

Defining a Mobile Health Roadmap for Cardiovascular Health and Disease

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Mobile telecommunication technologies have spurred growth and innovation in multiple sectors including commerce, media, and finance. Arguably, health care is the sector in which the potential of these new technologies is both the greatest and the most unrecognized. With the rapid adoption of electronic health records (EHRs) and patient access to mobile communication devices, mobile health (mHealth) is no longer a novel concept. At the 2009 meeting of the Foundation for the National Institutes of Health, mHealth was defined as “the delivery of health care services via mobile communication devices,” thereby promising not only to improve health care delivery but to ignite patient-powered research.¹

Several broad undercurrents in modern health care are likely to bolster efforts to apply mHealth to research, care delivery, and population health. First, the unsustainable rise in spending combined with an aging population in the United States is increasing the demand to promote healthy behaviors and to create innovative solutions for health care’s inefficiencies. Second, 80% of Internet users search for health information online, with more than half looking for specific information about a medical treatment or disease.² With access to online health information, patients are increasingly engaged in their own care and research; this includes virtually every age, gender, and race segment as well as those with chronic health conditions like cardiovascular disease and diabetes mellitus.² Third, with the support of a new presidential initiative, the concept of precision medicine is emerging: Precision medicine encourages prevention and

treatment strategies to be tailored to an individual patient’s genotypic and phenotypic data (including data collected by mobile devices).³ Finally, devices and health-monitoring “wearables” that can be integrated into daily life offer promise for early diagnosis and health promotion.

Cardiovascular disease (CVD) is the leading cause of death not only in the United States but in the world⁴; therefore, it is one of the largest health-related areas in which mHealth could advance health care for patients, providers, payers, and policymakers. Several modifiable lifestyle behaviors are associated with the risk of developing CVD, and control of these behaviors can significantly lower a person’s lifetime CVD risk. With a nascent evidence base, many mHealth interventions have the promise of promoting successful and sustained behavioral change. Consequently, within the field of CVD, we outlined specific opportunities for mHealth; potential challenges to the development and adoption of solutions; and a framework for developing safe, effective, and evidence-based mHealth solutions for CVD.

Landscape, Evolution, and Growth

The primary catalysts for the rapid growth of mHealth have been the implementation of health care reform and the rapid penetration of mobile phone technologies. In 2009, the Health Information Technology for Economic and Clinical Health (HITECH) Act was passed, providing \$19 billion to accelerate the adoption of EHRs.⁵ This enabled rapid uptake of EHRs, which were adopted by 78% of physicians in the United States by the year 2013.⁶ The passage of the Affordable Care Act in 2010 promoted a progressive shift of Medicare reimbursement and health care organizational structure from a fee-for-service model to a value-based accountable care organization model.⁵ This migration to value-based care creates incentives to manage patients outside hospital walls in an effort to reduce the use of acute care services, to control costs, and to improve patient outcomes. Extending ambulatory data collection capabilities may help achieve these objectives by identifying opportunities to intervene with patients outside the hospital before they need costlier services within the hospital.⁷

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The rapid global adoption of mobile phone technology has occurred in parallel with these health care reform developments. From 2011 to 2014, the proportion of Americans who owned a smartphone increased from 35% to 64%.⁸ Smartphones often contain sensors such as accelerometers and cameras that can be leveraged for diagnostic measurements. Wearable devices designed with physiological sensors that can store and transmit data have also emerged, such as watches, wristbands, cutaneous patches, and clothing. Often, these wearable devices may be wirelessly connected or “paired” with a smartphone, which allows passive or active collection, analysis, and transmission of sensor data. Sensor-collected data can be linked to powerful computing either locally (ie, phone) or through linking to the Internet or the cloud. The “Internet of Things,” a conceptual framework for networking physical devices through software, has affected medical and health-oriented devices by enabling them to collect and exchange data and move care from the clinic to the home.

The breadth and sophistication of these devices is growing rapidly. Wearable activity trackers, which measure steps taken, activity counts, time in sedentary versus upright postures, and energy expenditure, have ushered in an era of monitoring and promoting physical activity. Through the collection of heart rate data, a newer generation of activity trackers may provide insight into the intensity of activity, beyond simply measuring steps and distance. Mobile ECG platforms now enable individual persons to obtain wireless, single-lead, real-time ECGs using iOS (Apple Inc) and Android (Google Inc) devices and have achieved US Food and Drug Administration (FDA) clearance for atrial fibrillation detection. Newer wearables will have ECG and pulse oximetry capabilities. Some have anticipated that within 5 years, such wearables may be used for continuous blood glucose and blood pressure monitoring.⁹ Embedding sensors in clothing could enable even more comprehensive physiological monitoring, including a full 12-lead ECG. In the past, these basic measures have been difficult to capture in a passive and unobtrusive way outside of self-report. If these previously uncollected streams of continuous data can be translated into actionable information and presented at meaningful decision points, patients and their providers may be better able to achieve health goals and manage chronic conditions.¹⁰

