearly indicate the extent to which there is evidence for actual and wide-scale health impacts. **Keywords**: wireless health, mobile health, mHealth, mobile phones, smart phones, cellular phone, cell phones, US public policy, mobile apps, and mobile devices

US Public Policy Considerations for Mobile Health Information Technology

Introduction and Background

The mobile health area of health information technology (HIT) is rapidly growing and has potential to improve care processes, expand access to care, augment home care technologies, improve efficiency, and reduce the costs of care. Increasingly, individuals around the world are using mobile technologies, especially cell and smart phones, to access health services. In addition, health care and public health professionals are formally and informally integrating mobile devices and technologies into public health practice and clinical care activities. [2] There is a fundamental paradigm shift from the use of cell and smart phones as phones and their use(s) for a vast array of other functions including banking and e-commerce.

There are questions about whether a distinct field of mobile HIT (mHealth) exists; how to define it, and if and how it relates to other discussions and policies about HIT, ehealth, telehealth and telemedicine. There is acknowledgement that individuals around the world are using mobile technologies to access health services and health information and that health professionals are integrating mobile technologies into health care, prevention, and wellness activities. [3, 4] The growing use and adoption of mHealth technology in clinical care and public health for health services delivery, data collection, treatment support, and information dissemination is increasingly documented.[5, 6, 7, 8] There is an accompanying proliferation of mobile applications ("apps") available to consumers. Questions about which agencies oversee and regulate what components or aspects of mHealth are not always clear, in part due to the wide array of US Federal agencies and Departments that are involved in various aspects of mHealth public policy, guidance, and regulation about devices, technologies, infrastructure, and applications.

Methodology.

With the assistance of a librarian from Oregon Health Sciences University (OHSU), the author searched several electronic databases (such as PubMed, EMBASE and the Cochrane Controlled Trials Register and Database of Systematic Reviews) using the following terms: wireless health, mobile health, mHealth, mobile phones, smart phones, cellular phone, and mobile devices. The author also reviewed the reference lists of identified studies and relevant articles. The review sought to include studies (reported in English) that reported on the use of mHealth, focusing on

outcome measures, including health-related behaviors, health service utilization, disease status, quality of life and functional outcomes. A total of 767 articles were initially identified for potential review using the keyword search and proposed inclusion criteria. Following an initial screening of the abstracts, a preliminary summary of 125 articles was compiled that depicted the study design, intervention methods, sample size and clinical outcomes that were extracted from each included publication.

Inclusion criteria

- Time frame 2000–2011
- English language
- Study conducted on use of cell or smart phone in the US
- Describes/applies an explicit evaluation/outcomes methodology
- Includes outcome measurements

Exclusion Criteria:

- Outside the time frame
- Studies published/available in languages other than English
- Studies focused on care in countries other than the US
- Studies focused on areas other than health service delivery, e.g., acceptability of mobile phones; health risks associated with cell phones"

Limitations.

The initial, intended literature review was delayed due to a variety of logistical factors. Furthermore, during the course of the initial data collection, the author became aware of several published systematic reviews on the topic [9, 10, 11] The identified studies included pilot studies, randomized-control trials, mixed methods studies, cross-sectional studies, cohort studies, qualitative studies (interviews), literature reviews, grey literature such as governmental and association publications and reports, and cost-analysis studies.

An additional effort to expand and update the intended literature review along with further screening and analysis would allow classification of the studies into topics according to mHealth benefits and types of intervention such as "patient follow-up and medication adherence", "patient education and awareness", "remote monitoring", "disease surveillance", "data collection", "intervention monitoring" and "data collection/transfer and reporting". Since many of the identified mHealth projects focus on various chronic conditions and diseases such as cancer, heart disease, HIV, and diabetes[12] an expanded review of the types of conditions, diseases, and populations is also recommended.

Objectives.

