Finding Real Value From Digital Diabetes Health: Is Digital Health Dead or in Need of Resuscitation?

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Digital health is in the doldrums. Despite venture funding in 2017 reaching $6B and $100M mega-deals becoming commonplace, there were fewer than 120 acquisitions of digital health companies that year and not one IPO that year.[1] The reasons for this disconnect between business aspiration and health care delivery in the real world are multifactorial but at least in part because of "irrational exuberance, excessive hype and an excess of digital snake oil."[2] Most notably, until now there is a paucity of quality clinical trial information—with most information coming from small, uncontrolled, short pilot studies designed merely to establish feasibility or acceptability of a technology. For example, diabetes is an ideal disease for innovations in digital health given its high prevalence and morbidity from potentially preventable complications as well as its reliance on lifestyle and data monitoring—health and fitness apps have grown 330% in the last 3 years, but the evidence of meaningful benefits for people with long-term conditions such as diabetes from this growth is still lacking.

The question for developers of digital health tools is what else should be done to increase engagement with the clinical community and payers? Given the costs required to run adequately powered, randomized, controlled, clinical trials that would be traditionally be necessary to increase interest from the clinical and especially payers, one venture capitalist has declared recently, because of the high ratio of hype to deliverables, that for investors, digital health is dead.[3]

Evolving Goals of Digital Health

At the outset of the digital health revolution, technologies introduced into the market-place were focused on helping individuals adopt more "healthy" lifestyles based invariably on nutrition and physical activity monitoring—important data for clinicians and people living with the diabetes as a well as for other chronic conditions including obesity, cardiovascular disease and cancer survivorship. With the forthcoming introduction of smart medicines and wearables (eg, smart insulin pens and medication tracking devices), the goal of digital health in diabetes (and other long-term conditions) will likely shift soon toward expectations of improved adherence/persistence with therapies leading to measurable improvements in clinical outcomes. In part, this shift will occur as a consequence of advances in sensor technology (especially miniaturization, increased power and improvements in aesthetics), smartphone computing capability, and artificial intelligence—all of which should contribute to enhanced understanding of the genetic, psychological, and behavioral determinants of human health and their impact on adherence with the goal of delivering the promise of precision medicine.

Another major limiting factor preventing greater adoption of digital health into mainstream medicine in general and diabetes in particular is that thus far these technologies appear to be biased towards younger and healthier individuals. Globally, the groups with the largest diabetes-related expenditures are those aged 60-69 years,[4] and in the United States the burden of diabetes is disproportionally more common among seniors and minorities.[5] Segmentation of the diabetes population might lead to fewer patients per subgroup, but allow an intervention to demonstrate better applicability for and greater adoption by a specific subgroup. As a corollary, digital health companies often lack the financial muscle that is commonplace within the pharmaceutical industry to cover the enormous costs of trials. Thus, robust and appropriately powered clinical trials of new digital approaches are usually non-existent. Digital technology offerings have often presented ongoing iterations that challenge the notion that a trial requires a static intervention. Although companies often report enthusiastic uptake of their technology, with time the euphoria often wanes.

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Facilitating Adoption of Digital Health

To achieve widespread adoption a digital health technology for diabetes must overcome five barriers: (1) usability to satisfy people with diabetes, (2) clinical benefit to satisfy clinicians, (3) economic benefit to satisfy payers, (4) security to preserve safety and satisfy product regulators, and (5) data privacy to satisfy legal regulators. Health care professionals and people with diabetes frequently have separate agendas for attractive features that promote usability. Generally professionals seek interoperability with other digital systems, compatibility with their hospital's or their primary health plan's electronic medical record, traceability to accepted medical standards, and improvement in (or no increase) in work, time, cost, as well as fewer individuals with poor outcomes. In contrast, people with diabetes seek easy entry to a technology (balancing security and simplicity), clear data/alert displays (because literacy and numeracy problems are commonplace), safety, and an absence of friction. Regulators seem to be enthusiastic about the potential of digital health technologies. To support digital health initiatives, this year the Food and Drug Administration will be establishing a digital health center for monitoring medical device security in the United States. International standards are also being developed for diabetes devices. For example in May 2018 Europe's strict new privacy laws (General Data Protection Regulations will become mandatory).[6]

Necessary Evidence

We would like to suggest that developers of digital diabetes products need to consider four key requirements as the basis for creating the necessary evidence: (1) identifying the target population(s) for their technology (ie, stratifying into subgroups); (2) defining metrics of success a priori; (3) linking with leading electronic health records; and (4) decreasing user burden, since any significant increase in time or effort will ruin the appeal and long term adherence of a digital health product. In addition, two currently neglected areas where we believe the application of digital health to diabetes could make a big impact with less initial financial outlay for research and development is by diagnosing diabetes with wearable sensors and by creating digital phenotypes with sensors to predict future behavior and outcomes.[7]

Fortunately, digital technologies for diabetes can meet their promises if the developers, entrepreneurs and investors recognize the absolute necessity for clinical trials and that these are executed in ways to create outcomes that matter to users, clinicians and payers. To achieve this will require new approaches to clinical trial design with intention control comparators (eg, testing a smartphone app may not need to be as a stand-alone technology but as a tool to integrate with existing care) and that the science of measuring adherence to a "digital solution" is clarified and agreed by stakeholders from the diabetes community (ie, what keeps people using these things and what are the relevant metrics to measure this). The true goal for digital diabetes health, although challenging, is to integrate technology with - not substitute for - the health care team.

The Future

In 2018 digital health for diabetes is at a crossroads. Despite the perception of significant financial returns, this aspect of the consumer technological revolution has not become mainstream in health care. Initial enthusiasm about technology allowing patient empowerment, behavior change and adherence to treatment by individuals and populations has not materialized. Furthermore, many clinicians remain skeptical about the potential negative impact on their workload and reimbursement and the majority of payers are unwilling to invest on a grand scale. However outside of health the world is turning to digital communication. For digital health, which is going through a reexamination of its capabilities and costs, as Winston Churchill said, "Now this is not the end. It is not even the beginning of the end. But it is, perhaps, the end of the beginning."

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