These advances have led to a large flow of financial support into the mobile and digital health space. In 2014, venture capital funding of digital health companies was a staggering \$4.3 billion, which was nearly equal to that of the prior 3 years combined.¹¹ In 2014, 258 companies were each receiving at least \$2 million in funding. The top-funded categories were analytics/big data, health care consumer engagement, digital medical devices, telemedicine,

personalized medicine, and population health management.¹¹ Startups and new technologies for cardiovascular care reach broadly across these and other categories, fueled by the abundance of new sensor technologies (electrocardiography, heart rate, blood pressure, motion and exercise, and drug adherence), incentives to improve quality and decrease readmissions (eg, for heart failure, myocardial infarction), and the movement toward tailoring therapy to physiological measurements for precision medicine.

The myriad of mHealth tools can be categorized as patient facing, physician facing, or related to patient–physician communication.¹² Within each domain, mHealth tools can have a big impact by improving early disease detection, outpatient monitoring, and health promotion and disease prevention. For persons at risk, the access to diagnostic tools that can detect disease earlier (eg, identifying atrial fibrillation through a self-acquired ECG) has great promise, but careful study and implementation will be needed to mitigate the risks of misuse and false results. Outpatient monitoring can extend some of the monitoring capabilities traditionally reserved for the inpatient setting to improve transitions of care, to reduce unnecessary rehospitalizations, and to improve the quality of life for patients at home. Several established technologies have already achieved this and provide a conceptual framework for emerging mHealth technologies. Mechanisms for arrhythmia reporting by implantable cardioverter-defibrillators and pacemakers, for example, can be informative for smartphone-enabled, self-acquired ECG tools that are seeking to achieve the same diagnostic goals in a scalable and cost-efficient fashion. Telemedicine, which is the use of medical information obtained by nontraditional means of communication from one location to another for the goal of patient care, may also provide a framework in which to consider multiple aspects of mHealth tools, including approaches to evaluation, reimbursement mechanisms, and regulatory requirements. Moreover, improving cardiovascular health prevention remains an area of important clinical opportunity; wearables that can measure health behaviors and engage users through feedback have the potential to address these opportunities. A common foundation, like the American Heart Association’s (AHA’s) “Life’s Simple 7,” which is discussed in further detail below, is needed to measure, validate, and ensure the success of mHealth solutions for the prevention and management of CVD.

Challenges to the Development and Adoption of Solutions

Patient and Caregiver Perspectives

Although wearables focus on consumers rather than clinicians and health care systems, several challenges remain with regard to increasing consumer adoption. First, developers

must demonstrate that their products have durable value. After 3 months, only 80% of consumers continue to use their wearables regularly. After 1.5 years, less than half of consumers remain faithful to their wearables.¹³ Applications (apps) that require active data entry may struggle with waning consumer engagement unless the value of entering data is readily demonstrable to the patient. Second, apps may not meaningfully engage caregivers and others who are critical to the support networks that help patients with the long-term management of chronic conditions. Third, socioeconomic and demographic disparities exist in the dispersion of any innovation, and the use of mHealth applications is no exception. Elderly and lower income patients may be able to derive the most benefit from mHealth solutions, but such groups traditionally have had the least amount of access to these devices; for example, only 12% of adults aged >65 years own a smartphone.¹⁴ Nevertheless, mobile phone use is high and growing among key subgroups such as older Americans. In 2012, the Pew Research Center's Internet and American Life Project found that half of adults aged >65 years were online, and once online, 70% of these older adults used the Internet daily. Finally, the privacy of patient data remains a central concern. Consumers who use mHealth products outside of traditional health care settings may not be considered "covered entities" and thus could be ineligible for privacy protections conferred by the Health Insurance Portability and Accountability Act.¹⁵ Furthermore, health plan security breaches raise concerns about whether the manufacturers and developers of mHealth products are capable of protecting health information.^{16,17}

Payer Perspective

The adoption of mHealth approaches also depends on payers, who must think creatively about health care incentives and implementation reimbursement. The ability to motivate providers through a stimulus or incentive from payers provides a potentially powerful tool that could enhance adoption and understanding.¹⁴ Beyond possible financial encouragement, payers also have the ability to aggregate and synthesize evidence to enhance learning and utilization of mHealth tools. In addition, mHealth-enabled care management programs have allowed some payers and self-insured employers to manage prevention and wellness programs that were previously outsourced. Cost-effective solutions will uncover opportunities for accountable care organizations or other groups for which the payer is also the provider. Consumer-interfacing mHealth solutions have been particularly popular in the payer arena; these have included platforms that enhance patient engagement and consumer retention. As the patient population becomes more tech savvy, mHealth can provide more convenient ways to interact with both

payers and providers through personalized channels, allowing for additional opportunities to measure patient outcomes and experiences.