The purpose of this paper is to review the US public policy environment related to the use of mobile devices such as cell and smart phones for health and wellness. This paper provides a snapshot of the use of mobile health information technology and applications in the US, along with findings and recommendations for future US public policy considerations. The paper is largely based on the original set of 125 studies obtained for the initial literature review as well as from the reviews of additional trade and professional publications. However, additional sources beyond those originally identified were been used.

Definitions.

The description of mHealth varies, but in general refers to the delivery of health-related services to patients, clinicians and caregivers through mobile technology platforms on cellular or wireless networks.[13, 14] Mobile technologies include tablets, cell phones (hardware and software), smart phones, mobile-enabled diagnostic devices, and devices with mobile alert systems. Among various definitions, the term "mobile health", or "mHealth", has been described as "mobile computing, medical sensor, and communications technologies for health care." [15, 16] mHealth is also used to describe informal and formal health-related uses of voice and text functions of basic mobile phone handsets or more sophisticated algorithm-based decision-support and data collection tools accessible through smart phones.[17] Mobile health has also been described broadly as the ability to provide and receive healthcare treatment and preventative services outside of traditional care settings. [18, 19, 20]

mHealth often refers to portable devices with the capability to create, store, retrieve and transmit data in real time to improve patient safety and the quality of care. In general, the flow of mobile health information can be characterized by portable hardware coupled with software applications and patient data that travels across wireless networks. [21] More broadly, other technology and devices that can be considered mHealth include remote patient monitors, video conferencing, online consultations, personal healthcare devices, and wireless access to patient records and prescription applications (i.e., using a cell phone, smart phone or wireless tablet). mHealth can also include the physical/virtual integration and interoperability of devices such as heart rate monitors, pulse oximeters, embedded sensors, and wireless scales. [22, 23,]

The mHealth Market

Events in the public and private sectors depict the growth and potential of mHealth, particularly in the US. [24,25,26, 27] According to the Centers for Disease Control and Prevention (CDC), 39.4 percent of U.S. homes report having at least one wireless device and no landline telephone. Approximately 38 percent of adults (99 million) and 45.4 percent of children (33 million) live in wireless-only homes.[28] Reaching average downstream speeds of 1,387 kilobits per second, mobile network connection speeds more than doubled in 2013 from 2012. [29] Wearable devices will represent 50 percent of app interactions by 2017. [30] A recent study looked at more than 40,000 healthcare apps available for download in the U.S. Apple iTunes app store and found that most efforts in app development have been in the overall wellness category, with diet and exercise apps accounting for the majority available.[31]

According to the Pew Internet and American Life Project, 9 in 10 Americans own a cellphone; over half of these are smartphones. [32] Apple iTunes reported that there were 10,000 medical, health care and fitness applications.[33] Furthermore, over 500 million people, about one-third of smart phone users, are expected to use health care mobile applications on their smart phones by 2015. [34] One study estimated the annual consumer market for remote/mobile monitoring devices to be $7.7 billion to $34 billion.[35] Forty percent of consumers surveyed said they would pay for remote monitoring devices and a monthly service fee to send data automatically to their doctors. [36, 37]

Innovations in the technology itself as well as enhancements to broadband access are propelling the mHealth marketplace. There is a wide range of applications and functions documented most frequently in pilot projects, and a few as large scale implementations within health programs. [38] Examples of mHealth uses and applications and overarching goals and objectives for mHealth technologies are noted below: [39, 40, 41, 42]

- Bi-directional communication between patent and clinicians[43]
- Clinicians sending text messages as an adjunct and follow-up to treatment.[44]
- Collecting vital statistics
- Collecting (remotely) data health indicators and transferring the data to another location/clinician [45]
- Conducting disease surveillance
- Monitoring patient status, compliance
- Monitoring personal fitness such as physical activity or weight
- Providing medical education and training
- Providing information to individuals [46]
- Reminding patients to take their prescription drugs[47]
- Remotely accessing or monitoring information, data, patient health records

