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Mobile Health: empowering patients and driving change

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Diabetes is a global epidemic, with insufficient medical management capacity. It is becoming increasingly relevant to develop sustainable methods of self-management and collaboration between clinical personnel and those living with diabetes. While there have been favorable advances in mobile self-management tools for the disease, few have been validated and acknowledged. Health policies are not being established as quickly as these tools are becoming available, and the public has taken action into their own hands.

Patient populations rising faster than clinician workforce

The number of people diagnosed with diabetes increased to 387 million worldwide in 2014 [1]. The current rate of medical training only supplies four physicians for every 1000 patients worldwide [2]. Given such a disparity and the limited capacity of health services, there is a high risk of escalating undiagnosed and incompletely managed diabetic cases.

Self-management has become a primary focus of health authorities and providers, with its potential to supplement care and decrease the demand for costly treatment through patient engagement in disease management. In recent years, the functionalities of self-management tools have evolved from largely clinician-guided analysis, to more diverse uses for patient-enabled analysis. Patient-initiated novel mobile health (mHealth) tools include mobile phone-based diabetes diaries, online and computer-based software, and wearable technology ('wearables'), which offer users a means to understand how a variety of lifestyle and treatment choices impact their health outcomes. Disease-specific smartphone applications ('apps') are among the top five most common novel mHealth tools, preceded by fitness, medication, and wellness tracking. With the ability to accommodate multiple inputs, apps and wearables hold the potential to offer comprehensive and intuitive diabetes self-management. However, patients do not always have the background to efficiently interpret the data that they are collecting. The diversity of data-gathering functionalities, input sources, influence on patient decisions, and privacy concerns of these novel mHealth tools, also presents challenges with respect to integration within the healthcare system.

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Changing environment for health and wellness innovations

There is a fundamental shift in healthcare systems around the world. Facilitated by the emphasis placed on self-management, technological possibilities, and the global trend of increasingly commercial healthcare systems, those living with diabetes are becoming more empowered. Patient-interest groups, such as the International Diabetes Federation (IDF), provide a link between how individuals experience the challenges of the disease and how the world should approach these challenges [3]. Patient autonomy has reached a new level in Kuwait, where 3-month 'formal training' sessions grant individuals medical privileges in hopes of closing the gap between supply and demand of health services related to chronic diseases (http://blogs.msdn.com/b/healthblog/archive/2008/10/27/patient-heal-thyself.aspx). With respect to treatment methodologies, this shift has introduced individuals as a new consumer target market. More mHealth and wellness tools are either being initially or solely marketed toward individuals for approval, as opposed to through clinical bodies or health authorities. An inexpensive and flexible development process has enabled the self-management functionalities of apps to be as focused or broad reaching as the developer desires. For example, private companies offering code-free development platforms are encouraging nonprogrammers, including physicians, to create apps for individual patients (http://mobistine.com/2-services). Furthermore, connecting to multiple devices has been made possible via Bluetooth. This communication between sensors, smartwatches, and smartphones, offers a more convenient way to enter and direct data from different sensing and monitoring devices into a central database on a mobile phone for patient support and review. This open and integrated market has made novel mHealth tools both possible and accessible.

Benefiting your health and your wallet

Given that mHealth and wellness tools can be distributed via the Internet and are often free, they are reducing the cost of self-management and are more available and affordable to a larger portion of the population, compared with expensive medical devices. In particular, mHealth apps, which are compatible with a patient's own smartphone, have taken significant strides in overcoming many of the barriers that patients have to self-management, including usability, relevance to the patient's lifestyle, compliance, and understanding of their disease through

long-term usage. Due to the speed that such technology is being developed and released, little scientific research has been possible surrounding the consequences of using these tools. However, studies have shown that patients believe that this management option is effective in increasing their sense of control over their disease [4]. Successful studies have focused upon developing mobile phone app-based approaches to self-management that incorporate multiple functions, including tracking measurements that are most impacting to disease management (i.e., insulin, blood glucose, physical activity, and diet).

Impatient patients take matters into their own hands

With the evolution of data-storage capacities of mHealth devices, both adults and families of children with type 1 diabetes mellitus (T1DM) are storing an abundance of clinically relevant data through medical devices such as continuous glucose monitors (CGMs) and insulin delivery devices. Given that most of these data are meant to be analyzed by clinical personnel, those living with T1DM often have to wait until their scheduled consultations before gaining an in-depth understanding of their management progress. Frustrated by this process, members of Facebook group, 'CGM in the Cloud', share their experiences with a Cloud-based data storage system that allows easy access to CGM data via a smartphone or even smartwatch. Users report that this system gives them a sense of freedom and autonomy. They are able to remotely track their child's glucose levels in real time and, also, because they no longer have to solely rely on the medical system, manage the challenges associated with T1DM (http://diatribe.org/issues/69/sum-musings).

