PERSPECTIVE

Watching for Disease: the Changing Paradigm of Disease Screening in the Age of Consumer Health Devices

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There has been a recent proliferation of consumer health devices (CHDs) that enable user-initiated screening for a variety of diseases. These devices represent a paradigm shift in the deployment of disease screening, a process that has historically been led by clinicians following the guidance of professional bodies. The detection of AF via CHDs is a contemporary example of this phenomenon and highlights several important implications of the shift of disease screening from clinicians to CHD users. These include responsibility for patient data and outcomes, healthcare costs and access, and an evolution of the patient-provider relationship. However, as CHD technologies mature and become more affordable, they have the potential to detect actionable subclinical disease and improve health. Rather than allow CHDs to enter the marketplace organically with the potential for unintended negative consequences, it is critical that clinical, research, and industry communities proactively collaborate and establish best practices for their use.

J Gen Intern Med 35(7):2173-5
DOI: 10.1007/s11606-019-05626-y
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Consider two patients we recently encountered in clinic. First, a 24-year-old woman who was gifted a smartwatch and subsequently developed intermittent palpitations and attended the arrhythmia clinic with a tracing indicating a supraventricular tachycardia (Fig. 1a). She underwent an uncomplicated 2-h procedure to ablate the arrhythmia substrate and was impressed with the efficiency of her care. Her gift rapidly expedited the identification of the source of her symptoms and likely saved the healthcare system the time and expense of a series of investigations.

The second patient, a 68-year-old man with hypertension, presented to his primary care physician because his smartwatch had notified him of a recent episode of atrial fibrillation (AF) (Fig. 1b). He was asymptomatic, and his

office electrocardiogram showed normal sinus rhythm. Both the patient and his physician were unsure how to proceed.

Recently, there has been a proliferation of consumer health devices (CHDs) that enable user-initiated screening for various conditions including arrhythmias, obstructive sleep apnea, and hypertension^{1,2}. These devices represent a paradigm shift in the deployment of disease screening, a process that has historically been led by clinicians following the guidance of professional bodies. Conventional screening programs are based on disease prevalence in defined cohorts and screening test characteristics. This approach aims to maximize predictive value, improve cost-effectiveness, and improve population-level health. Screening for various cancers and osteoporosis is an example of such programs. However, even in high-risk cohorts, several screening programs have been re-examined given a lack of apparent benefit and concern for overdiagnosis and overtreatment³⁻⁵.

Individuals can now engage in disease screening regardless of their underlying risk and independent of clinical guidance with commercially available CHDs. This shift in screening practice leaves the clinician with several challenges. Among these is that for a given disease a proportion of CHD users are unlikely to be representative of patients in whom screening is typically indicated. These users, who have the means to afford CHDs, may have a lower disease prevalence. This may result in diminished positive predictive values and higher false positive rates for the CHDs utilized in these cohorts. In addition, the test characteristics of a specific CHD might not be well understood at the time a user presents with a device alert. Therefore, how healthcare providers should evaluate and manage patients presenting with device alerts is poorly defined. The detection of AF via CHDs is a contemporary example of this phenomenon and highlights several important implications of the shift of disease screening from clinicians to CHD users.

A likely consequence of CHDs is that users presenting with device alerts will undergo a cascade of testing to confirm or rule out a specific disease. CHD alerts suggesting AF may lead to confirmatory rhythm monitoring, lab work, and an echocardiogram. Additionally, CHD alerts may lead to increased patient anxiety and lost productivity while confirmatory testing is completed. If an abnormality is found on this initial evaluation—for example, a wall motion abnormality on

Received September 18, 2019
Revised November 5, 2019
Accepted December 18, 2019
Published online January 15, 2020

Figure 1 a Smartwatch tracing of supraventricular tachycardia. b Smartwatch atrial fibrillation alert.

echocardiogram—patients may undergo additional noninvasive or invasive testing. Thus, the evaluation of these individuals will expose them to risks associated with not only initial testing, but also any follow-on testing done to investigate

incidentally discovered abnormalities. Though follow-on testing may identify previously unknown comorbidities, it is unknown if the expense and risks of this approach will lead to a net improvement in clinical outcomes.

Certainly, this testing will generate additional healthcare expenditures. It is unlikely that CHD manufacturers will bear any of the cost of this testing, even if a CHD alert is a false positive. Thus, the financial burden of increased testing will fall on payors (including government entities and, by proxy, taxpayers), healthcare systems, and/or patients themselves. If the costs of additional testing do not lead to the diagnosis of a clinically actionable entity, CHDs may exacerbate the growing discordance between healthcare expenditures and health outcomes^{6, 7}. Healthcare systems and payors should contemplate how to address a likely increase in utilization associated with CHD use.

Moreover, who should ultimately be responsible for acting on CHD alerts remains unclear: if a stroke patient's CHD review demonstrates recurrent bouts of AF in the preceding month, does the CHD manufacturer bear any responsibility for his poor neurologic outcome? Currently, clinician-initiated screening test results fall to the ordering clinician for follow-up while CHD users, who may have limited healthcare literacy, are instructed to inform their physician of any concerning device alerts. However, clinicians may have many CHD users in their patient panels, and device alerts are not communicated to them in a systematic fashion. Furthermore, even if CHD alerts were to be transmitted to providers, how they should triage and manage this potential tsunami of data is not defined. Aptly integrating CHD alerts into clinical workflows will be crucial to facilitate the clinical benefits of these devices.

A complicating factor is that behavior change requires more than notification of an anomaly by CHDs. In the recently presented Apple Heart Study, which involved more than 400,000 participants, less than half of subjects who received an alert for possible AF engaged in the first study visit, and only a fraction ultimately used and returned a clinical-grade patch monitor utilized for confirmatory testing⁸. Behavioral techniques to nudge responses to CHD alerts will likely not improve this low level of engagement by more than a few percentage points⁹. Between the CHD manufacturer, clinician, and CHD user, who is responsible should a CHD alert not be acted upon and an untoward medical event occur?

Beyond the clinical and financial uncertainties lie the philosophical ones: even if CHDs are costly and do not improve health outcomes, how should our profession respond to these laudable efforts to encourage individual involvement in health? It is possible that increased health engagement through CHDs may motivate users to prioritize healthy behaviors such as medication adherence and exercise. Moreover, as CHD technologies mature, they have the potential to detect actionable entities and improve health if they are thoughtfully incorporated into clinical operations.

In patients presenting with symptoms and a clear diagnosis, CHDs may improve clinical outcomes and health system

efficiency. However, the routine use of CHDs in asymptomatic users raises various concerns with important implications for societal expenditure and health outcomes. CHDs will shift screening initiation from clinicians to users. Although they present a new set of hurdles for patients, practitioners, payors, and healthcare systems, appropriate study and use of their capabilities may benefit population health. Rather than allow CHDs to enter the marketplace organically with the potential for unintended negative consequences, it is critical that clinical, research, and industry communities proactively collaborate and establish best practices for their use.

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Compliance with Ethical Standards:

Conflict of Interest: The authors declare that they do not have a conflict of interest. David T. Martin: consulting fees from Biotronik, Inc. and Abbott, Inc.

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