Remote monitoring allows health care providers to manage their patients' medications, potentially reducing the frequency of hospital visits, and improving patient care. Wireless technologies enable home-use medical devices to transfer information from several sources into patient and electronic health records.

mHealth Market Trends

Portable technology through the use of wireless devices is a rapidly expanding segment in the communications and information technology industries. The GSM Association estimates that it took 12 years to reach 1 billion connections, but only 30 months thereafter to reach 2 billion connections. [48, 49] Numerous market and financial analyses assess the evolving financial, business, technical, regulatory and operational aspects of mHealth. [50,51,52,53] Reports provide estimates about potential revenue from digital health technology as well as data regarding the thousands of mobile health applications designed for smart phones and the extent to which such

applications are aimed at and being adopted by health care professionals. The reports forecast that mobile and wireless health care services will expand significantly as will the numbers of smart phone and portable tablet users and mobile health applications. [54 ,55, 56.57]

The deployment of mHealth technology in developing countries for health care delivery and public health services, data collection, treatment support, and information dissemination), has been widely documented. [58,59,60,61,62, 63] While mHealth adoption within in the US has been slower, recent activities depict the growth and potential of mHealth. [64,65,66] The literature suggests that mobile applications and technology have the potential to reduce medical costs and errors, reduce geographical and economic disparities and reinforce consumer-focused and personalized healthcare. With millions of wireless subscriber connections in America, mHealth solutions are viewed as vital to making healthcare more efficient, effective and patient-focused. [67,68,69,70,7172]

There has been an increase in the number of organizations focusing on various aspects of mHealth. For example, the mHealth Alliance[73] was formed in February 2009 by the Rockefeller Foundation, United Nations Foundation and Vodafone Foundation to facilitate global innovation and ensure maximum impact in the field of mobile health. The Alliance hosts HUB (HealthUnBound), a global online community for resource sharing and collaborative solution generation.

The Wireless Health Academic/Industry Conference was established in 2010 to provide the highest profile academic and industrial research forum for the emerging field of Wireless Health. Their meetings aim to provide a forum for practitioners and researchers to interact and exchange experiences about theoretical and practical aspects of wireless healthcare networking and systems. [74]

CTIA-The Wireless Association® is an international nonprofit membership organization of wireless carriers and their suppliers, as well as providers and manufacturers of wireless data services and products that has represented the wireless communications industry since 1984. They assert that through mobile applications and technology, mHealth solutions have the potential to reduce medical costs and errors, remove geographical and economic disparities and

reinforce consumer-focused and personalized healthcare for millions of people regardless of location, race, age, gender or disability. [75, 76,77]

The mHealth Working Group,[78] started in 2009 and is now an international community of over 1400 members representing more than 450 organizations in 70 countries. Its mission is to frame mobile technology within a larger global health strategy. By applying public health standards and practices to mHealth, the working group promotes approaches that are appropriate, evidence-based, scalable and interoperable in resource-poor settings.

The Knowledge for Health (K4Health) Project [79] is a health knowledge management project of the U.S. Agency for International Development (USAID) Bureau for Global Health, Office of Population and Reproductive Health. One of K4Health's growing practice areas is mHealth—the use of mobile technologies (including phones, tablets, and netbooks) to improve public health. [80]

Public Policy Obstacles and Challenges

The increased interest and attention on mHealth presents additional complexities and areas of potential concern and challenge. There are several uncertainties surrounding regulation and reimbursement, data and device integration standards and interoperability, privacy and security, and the lack of clear evidence that mHealth solutions are viable on a wide scale and can deliver real efficiencies, outcomes and results. Adding to the complexity of mHealth regulation and payment is the difficulty in distinguishing between consumer electronics and clinical devices. [81, 82] Tracking the sheer volume and types of mobile devices, technologies, and applications and their use also presents challenges.

