ExecutiveInsight

mHealth Landscape
Reimbursement for mobile health technology is the last piece of the mHealth puzzle

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It's no surprise that healthcare delivery in the U.S. has arrived at a critical, transformative time. The healthcare costs of an aging population coupled with an epidemic in chronic disease have increased the need for care just when the pool of healthcare providers is shrinking. This healthcare gap accentuates the need for new approaches to managing chronic disease.

Many experts look to innovative technology to address this pending healthcare chasm-and for good reason. Approximately 80 percent of all physicians use a smartphone or tablet today, and consumer mobile use is even higher. This widespread adoption of data-enabled devices by patients and prescribers holds great promise for better-informed patients, more connected care networks, increased efficiencies for practitioners and payers, and even improved health outcomes. However, with thousands of solutions rapidly emerging, how does one identify the few products that will make a safe, sustainable, and meaningful clinical and economic impact?

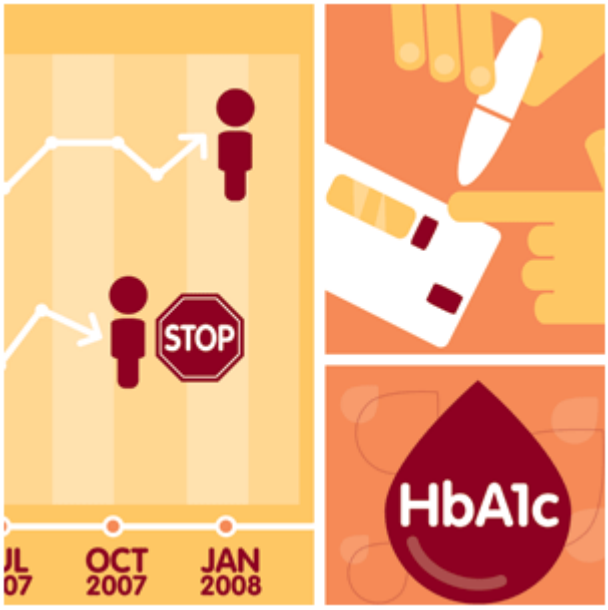
mHealth

Mobile health, or mHealth, is generally defined as the decentralization of healthcare and the empowerment of patients and providers through the use of wireless mobile devices and the internet. Because mHealth facilitates the exchange of healthcare information and/or transmission of patient data to care teams, it can lead to more meaningful patient-practitioner interactions, contextually relevant educational content, real-time disease coaching and even clinical decision support. As clinicians, patients and payers adopt these tools widely, they will generate the quality and breadth of clinical data that validates outcomes and supports their use and reimbursement.

mHealth solutions include a wide variety of innovations: personal monitoring devices, remote diagnostic tools, health and wellness apps (HWAs) and integrated care platforms (ICPs) to name a few. ICPs are mobile systems that integrate patient-reported data with clinical decision support for prescribers via an expert analytics system. Broadly speaking, these tools are designed to help patients self-manage their condition by providing them with personalized messages and content focused on lifestyle support, medication and symptom management, and care plan adherence. Many of these tools provide care teams with real-time, analyzed data to support timelier, more informed decisions.

FDA Guidelines

Of the 500,000 apps now available in the iTunes store, nearly 6,000 are focused on health and wellness. Given the dramatic rise in the availability of these tools, the mHealth market has come under increasing scrutiny by regulators who are demanding the rigors of scientific validation. In July 2011, the FDA released its new guidelines for defining mobile medical apps, calling into question the efficacy and safety of apps that purport to provide a medical benefit. The guidance states: "When the intended use of a mobile app is for the diagnosis of disease or other conditions, or the cure, mitigation, treatment, or prevention of disease, or is intended to affect the structure or any function of the body of man, the mobile app is a device."



By this definition, HWAs that were not viewed as medical devices may now fall into that category. As such, they'll face the same clinical, labeling and quality requirements as traditional medical devices. No doubt this will trigger a shakeout in the HWA category, distinguishing products whose manufacturers have invested appropriately in product development, clinical data and quality control

systems from those of nominal clinical value. Interestingly, it was the Federal Trade Commission (FTC), not the FDA, that first flexed its enforcement muscle in September 2011 by removing apps from the iTunes store for making false and misleading medical claims.

Clinical Trials

The increased regulatory oversight of mHealth products underscores the role of randomized clinical trials (RCTs). Few manufacturers have conducted trials due to their expense and the implicit uncertainty over trial results. WellDoc®, a leading mHealth company, pioneered an early path to clinical data by conducting several clinical trials in support of its groundbreaking product, the WellDoc DiabetesManager®. This software-based ICP is cleared by the FDA as a class II medical device and powered by WellDoc's proprietary Automated Expert Analytics System™.

In September 2011, the American Diabetes Association's scientific journal, *Diabetes Care,* published the results of a cluster-randomized study of a mobile phone-based diabetes coaching intervention using WellDoc's system, conducted over a one-year treatment period. The mean declines in A1c (the gold-standard measure for diabetes control) were 1.9 percentage points in the primary intervention group (usual care plus WellDoc) and 0.7 percentage-points in the control group (usual care alone), a difference of 1.2 percentage-points (P<.001). By comparison, many currently available pharmacologic agents can only claim an A1c reduction of between 0.6 and 1.5 percentage-points.

Reimbursement

Evidence of clinical efficacy is important for patient safety and for making promotional claims, but it is critical for establishing mHealth reimbursement-a critical remaining piece of the current mHealth puzzle. Once again, the WellDoc DiabetesManager is one of the first mHealth solutions to demonstrate real potential savings. In December 2011, data from a demonstration trial conducted by the George Washington University Medical Center under the supervision of Dr. Richard J. Katz, MD, showed that patients using DiabetesManager for an average of 12 months reduced their ER visits and hospital stays by 58 percent compared to the 12 months prior to the program.

The macro trends in healthcare point to the need for new approaches to delivering high-quality care while reducing costs. If mHealth is to be more than a fleeting fad, manufacturers will need to lead in the innovation of care delivery business models that address the existing healthcare ecosystem. To do this successfully, mHealth manufacturers will need to invest in FDA-worthy systems and deliver clinically validated health and economic outcomes.

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View this YouTube video featuring Dr. Charlene Quinn of the University of Maryland School of Medicine, the principal investigator of the clinical trial referenced in this article, explaining the importance of clinical trials in mobile health. http://www.youtube.com/watch?v=MA4eMdHmdEA