Provider Perspective

As providers increasingly share risk with payers through value-based care, mHealth tools are also focusing on providers as the purchasers of these tools. Several reasons may explain why clinicians have been the slowest of all stakeholders to adopt mHealth.

First, clinicians may be frustrated with current health information technologies, particularly the EHR. Poor workflow integration, detracting from time spent with patients, and lack of interoperability may all contribute to providers' reluctance to accept newer forms of health information technology. Furthermore, clinicians must bear the burden of acting on the additional data these technologies provide. To be useful to providers, data generated from mHealth tools can be integrated with other clinical information and made accessible through EHRs. Devices compatible with Apple's HealthKit software platform, for example, can transfer mHealth data into a patient's record in Epic (Epic Systems). Use of application programming interfaces like HealthKit to integrate patient-level mHealth and EHR data remains limited. Uncertainty about the fidelity of the data and provider reluctance to manage continuous streams of patient data without adequate decision support may be among the reasons that these application programming interfaces have not been used more widely to integrate patient data. Nevertheless, some institutions have chosen to use this approach to integrate patient data within the EHR environment to improve outpatient monitoring for chronic diseases like diabetes mellitus.¹⁸ Furthermore, providers may be more enthusiastic about using these data to personalize care for their patients if they are not responsible for monitoring continuous streams of data but instead are alerted when clinically meaningful thresholds have been crossed. Enriching EHRs with data from mHealth tools can give providers a more holistic view of a patient's condition, but this does not help patients become more informed about their own conditions; therefore, patients are no better equipped to manage their conditions. Patients have historically struggled to get copies of their EHRs. Enabling patient access and management of their own records could make them better participants in their own care and in the clinical research that will advance care for others.¹⁹

Second, to date, most mHealth interventions lack the high-quality evidence that providers and payers demand from diagnostic and treatment strategies. A recent AHA scientific statement on the use of mHealth for CVD prevention found that very few applications have undergone rigorous study; among those that have, many lacked a randomized

comparator.²⁰ Recent studies have mixed conclusions on the effectiveness of different mHealth approaches. The Tobacco, Exercise, and Diet Messages (TEXT ME) randomized clinical trial demonstrated the simultaneous benefit of mobile phone text messaging for multiple important CVD parameters including low-density lipoprotein cholesterol, blood pressure, body mass index, exercise frequency, and smoking status.²¹ In contrast, a recent randomized clinical trial showed no benefit of using smartphone-enabled biosensors regarding health care costs or use among patients with hypertension, diabetes mellitus, or cardiac arrhythmias.²² Such findings are consistent with prior studies of more traditional telemonitoring approaches,²³ highlighting that ambulatory diagnostic tools require not only long-term patient engagement but also clinical oversight to tailor care according to the generated data. Long-term patient engagement and clinical oversight will be needed to demonstrate meaningful changes in surrogate markers and, ultimately, clinical outcomes for patients.

Third, with the mixed evidence to date, providers remain unclear about not only the safety and effectiveness of mHealth but also how these digital interventions should be implemented and reimbursed. Unlike drugs that can be prescribed and devices that can be implanted, the method by which digital interventions should be administered is unclear. In the current fee-for-service environment, this is particularly the case for mHealth interventions that seek to modify downstream CVD risk by improving behavior and prevention. Finally, many apps seek to bypass traditional brokers of health care services altogether and use a direct-to-consumer model. Nevertheless, circumventing providers, rather than engaging them, may ultimately hinder mHealth products from reaching their full potential because clinicians remain the trusted brokers of accurate medical knowledge. More than 90% of people state that they turn to health care professionals when in need of an accurate medical diagnosis.²

Regulatory Approval

The rapid proliferation of mHealth products that resulted from the unbridled enthusiasm of developers and funders has created regulatory challenges for the FDA. Developers of direct-to-consumer apps have been fined for making unsubstantiated health claims. Two apps that claimed to reduce acne through colored lights emitted from smartphones were fined by the Federal Trade Commission and ultimately removed from the iTunes App Store (Apple Inc) and the Android Marketplace (Google Inc).²⁴ Another example is the Instant Blood Pressure app, which purported to measure blood pressure by using the microphone and LED light of an iPhone placed on the chest of a consumer; this app was once among the highest grossing apps in the Health section of the iTunes App Store but has since been proven unreliable. A

recent comparison of measurements from the app and from calibrated and validated sphygmomanometers revealed that the app would falsely reassure 4 of every 5 hypertensive persons that their blood pressure was not elevated.²⁵