Multiple U.S. Federal agencies, the Administration and Congress have various efforts underway and planned regarding mHealth. These include funding and offering mHealth applications, convening meetings, providing training and education, and conducting evaluations of mhealth. Federal Agencies such as AHRQ, NIH, and the DHHS Office of Minority Health fund research and grants in mHealth. [83] Various Federal agencies have jurisdiction over aspects of mobile health information technologies and software development, adoption, and use (including safety and efficacy). However, it is not clear which agency (ies) ultimately will have oversight for

specific components of this evolving field; nor is it yet known the extent of US regulation and guidance.

For example, the NIH has offered training for early career investigators with interest in mHealth,[84] and has convened workshops on evidence generation. [85] DHHS has established a mobile health Community of Practice (CoP) to assist in an evaluation of mHealth activities and practices across the department.[86] The Agency for Healthcare Research and Quality (AHRQ) identifies and monitors emerging technologies and innovations in health care and maintains an inventory of emerging technologies.[87] Several federal agencies have launched mhealth applications and launched contests to stimulate development of mHealth applications. [88, 89, 90, 91, 92, 93, 94]

Legislative and Regulatory Issues

A number of dynamic regulatory and legislative activities demonstrate the ongoing and evolving public policy complexities and concerns about mHealth. Examples of activities in this arena are described in the following sections. In some instances mHealth is included as part of overall HIT efforts.

Privacy and Security

Agencies such as the Commerce Department's National Institute of Standards and Technology (NIST) offer guidance that provides a structure that organizations, regulators and customers can use to create, guide, assess or improve comprehensive cybersecurity programs for cybersecurity. [95] NIST also released a "Roadmap" document that depicts a future framework to identify and address key areas for cybersecurity development, alignment and collaboration.[96]

The U.S. Department of Health and Human Services' Office for Civil Rights (OCR) is responsible for implementing and enforcing the Privacy and Security Rules of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and has included numerous incidents of security breaches related to mobile devices in its public reporting. [97, 98,99]

Stage 2 Electronic Health Record Incentive Programs Final Rule and CMS Meaningful Use Stage 2 guidance explain that eligible professionals or hospitals must conduct or review a security risk analysis that includes addressing the encryption/security of data stored in certified

EHR technology.[100,101] ONC's 2014 Edition Standards and Certification Criteria explains that if data is locally stored on a mobile device that is a certified EHR technology, the EHR technology must be designed to encrypt the locally stored electronic health information by default.[102]

The Federal Trade Commission (FTC) works for consumers to prevent fraudulent, deceptive, and unfair business practices and is involved in consumer privacy and data security, including issues arising in the mobile and health areas. In 2013, the FTC issued guidance specifically for mobile applications.[103] The FTC also introduced a data security guide for developers.[104]

In February 2013, President Obama issued Executive Order 13636: Improving Critical Infrastructure Cybersecurity. The order calls for the development of a voluntary, risk-based Cybersecurity Framework—a set of existing standards, guidelines and practices to help organizations manage cyber risks.

Patient Safety and Regulation of mHealth Apps and Devices.

In 1989, FDA prepared a general policy statement (FDA Policy for the Regulation of Computer Products) on how it planned to determine whether a computer-based product and/or software-based product is a device, and, if so, how the FDA intended to regulate it. Since 1989, however, the use of computer and software products as medical devices has grown exponentially, and the types of products diversified and grew more complex. In 2005, the Draft Software Policy was withdrawn after the FDA determined that the draft policy did not adequately address all of the issues related to the regulation of all medical devices containing software.[105, 106] In 2011, FDA released draft guidance to clarify its intentions with regard to regulation of mobile health information technology.[107]

In 2012, Congress mandated, (via the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 (Pub. L. 112-144)) and directed the Secretary of the Department of Health and Human Services (HHS), to publish a proposed strategy and recommendations for an appropriate risk-based Health IT regulatory framework that would include mobile medical applications and promotes innovation, protects patient safety, and avoids regulatory duplication. In May 2013, the FDA, ONC and the FCC jointly sought "broad input" on what elements should be considered for a risk-based regulatory framework to be proposed for health IT. The

framework addresses mobile medical applications, innovation, patient safety and regulatory duplication. [108,109,110]

