Watched by Apple

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After taking over media, social communication, and the consumer economy, the forces of digital innovation are moving into the worlds of medical practice and medical research. Both the power and the limitations of digital innovation in medicine are evident in a report by Perez and colleagues, "Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation," published in this issue of the *Journal*.[1] The study was sponsored by Apple, and in 8 months it managed to enroll some 419,000 participants through the use of a smartphone application (app). Having an iPhone and an Apple Watch were entry requirements, so the study participants were in fact customers of the sponsor. Not surprisingly, most of the enrollees were young: 52% were younger than 40 years of age and only 6% were 65 or older, which may be the opposite of a desirable age profile for a study of atrial fibrillation.[2] Irregular rhythms were identified initially by the watch's optical sensor and interpreted by algorithm. In 0.52% of participants, rhythm patterns suggestive of atrial fibrillation were detected, which led to more conventional monitoring with an electrocardiography (ECG) patch sent by mail. There was documentation of atrial fibrillation in slightly over a third of those who returned the patch. Most of the irregular rhythms detected by smartwatch as possible atrial fibrillation were confirmed as such by the ECG patch, with a positive predictive value for a subsequent irregular tachogram of 0.71.

The main message from the Apple Heart Study lies not in the technology tested, which is rapidly evolving and changing. The lessons lie in how the study was done and why it was done. People have been wearing fitness monitors for many years, but now we're seeing the appeal of a watch with an app that can detect arrhythmias that may justify medical evaluation and treatment.[3] There is now wide public awareness that atrial fibrillation is a common cause of stroke.[4] Over 400,000 people downloaded the app and enrolled in the study, not because of any health problem but because they were curious and wanted the reassurance of high-tech, zero-effort heart monitoring. In fact, of the 219,179 participants younger than 40, over 99.8% received no notifications of an irregular pulse. It's difficult to draw any conclusions about the true frequency of atrial fibrillation, since only 21% of those with irregular pulse notifications based on monitoring by the smartwatch subsequently returned the ECG patch for analysis. In a study with easy, app-based enrollment, the percentage of people who dropped out was high and full follow-through with the research protocol was low. The study tried to exclude enrollees with a history of atrial fibrillation, but some of the detections were in patients who later admitted to a previous diagnosis of atrial fibrillation.

The results of the Apple Heart Study could be very valuable. The study challenges us to reassess the relation of atrial fibrillation to stroke. The data on that relation have been based on traditional, less-sensitive approaches, such as ECG and shorter-term monitoring of patients with symptoms. Patients with atrial fibrillation detected the "old-fashioned" way clearly have an increased risk of stroke (with the magnitude of increase depending on their $CHADS_2$ or CHA_2DS_2-VASc score).[5] But whether brief episodes of atrial fibrillation that may be detected by longer-term monitoring carry similar risks is not at all clear. Indeed, a study from a large registry suggests that patients with brief episodes of atrial tachycardia or atrial fibrillation detected by pacemakers or defibrillators may not have an increased risk of stroke or other adverse cardiovascular events.[6] This issue will require more research and probably large, controlled trials of anticoagulation in low-risk, but worried, populations. We certainly want to avoid the risks of anticoagulation if there are no benefits in patients with brief, isolated bouts of arrhythmia.

Technological progress commonly allows miniaturization, and we will be seeing more and more wearable, implantable, and even ingestible devices for detecting, monitoring, and treating diseases ranging from diabetes to seizure disorders.[7] Easy-to-use, wearable devices will facilitate research and allow more immediate, reliable patient reports than are available with traditional

interviews. Nonetheless, obtaining long-term participant commitment and compliance may become a greater challenge, as the results of the Apple Heart Study suggest.

In addition, the initial enthusiasm for new technologies can be overtaken by suspicion about who will be using the personal data and to what ends. People feel strongly about the right to privacy of their personal health data. When patients meet and get to know a medical research team, trust can grow. It is far more difficult to trust in freestanding device technologies and the billion-dollar companies behind them. As more of our health data become more accessible and move to the cloud, which few of us really understand, suspicion and worry grow even stronger. Again and again we have seen privacy violations, sometimes because of negligent security and sometimes because of deliberate and deceptive misuse of personal data. The uncomfortable fact is that our personal health data have considerable financial value to those who want to use them in the myriad marketplaces connected to our $3.7 trillion health economy. As we implement novel technology for improving human health, physicians need to help protect the interests of patients against the use of technology that ignores the greater good.

Disclosure forms provided by the authors are available with the full text of this editorial at NEJM.org.

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