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Requirements of an Effective mHealth Solution

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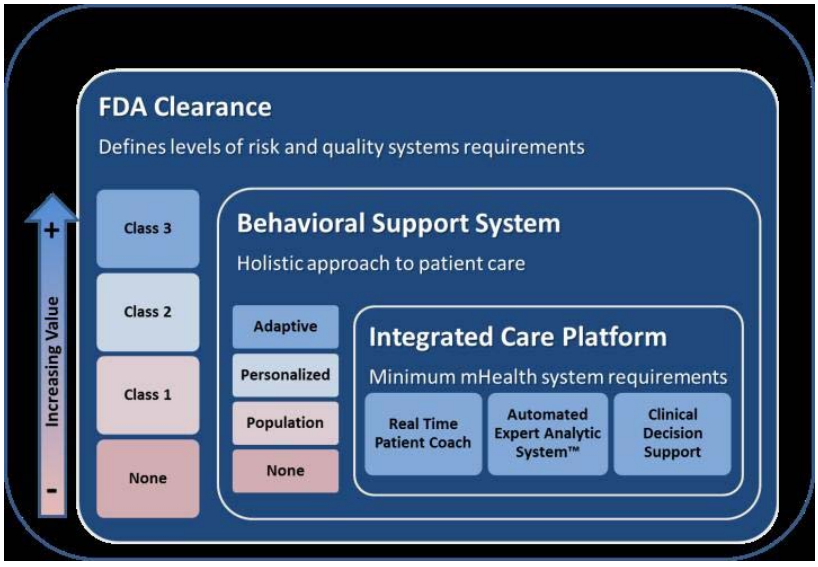
mHealth Coming of Age

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. As an emerging science, mHealth offers the allure of reducing healthcare costs while improving outcomes and care quality associated with the management of chronic disease. The scientific credibility of mHealth has been bolstered over the past several years by mounting data from randomized controlled trials, research support from agencies such as the National Institutes of Health (NIH) and through the proliferation of organizations focusing on the science, such as the mHealth Summit and mHealth Global Congress.

Recent actions by the federal government have further heightened the interest in mHealth among software and device manufacturers. The passage of the Affordable Care Act in 2010 seeks to tie quality metrics and cost reductions to physician reimbursements. The Center for Medicare and Medicaid Services' (CMS) recently announced the Health Care Innovation Challenge, which provides $1 billion in grants to "applicants who will implement the most compelling new ideas to deliver better health, improved care and lower costs." CMS also supports the move to electronic health records (EHR) through an incentive program that encourages physicians to convert from paper-based patient records to digital approaches.

The response to these initiatives has created a feeding frenzy of software developers and hardware manufacturers, all aiming to manage chronic disease more effectively using novel technology. The race is on to deliver measurable and effective outcomes that will positively impact patient health over the long haul.



As software and device manufacturers develop more elaborate and invasive approaches to managing chronic diseases, however, questions of both efficacy and safety arise. The Food and Drug Administration (FDA) has taken notice. In July 2011, the FDA released its draft guidance for mobile medical applications to address the proliferation of health related apps. 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." This new guidance provides a regulatory framework that differentiates common health and wellness apps (HWAs) from more sophisticated mobile systems that are designed to meet FDA standards for efficacy and safety.

Creating Value in mHealth

Although the mHealth market is rapidly evolving, three best-of-breed features have emerged for a sustainable mHealth solution: an integrated care platform, a robust behavioral support system and FDA clearance. These elements build upon each other to create a clinically meaningful and commercially viable mHealth solution.

The integrated care platform (ICP) is the basic building block of any effective mHealth solution. To support both the patient and clinician, the ICP must integrate three elements:

- *Real time feedback and coaching* - Via patient reported data, this feature allows patients to make timely decisions regarding their health. The system provides patient feedback that is the right information, at the right time and in the right context.
- *Expert analytic system* - An expert system uses artificial intelligence to longitudinally analyze patient data, and provides coaching to both patients and clinicians based on robust clinical algorithms.
- *Clinical decision support* - This feature provides clinical guidance to healthcare providers for patient and population decisions based on the aggregation of clinical knowledge and patient information.

Behavioral support is the second key feature of a successful mHealth solution. Manufacturers must invest in the appropriate patient behavioral systems that communicate patient messaging in a motivating and supportive manner. For the most meaningful patient experience, behavioral systems need to adapt to the patient's dynamic condition, mood and general wellbeing on an ongoing basis, rather than simply providing standard responses to the patient. A one-size-fits-all-approach will not address individual patient needs.

The young lifecycle of the mHealth market has reached an inflexion point regarding FDA clearance, making it the third key feature of a compelling mHealth solution. With an increasing number of mHealth products being classified as a medical device, manufacturers' quality of their systems, manufacturing procedures and post launch monitoring must now meet FDA standards. Furthermore, elements such as clinical decision support are also under the regulatory purview of the FDA. As a result, FDA influence on the market will continue to grow, sorting out common HWAs from clinically meaningful mHealth solutions.

Caveat Emptor

There are significant degrees of differentiation among mHealth products. More than 6,000 health and wellness apps are available to consumers at Apple's app store, with many offering some, but rarely all, of the key features of a true mHealth solution. Superficially, HWAs and mHealth solutions may appear very much alike on a mobile device, making their differences difficult for the average consumer to assess.

The WellDoc DiabetesManager is one example of a mHealth solution that utilizes all of the aforementioned features, including FDA clearance. This is the first mHealth solution cleared by the FDA as a class II medical device for real-time feedback and clinical decision in type 2 diabetes patients aged 21 years and older.

DiabetesManager is a software system that provides contextually relevant, real-time feedback and coaching to patients regardless of the type of hardware they use (e.g. mobile phone, laptop, or tablet). It is powered by a proprietary Automated Expert Analytic System, comprised of a unique set of clinical and behavioral algorithms, to address the needs of patients in a way that is reflexive to their current mood and

mindset as well as their physiologic state. Additionally, a robust quality control system is used to monitor for adverse events and to ensure that the product is always compliant with its FDA clearance and approved indication.

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 DiabetesManager, 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 DiabetesManager) 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.

As the mHealth market continues to mature, the scientific rigor and regulatory oversight applied to these solutions will continue to rise, especially as mHealth products become more sophisticated and intrusive. Device manufacturers who have invested in the requisite systems and processes to deliver a product that is safe and effective by FDA standards will be well positioned for long term success in the mHealth market.

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