In September 2013, the FDA issued its final guidance on mobile medical applications, [111] and indicated that it is focusing its oversight on mobile medical apps that: *are intended to be used as an accessory to a regulated medical device; or transform a mobile platform into a regulated medical device.* [112] [113]

In October 2013, the Sensible Oversight for Technology which Advances Regulatory Efficiency (SOFTWARE) Act [114] was introduced in the House of Representatives to provide regulatory clarity regarding mobile medical applications. [115] The Preventing Regulatory Overreach to Enhance Care Technology (PROTECT) Act of 2014 was introduced in the Senate as a companion bill to the SOFTWARE Act. Both bills seek to limit the FDA's statutory authority in regulating clinical and health software. The PROTECT Act removes FDA regulation from some high-risk clinical decision support (CDS) software, mobile medical apps and other medical device functionality. The proposed legislation would make NIST the federal agency with oversight responsibility for technical standards used by clinical software. [116, 117]

In March 2014, the FDA proposed to simplify the way it classifies and reclassifies medical devices, opting to do so by administrative order rather than a rulemaking process and issued a Notice in the Federal Register seeking public comment.[118]

Connectivity, Infrastructure and Broadband

There is growing complexity and possible confusion about which parts of government have jurisdictions over connectivity for mhealth. For instance, President Obama announced his National Wireless Innovation and Infrastructure Initiative that would expand wireless coverage in the U.S. [119]

The FCC established a new healthcare taskforce to focus its national broadband efforts on connectivity; through health IT solutions like e-care, to improve access/utilization, care coordination and ensure privacy and security. The FCC's discussions with the FDA will ultimately determine the FCC's role of regulating general purpose communication and the

FDA's jurisdiction over devices used for medical purposes. In August 2013, the FCC appointed its first Director of Healthcare Initiatives to manage and oversee the FCC's work. [120]

In March 2014, the FCC announced the launch of a new Connect2Health Task Force, to better intersect broadband connectivity, and advanced technology and health, and to consider ways to accelerate health IT adoption by leveraging broadband services. The FCC authorizes a wide variety of Radio Frequency-based medical devices. It also authorizes carriers whose networks are used by a wide variety of mobile devices to access, store or transmit health information, and it establishes technical rules used by Wi-Fi and other similar networks.

Given the complexity of the issues and the evidence of several pieces of legislation that pertain to various aspects of the mHealth continuum, there is an increasing need to sort out the relevance of these rules, regulations and guidances. There are also evolving tensions between government regulators and the private sector business community to balance the needs for patient safety with the desire to promote technological innovation.

Public Policy Issues

There is a growing global interest to take advantage of the overall improvements inherent in the uptake of mobile communication technologies and telecommunications. The field of mHealth is evolving and transforming healthcare delivery in the US. A number of technologies, approaches, and applications are converging: mobile and wireless devices, EHRs, personal health records (PHRs), health information exchange (HIE), imaging, remote monitoring and video conferencing. Mobile phones and other portable health information technologies offer unprecedented opportunities to improve the health of the U.S. population and reach traditionally underserved subgroups (e.g., rural communities, disenfranchised urban communities, low-income groups, and ethnic minority populations). [121] In the US, it is particularly important to sort this out because of a broad array of legal and regulatory implications. Long-term growth and market potential of mHealth may depend on the longer term evolution and reform of the US healthcare structure, including new forms of payment as well as healthcare delivery. [122] In part, because of the varying interpretations of terms and terminology, it is not clear which Federal agencies can and should address certain aspects of public policy considerations for this growing array of devices, technologies, infrastructure, and their uses within the health eco-system.

