

## VIEWPOINT

# The Outlook of Digital Health for Cardiovascular Medicine

## Challenges but Also Extraordinary Opportunities

**Mintu P. Turakhia, MD, MAS**

Department of Medicine and Center for Digital Health, Stanford University School of Medicine, Stanford, California; and Veterans Affairs Palo Alto Health Care System, Palo Alto, California.

**Sumbul A. Desai, MD**

Department of Medicine and Center for Digital Health, Stanford University School of Medicine, Stanford, California.

**Robert A. Harrington, MD**

Department of Medicine and Center for Digital Health, Stanford University School of Medicine, Stanford, California.

### Corresponding

**Author:** Mintu P. Turakhia, MD, MAS, Veterans Affairs Palo Alto Health Care System/Stanford University School of Medicine, 3801 Miranda Ave, Cardiology 111C, Palo Alto, CA 94304 (mintu@stanford.edu).

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**The framework of health care delivery** has fundamentally changed over the last 8 years with reforms, including the Affordable Care Act, incentivizing the quality and efficiency of care. Cardiovascular care has been at the center of this transformation, with the earliest readmission payment penalties and cost bundling focused on myocardial infarction, heart failure, and revascularization. In addition, electronic health record adoption, reimbursement for chronic care management that is not face-to-face care, and payer risk sharing with accountable care organizations and employers have fostered innovation to develop new care delivery models. The focus to deliver care outside traditional brick-and-mortar settings has been fueled by rapid innovation and economic growth in mobile technology development and consumer adoption. Last year, 64% of individuals in the United States owned a smartphone, and ownership will probably exceed 90% by 2018.<sup>1</sup>

*Digital health* is a broad term that describes the use of digital information or data and communications technologies to collect, share, and manipulate health information to improve patient health and health care delivery.<sup>2</sup> Digital health includes (among others) elements of mobile health, wireless or connected health, big data, wearable computing physiological sensors, telemedicine, precision medicine, and personalized health. Cardiovascular disease management, including prevention, has been a major focus of digital health, owing not to just the high disease prevalence and societal costs, but to the ability of technologies to measure relevant biological signals continuously or near continuously, including heart rate, blood pressure, oxygen saturation, heart rhythm, and physical activity. The low cost of developing smartphone apps and monitoring technologies has reduced market barriers.

Companies, small and large, have increasingly turned their attention toward digital health across many industries including consumer electronics, internet technology, telecommunications, apparel, and personal transportation. In 2015, total digital health investment was \$4.5 billion, and there were 267 digital health companies that each raised more than \$2 million—overtaking investment in traditional medical devices.<sup>3</sup> As the field of digital health evolves and the application of these technologies becomes more diverse, a number of exciting opportunities are emerging along with an array of challenges.

### Making the Data Useful and Actionable

Even though a number of issues remain around data including ownership, interoperability, and sheer volume,

a central challenge in digital health is to present data that are actionable for clinicians, patients, and caregivers. This problem can be generalized to that of user interface and experience. There is already a major problem of data excess with electronic medical record systems, which have user interfaces that display cataloged data well but contextually aggregate data poorly. Adding continuous data generated from wearable monitoring devices and patient-reported data to the electronic medical record will likely not improve care unless clinicians are given tools to meaningfully aggregate and interpret the data to make it actionable, including at the point of care.

For patients, merely looking at data (sometimes considered to be engagement by digital health companies) is not likely to improve clinical outcomes. Rather good data visualization that is actionable may empower patients to develop insights that could motivate behavioral change without requiring assistance from a clinician. The interface should not be prescriptive or predictive, which could have regulatory implications, but this would be an exciting mechanism to motivate changes in behavior regarding medication adherence, disease management, and lifestyle modification.

### Mobile Applications

The notion that digital health tools can work on their own as active therapeutics, such as prescription drugs or medical devices, is currently a false hope. Studies of mobile text messaging, apps, and connected devices have not consistently demonstrated efficacy when the care team has not been actively and concurrently engaged with the patient. In a small trial of 160 patients randomized to smartphone-connected devices that measure electrocardiogram rhythm (AliveCor), blood pressure (Withings), and blood glucose (Sanofi), there was no difference in the outcomes of health care utilization or cost.<sup>4</sup> Notably, neither the patient's care team nor treating physicians were integrated with these interventions. Other cardiovascular trials of 1-way text messaging to patients to improve medication adherence for hypertension and heart failure also have not demonstrated improvements in efficacy.<sup>5</sup>

In contrast, several companies that incorporate personal health coaches into their digital health disease management programs have had greater success. In 1 study, the use of personalized health coaching (Omada Health) was associated with reductions in body weight and hemoglobin A<sub>1c</sub> that were maintained at 2 years.<sup>6</sup> Similar trends have been observed at the Stanford Health Care Alliance accountable care organization in which wellness coaching and ancillary

services such as delivery of prescription medications are offered as part of ClickWell Care, which is a virtual primary care visit program. Therefore, it is critical that clinicians, patients, and stakeholders understand that digital health technologies should be integrated into an overall care model rather than attempting to replace that model as a stand-alone technology.

### Gathering Generalizable Evidence and Learning From Implementation

The deluge of digital health companies and solutions make it difficult for patients, clinicians, and health care systems to determine which solutions are useful and viable. Poorly designed and nongeneralizable pilot studies of highly selected patients and practices are abundant. Digital health startups are often only incentivized to gather minimal evidence (or no evidence) to facilitate fundraising or adoption. An approach of disruption with impunity will not sustain. The criminal investigation and class action lawsuits claiming fraud filed against consumer diagnostics company Theranos serve as a cautionary tale.<sup>7</sup> Rigorous study of validation, effectiveness, and implementation in real-world health care settings will be necessary for commercial success and improvement of health care outcomes.

Rather than traditional patient-level randomized trials, implementation studies and pragmatic trials may be better suited to assess the effectiveness, barriers to implementation and adherence, patient and clinician experience, best practices for optimizing care,

and the budgetary or economic effects. Incentives for hospitals to share implementation solutions could accelerate adoption. Training clinicians in digital health will be required and may call for a revamping of medical school curricula and residency programs.

### The Future

Digital health is still in beta testing. However, its future is bright. Perhaps the strongest tailwind is that stakeholders are aligning. Technology companies are more willing than ever to conduct rigorous clinical research, and hospitals, clinicians, and researchers have deftly reciprocated. Hospital systems are starting to adopt these technologies and appear more open to collaborating with technology companies and researchers on implementation. Proposed changes in reimbursement and policy continue to further incentivize digital health adoption. Patients are demanding access to their health data, including the data generated from cardiac medical devices.

The National Institutes of Health and the US Food and Drug Administration have launched a series of initiatives and grants to address gaps in digital health science, translation, and device regulation. There are 484 studies registered on ClinicalTrials.gov that mention smartphones (63 of these mention the term *cardiovascular*). There is an extraordinary opportunity to innovate health care delivery, patient experience, and clinician experience not only with technology creation, but also with rigorous scientific evaluation and careful implementation.

#### ARTICLE INFORMATION

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