By offering an engaging and relevant platform for self-management through development processes that are directed at end-users, these tools have enabled those living with diabetes to feel more empowered and, therefore, more motivated to make positive health choices [5]. However, there is a balance between an effective and useful amount of information and information overload. Those using novel data-gathering apps and tools are often overwhelmed with the number of app choices and many do not have the medical training to accurately interpret the data and assess their metabolic condition. While this new technology supports patient autonomy, apps and mobile tools cannot replace practical training in disease management and clinical guidance.

Potential for integration and more informed consultations

While the tools that are most accessible for individuals are not formally integrated into the medical system, they hold the potential to offer benefits to not only patients, but also care providers. By enabling patients to educate themselves as to what positively and negatively affects their clinical health outcomes, such tools have the potential to empower the patient to enter into a more-informed conversation with their physicians. It has become increasingly common for patients to BYOD, or 'bring your own device', to their consultations [6]. This more collaborative care approach may strengthen the communication and relation between patients and their physicians, while enabling the latter to make more tailored and informed clinical recommendations. Therefore, new methods need to be proposed to structure this

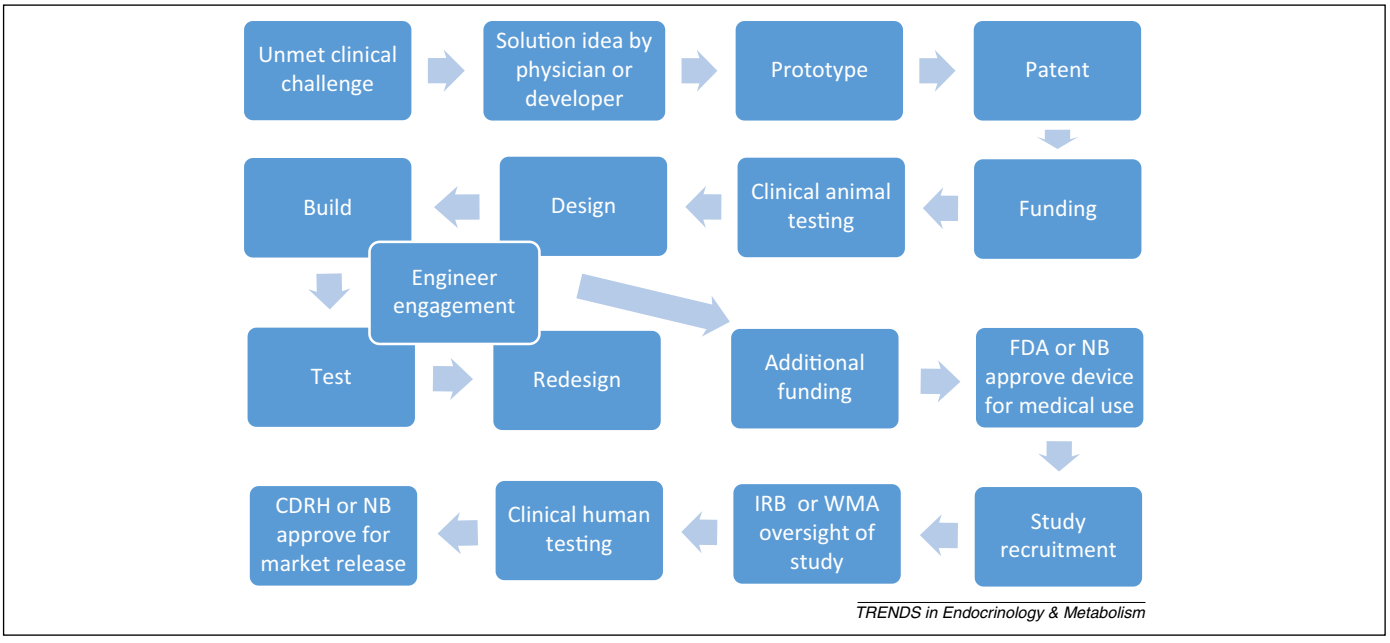

Figure 1. Medical device development process. A typical medical device costs innovators millions in USD, which is often personally funded, and requires 2–3 years for development. To reach clinical human trial stages requires additional funding from investors or interested parties in addition to approval by a regulatory body such as the US Food and Drug Administration (FDA) or independent organizations called 'notified bodies' (NB) in the European Union (EU), to approve device use. The World Medical Association (WMA) through the Helsinki Declaration requires that the Internal Review Board (IRB) ensures safe involvement of human subjects. Healthcare professionals are key because of their ability to integrate knowledge of the disease process with oversight of self-management product development to ensure effectiveness. For distribution within in the USA, approval by the US Center for Devices and Radiological Health (CDRH) of the FDA, or NBs within the EU, is categorized by the intention and perceived risk, each of which is subject to additional regulatory review and requirements. While developmental processes differ between countries in terms of time and cost, all require many years and extensive testing. Based upon [10].