Charged with ensuring that medical devices are safe and effective, the FDA has issued guidance to help manufacturers understand what items fall under the purview of regulators.²⁶ The FDA does not intend to regulate platforms (eg, smartphones) or mobile apps that do not meet the definition of a device under Section 201(h) of the Federal Food, Drug, and Cosmetic Act.^{25,27} Instead, the FDA seeks to apply its regulatory oversight only to “mobile medical apps” that could pose a risk to patient safety if they do not function as intended. Specifically, the FDA limits its scope to mobile medical apps intended to “be used as an accessory to a regulated medical device” or to “transform a mobile platform into a regulated medical device.”²⁶

Current Opportunities with the AHA

Mobile devices and apps can collect meaningful data to inform clinical decisions. For some acute and chronic conditions, mHealth could even improve the ability of providers to preemptively intervene by giving patients more accessible diagnostic tools and information. Ultimately, clinician engagement is paramount to maximizing the value of any mHealth product because software applications cannot actually treat patients. Many products may simply augment the ability of health care professionals to optimally provide care by matching the right patient to the right service at the right time.

The mHealth solutions could gain traction with providers by generating data on key measures of success, including quality measures and guideline compliance. Quality improvement programs supported by the AHA, such as “Get With The Guidelines” and “The Guideline Advantage,” could integrate data from mHealth solutions to improve their ability to measure quality of care and quality of life. “Connected Heart Health” is a joint initiative of the AHA and leading technology companies to help accountable care organizations deliver patient-centered care beyond the clinic; this initiative will provide further opportunities for integrating mHealth solutions directly into care delivery.

The AHA hosted an inaugural interdisciplinary forum on health technology in September 2014 to identify a framework for how mHealth could be incorporated into health care. The forum was designed to explore ways to drive innovation and collaboration in the marketplace with the ultimate goal of using health technology to improve patient outcomes. Approximately 130 leaders and 40 speakers representing various health and health technology organizations were invited to the forum. Discussions focused on ways to foster

collaboration between leaders in health care and health technology, to identify clinical opportunities for mHealth to improve cardiovascular health, to standardize key health metrics for mHealth solutions, and to determine research opportunities to advance the field of mHealth. Based on these discussions, the members of the health technology science advisory panel recommended fostering the success of mHealth solutions for the prevention and management of CVD using the AHA's Life's Simple 7 as a guiding framework.²⁸ Each of the 7 components of Life's Simple 7—eating better, getting active, stopping smoking, controlling cholesterol, managing blood pressure, losing weight, and reducing blood sugar—has gone through a rigorous evaluation process to determine the most effective assessment.²⁶ Physical activity, for example, is measured in steps, distance, calories, or minutes, depending on the type of device. The Life's Simple 7 measurement of physical activity is minutes per week of moderate and vigorous activity. In the case of nutrition, Life's Simple 7 establishes a framework for key nutrition-related measures, including consumption of fruits and vegetables, whole grains, sodium, and sugar-sweetened beverages.

With a guiding framework like Life's Simple 7, CVD prevention represents an ideal space for mHealth. Cost-efficient and scalable approaches are urgently needed to provide population-level insights into the behaviors that shape the cardiovascular health of patients. Such solutions can inform interventions that seek to effect behavioral change. Providers, payers, and professional societies like the AHA are eager to partner with mHealth developers to create safe and effective solutions. Through such partnerships, mHealth can gain the large-scale adoption that is needed to have a meaningful impact on cardiovascular health.

The Road Forward

The evolution of mHealth is still in the beginning stages, but it is a burgeoning field that represents the promising convergence of health care and mobile technologies. To have a substantial impact on patients' lives, developers must work closely with patients, providers, and payers. Through such collaborations, developers can understand the pressing problems in contemporary health care early in the design process. These collaborations will allow developers to solve meaningful problems rather than search for problems that legitimize "solutions" they have already developed. Furthermore, these collaborations will enable developers to better integrate their products with care delivery systems and providers on which patients continue to rely.

Conversely, patients, providers, and payers must help developers demonstrate the value of mHealth interventions.

Evaluation of mHealth products must generate early evidence at a pace that matches the business and software life cycles governing the development of mHealth companies and their products. At the same time, patients, providers, and payers share the responsibility for conducting longer term, outcomes-oriented studies that will produce long-term safety and effectiveness evidence, which is needed for broad-scale adoption of mHealth products. In the spirit of the inaugural AHA Health Tech Forum in 2014, future conferences are needed to bring together multidisciplinary groups from both the health care and technology fields. These meetings will help identify valuable clinical opportunities for mHealth, create guidelines and frameworks to promote success, and design evaluations that will uncover safe and effective solutions for patients.

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