Need for comprehensive mHealth strategy. There is a pressing need for an overarching comprehensive and cohesive national strategy on health IT (including mhealth (mobile medical devices and applications); telehealth; embedded and implantable devices; wireless devices and technologies). Such an approach would allow for identification and reconciliation of potential ambiguities, overlap, redundancies, inconsistencies and deficiencies in existing policies. It would also help provide clarity on current or anticipated overlapping issues; promulgate a cohesive and comprehensive public policy that is technology independent/neutral. For example, at one end, general-purpose communications devices such as smartphones, video-conferencing equipment and wireless routers are regulated solely by the FCC when not created or intended for clinical purposes.[123] At the other end, devices such as remotely controlled drug-release devices are regulated by the FDA. However, the growing variety of devices and applications that leverage communications networks to transmit information or to provide decision support to both clinicians and consumers presents challenges to the current approach to federal regulations.[124]

There is a growing need to adjudicate the inter-relationships between agency oversight and jurisdiction activities (for example, how broadband access and/or limitations could impact the ability of providers to meet Meaningful Use requirements). Thus, public policy efforts should:

- Accept the ubiquitous nature of HIT (including mHealth) and the increasing convergence between communications, consumer, and clinical technologies and devices and anticipate ongoing technological advances and cultural shifts
- Respond to legal and practical concerns regarding privacy and confidentiality of patient data and information and overcome interoperability problems stemming from differences among organizations, proprietary systems, terminologies, the coding and structuring of data and information. [125] Concerns about the privacy and security of health data are not new[126, 127] and continue today as the potential technological capabilities of mobile devices and applications increase. [128, 129 ,130 ,131 ,132, 133 ,134, 135, 136, 137]
- Identify potential adverse or unintended consequences mHealth as part of the discussions underway relating to other components of HIT, such as adverse event reporting to Patient Safety Organizations (PSOs)[138] and the SAFER Guides. [139]

Cohesive and comprehensive public policies to address mHealth as part of efforts involving the larger picture of health information technology (HIT). Confusion about what falls under

telemedicine, telehealth, ehealth or mHealth is increasing as communications and information system techniques and technologies have advanced and converged. Yet, it is not clear if the distinctions are valid for public policy considerations or simply differences in semantics. mHealth public policy needs to focus on strategic public and population health areas such as: smoking cessation, emergency response/preparedness, early childhood health, maternal/child health, chronic diseases (such as heart disease, diabetes, and mental health), oral health and obesity. [140] Other policy efforts could address the availability, use, and adoption of mHealth for potentially socioeconomically disadvantaged, needy, remote and vulnerable populations /sites/communities (such as elderly, racial and ethnic minorities or low-income rural and urban communities).

Ongoing and focused research and evaluation. Public policy needs to assure that there is an evidence base on the effectiveness of mhealth devices, technologies and applications as part of current, ongoing and planned health information technology (HIT) initiatives. HIT (including mHealth) is dynamic and new/emerging technologies and their potential uses needs to be tracked and explored. Many technologies and devices are purported to or may hold potential to diagnose, treat, or otherwise manage a particular condition or to improve care delivery for a variety of conditions. Yet, the specific circumstances in which these new and evolving interventions might work and their potential impact on clinical care, the health care system, specific types of patients, patient outcomes, and costs is not yet well understood. The feasibility and potential of mHealth implementations for patient adherence to treatment and follow-up is unanimously agreed upon across the studies. However, the reproducibility and scalability of these projects is far from certain. One of the major weaknesses of studies on mHealth projects lies in the fact that the claimed benefits are unclear and long-term results remain uncertain. In addition to these technical challenges, legal issues arise in terms of privacy and security measures to be taken for obtaining, handling and transmitting data. There is insufficient discussion of legal factors, standards and regulations surrounding the use and application of mHealth for healthcare services.[141] There have been numerous reports and studies regarding health IT, unintended consequences and potential safety risks. To date, however, this work has not focused on the potential magnitude of harm and impact of mHealth.

