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Editorial Commentary: Hard questions for mobile technology in cardiology

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Nearly every aspect of modern life seems vulnerable to disruption by smartphones, and health care presents an irresistible target for entrepreneurs and scientists. Further growth in smartphone use, wireless connectivity, and a broadening array of wearable sensors and other diagnostic tools will increasingly challenge patients and providers to consider the strengths and weaknesses of a “virtual” clinic model leveraging this technology. Cardiovascular care and arrhythmia management in particular may be particularly well suited to these innovations. Simplifying the screening and management of atrial fibrillation (AF), for example, illustrates the stakes and opportunities. AF will become increasingly prevalent as the US population ages, and yet remains clinically silent in many cases prior to presenting with thromboembolic complications [1]. New technology targeting incident AF in select populations may facilitate initiation of therapeutic anticoagulation: a study screening older adults (using a stand-alone handheld device with remote connectivity) found that 9% of previously undiagnosed patients met criteria for starting systemic anticoagulation [2]. Improvements in mobile technology aimed at this public health target may have a measurable impact on outcomes such as stroke attributable to AF.

Perhaps due to possibilities such as these, popular enthusiasm for smartphones in health care is growing. Outlets such as *CNN* and *US News and World Report* have applauded the coming “Uberization” of health care [3,4]. But not all innovations targeting arrhythmia care or other cardiovascular targets will necessarily be progress, and even useful comparisons with other industries may obscure unique aspects of health care delivery. The regulatory structure of U.S. health care is fundamentally aligned against an approach that eagerly distributes new technology and lets the market pick winners. The rapid rise of consumer-oriented digital technology thus challenges not just specific diseases or care models, but the way in which we critically evaluate and regulate novel device development.

This issue of *Trends in Cardiovascular Medicine* includes a timely review [5] of smartphone technology in cardiology. This broad overview includes device/application combinations for arrhythmia detection or imaging, as well as standalone applications targeting more cognitive tasks such as medication management, weight-loss programs, and smoking cessation. Both inpatient and outpatient settings provide important venues for improving diagnosis, care delivery, and communication, with theoretical opportunities for better care, lower costs, or

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both. The authors also highlight the tremendous research potential of rapidly generating large data sets from “connected” patients and the associated deluge of physiologic or behavioral data. At the same time, this review also provides important caveats regarding data security, interoperability and highly variable costs, and usability of each system. These authors also point out the dangers of information overload, already manifest on much smaller scales through the “alarm fatigue” phenomenon in inpatient settings.

Despite these notes of caution, the authors themselves seem vulnerable to catchy marketing, like the ability of sensors to transform “any bed into an ICU bed”—comments that obscure the enormous effort involved in monitoring, processing, and responding to physiologic signals. Intensive care nurses typically care for 1 or 2 patients at a time, supported by layers of physician and specialist oversight and their other staff collaboratively monitoring telemetry, respirator data, and other information streams. This small example illustrates the dangerous potential to overpromise the impact of digital technology while undervaluing the human factors in health care delivery.

The authors also provide only limited counterpoints to the research opportunities generated by large digital data sets. They rightly point out that traditional research methods questions will remain important, such as data quality and standardization of parameters across devices. However, there are much more serious methodological problems inherent in the broad collection of intensely granular physiologic data. Very large data sets are critical for testing hypotheses in populations such as small effects of genetic polymorphisms. However, this tremendous statistical power amplifies the strength or weakness of the underlying hypotheses. The ease with which a “positive” p value emerges from looking at 1,000,000 or more records may encourage “fishing” in lieu of hypothesis-driven research, and should be countered by strict peer review and statistical standards such as those used in genetics analyses. Common challenges of sample selection bias, confounding, and missing data may be amplified when data are collected in large volumes outside of the typical oversight provided by monitored studies. Newer methods of analysis that can account for the “high dimensional” nature of the data will be needed.

Even with well-formed hypotheses and careful analysis, the promise of smartphone-based technology to improve outcomes should be met with healthy, constructive skepticism. The authors cited heart failure monitoring as an opportunity to predict and prevent morbidity [5], despite very mixed clinical trial data [6]. With sufficient power—as would be seen with millions of patients and thousands of outcomes—it should be possible to identify a large list of factors associated with worsening heart failure—but this may provide little value to patients without an associated intervention.

Ultimately, what clinicians and patients need to know is not whether these applications or device-phone combinations are novel, flashy, or fun, but whether they are safe and effective. The Food and Drug Administration (FDA) is responsible for oversight of products, including mobile technology that perform medical functions like monitoring or disease management, albeit with significant leeway regarding exactly what applications are subject to oversight [7]. Most of the applications or device-application combinations reviewed here are subject to the FDA oversight applied toward lower (class I) or moderate risk (class II) devices. This

may include simple registration of the technology for most class I devices. Most class II devices are cleared for marketing via the 510(k) pathway, which evaluates safety and effectiveness in reference to a predicate device already on the market. The most rigorous review pathway, pre-market approval, is reserved for class III devices, and few applications or phone-based devices are likely to be subject to such scrutiny. Importantly, the 510(k) process has been heavily criticized by the National Academies of Medicine for failing to adequately fulfill the FDA's statutory mandate [8]. As the general structure of FDA regulation seems unlikely to change, however, clinicians, patients, and ultimately payers will have to determine which, if any, smartphone-based therapeutics provide meaningful clinical value.

Indeed, the need to demonstrate value will also require reconciling, promising new interventions with reimbursement systems not easily aligned with newer models of reviewing patient data and communicating results. Physicians could easily become buried in excessive notifications of variable importance, and without an associated reimbursement scheme may lack the necessary incentives to learn and test new technology. At the same time, the relative ease with which remote or mobile data might be retrieved and reviewed could, in a fee-for-service model, grow to pose significant economic burdens on the health care system. Rigorous evaluation of this technology, then, will be essential not only to protect patients but also to guide sensible resource allocation.

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