Harmonize oversight, compliance and regulatory activities and efforts. Coordination of activities and initiatives among Federal government agencies is essential. There are an increasing number of federal agencies involved in HIT and mHealth as described above. There is a pressing need to clarify and assure all stakeholders how various agencies' activities relate to each other. Currently stakeholders need to interpret an array of increasingly complex and potentially discrepant rules, regulations, guidances, and obligations. Some mobile medical apps have been approved by the FDA and require a prescription.[142] A diverse set of public policy hurdles for widespread app-prescribing currently exist such as reimbursement and privacy and security. [143]

It is not clear if and/or which agency(ies) will ultimately be involved in protecting patient privacy, assuring data and information security, and promulgating guidance and/or regulation about mobile devices and applications in health care. Issues relating to payment for mHealth, ehealth and/or telehealth also require regulatory attention. The American Telemedicine Association (ATA) recently asked the Federal Government to allow Medicare providers paid under alternative payment methods the flexibility to use telehealth as a means to add value for Medicare and its beneficiaries. [144]

The potential role of mobile health tools in helping providers to meet the federal government's Meaningful Use (MU) guidelines for the implementation of electronic health records remains unclear. However, with the ongoing emphasis on consumer engagement, it is possible that mHealth tools will help engage patients in their own health care and data. [145, 146] Emerging state of-the-art technology raises questions about the difference between consumer health data versus protected health information. The HIPAA implications of such technology and the data collected will need to be considered when designing and implementing such systems.[147] Furthermore, increasingly, individuals are tracking a variety of health-related data via a growing number of wearable devices and smartphone apps.[148] The extent to which such data is consider protected health information and/or can be used for patient care and/or research also requires public policy discussions. [149] It is not clear where 3-D devices and/or limbs may fall along the regulation continuum.

As new devices and technologies are introduced and as their technological capabilities advance, it seems increasingly prudent to consider developing public policy (including considerations like

HIPAA) that is technology-independent/neutral so that there is a lessoning burden to update/revise the rules and regulations.

Standards and Interoperability. The need to develop new and/or harmonize/integrate standards regarding mHealth devices, applications and communications is critical.[150, 151] This will help ensure that a variety of devices from different manufacturers can use multiple networks to access different back-end analytics providers, who in turn could connect with the patient. [152] mHealth applications need to be available across diverse segments of the population, and must be able to work between and among various mobile devices, operating systems, and telecommunications networks. As with other HIT efforts there is a need to move away from proprietary, closed end-to-end solutions. The US needs policy that supports the ability of systems to communicate with each other across a dozen other devices and apps. In the end, interoperability across diverse organizations, providers, payers, systems and vendors is essential to create truly scalable mHealth solutions. [153, 154] Federal agencies efforts addressing the approval of devices and medical apps, interoperability and communication standards while at the same time balancing the need for patient safety and innovation are absolutely essential.

Overarching approach to assure adequate research about privacy and security associated with HIT including mHealth. There is also the need to establish appropriate guidelines, rules, and /or regulations for managing privacy and security issues. In the absence of applicable public policy rules, guidances or regulations, in order to maintain a secure environment for mHealth that builds trust among clinicians and patients, health care providers will need to invest in a robust mobile infrastructure.[155,156]

According to a 2011 World Health Organization report, governments cite issues related to data privacy and security and the protection of individual health information as two of the top barriers to the expansion of mHealth; at the same time protecting personal health information that is collected and transmitted over mobile devices is essential to bringing mHealth to scale and providing a mature foundation for its continued growth. [157] It appears that consumers, clinicians, and patients are adopting mobile technologies faster than public policies can adequately address and ultimately protect security and privacy.[158] The loss or theft of a mobile device with unencrypted consumer and /or patient data could result in a security breach with significant consequences.[159] Consumers are concerned that the privacy and security of their personal

information might be at risk when using a mobile device to access health records or tests online.[160] Furthermore, ongoing efforts to accelerate the inclusion of patient generated and patient mediated [health] data into electronic health records will require additional public policy attention.

There is a need for public-private sector efforts to develop and implement robust security and privacy programs in order to be able to manage and address the growing likelihood of risks associated with mobile assets and their use. All stakeholders need to make sure that their current practices for securing health information are consistent and in compliance with generally accepted security and privacy controls and standards. Furthermore, there is a growing need to harmonize and update and maintain existing regulations and guidances, such as the NIST Security Standards and 800 series publications, CMS Harmonized Security and Privacy Framework, and HITRUST Common Security Framework. There is an increasing need to clarify the scope of various rules and regulations. Various industry stakeholders have issued white papers and convened task forces on issues related to mobile and cybersecurity. [161] However, it does not yet appear that the challenges and nuances specific to health data, patient privacy and security, and infrastructure are sufficiently addressed. Ongoing exploration of the technical and technology considerations as well as related public policy issues is warranted.

Research agenda to support public policy. Despite the interest in mHealth, in-depth examination and synthesis of what works and what does not still needs more rigorous assessment. Ongoing research and evaluation to inform public policy considerations is suggested in the following areas:

- comparison studies of various applications and technologies;
- how one technology/approach works in various settings and for particular populations—what is similar, what is different);
- measure tangible health and patient outcomes
- standardized indicators for monitoring and evaluating effectiveness and impact at different levels of the health system and among settings/users

Stakeholders need to consider best practices, evolving standards, compliance and reporting/notification requirements as well as business and operational factors. The lack of such

information might ultimately hamper US efforts to capitalize on successful mHealth pilot projects.

Additionally, as the continuum of care and care coordination evolves within the U.S, the potential use of mHealth devices, technologies and applications to assist patients, consumers and their caregivers in their homes and other sites of care warrants further exploration. Remote monitoring and integration of clinical devices with other HIT is likely to offer potential benefits while it stimulates additional public policy discussions.

Ideally, efforts across the health, pharmaceutical, medical device, telecommunications, health information technology, telephone manufacturer, consumer, and life sciences communities need to be addressed so that evolving public policy challenges especially cybersecurity, privacy and legal implications, and standards and interoperability are considered. Other public policy challenges include payment and reimbursement systems for mhealth; integration of mobile health into current, ongoing, and planned efforts for EHR adoption; impact on the quality, safety, and efficacy of services; regulation of mHealth devices and/or applications; need for interoperability and data transmission standards; usability issues; ethical considerations; and liability and other legal issues related to delivery of health care across state borders.

Summary and Conclusions

This paper gives a snapshot of mHealth technology and applications in the US as well as related public policy considerations. The literature indicates increasing activities demonstrating that mHealth is thought to contribute to improvements in clinical care and population health delivery and services. Advances in wireless broadband networks, almost ubiquitous mobile phone penetration, and data access and compression technologies are providing new avenues for potential radical change in health care delivery, consumer health and wellness, and access to data and information. The literature on the use of mobile technologies to support health professionals and service delivery in the US is growing but is still mostly anecdotal and fragmented.

There is a need for a strategic public policy approach to leverage current research, evidence and findings in order to implement mHealth applications on a more tangible scale and to better understand how health information technology, including mHealth can improve health outcomes or individuals' behaviors. While mHealth has great potential, current efforts do not provide

much evidence for actual and wide-scale health and outcomes impacts.[162] While there is a growing literature that documents the promise and increasingly the results of mHealth, the current evidence base does not seem to be sufficient to adequately inform public policy.

A major challenge is to confirm which mHealth technologies should be regulated and how they should be regulated. Ultimately there is a desire to assure that the environment allows for ongoing technological innovation while assuring patient safety and trust. Efforts across the health, pharmaceutical, medical device, consumer, and life sciences communities need to be harnessed so that evolving public policy challenges especially those related to cybersecurity, privacy, and standards and interoperability must be considered. Further efforts are required to sustain public policy efforts to keep pace with the dynamic nature of the healthcare, health information technology and telecommunications industries. Ongoing public-private sector collaboration is critical.

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