Wearables for arrhythmia care: Challenges and future prospects

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Wearable technologies (wearables) represent a diverse category of user-worn digital devices that are used for the measurement and transmission of physiological signals, including heart rate and rhythm, peripheral oxygen saturation, blood pressure, and measures of activity for health management. These devices also can integrate geospatial and environmental data. Wearables initially gained traction among consumers as fitness and wellness accessories to monitor simple functions such as heart rate and physical activity.

The promise of wearables as health management tools has drawn strong interest from a wide variety of stakeholders, including clinicians, medical device and technology companies, regulatory agencies, and patients. Pulse irregularity, as detected by wrist-worn photoplethysmography sensors, can be leveraged to identify atrial fibrillation (AF). The Apple Heart Study recruited 419,297 participants over 8 months to demonstrate the feasibility yield and positive predictive value of this approach at scale in a siteless, pragmatic study that leveraged user-owned devices. Devices and algorithms from Huawei (Shenzhen, China) and Fitbit (San Francisco, CA) have been tested in similar studies. Limb-lead electrocardiograms (ECGs) can also be obtained via smartphone accessories and smartwatches. For heart rhythm disorders, wearables have demonstrated potential as screening and prediagnostic tools to prompt definitive medical evaluation and potentially guide medical therapy. The horizon for wearables research may center on whether and how these devices can evolve further—into complex diagnostic tools that can fully meet the needs of patients at home for actionable disease management. We outline relevant prospects and potential challenges for the future of wearables research for arrhythmia management.

Moving from prediagnosis to actionable disease management

The United States Food and Drug Administration (FDA) has considered many of these devices to be “over the counter” and “not intended to replace traditional methods of diagnosis or treatment.” Presently, these wearable features are considered “prediagnostic” tools pending confirmation from a clinician or medical-grade device, although certain smartphone-connected ECG devices have FDA clearance for rhythm diagnosis.

For these technologies to make an enduring impact on health care, they must be integrated into disease management. This will require a series of important steps: (1) creation of patient- and clinician-facing software solutions for disease management; (2) determination of efficacy at scale—not just diagnostic accuracy but favorable improvement ranging from health care utilization to hard clinical outcomes such as stroke and death; (3) implementation and integration into clinical workflow; and (4) viable and enduring reimbursement or care incentives. The evolution and maturation of remote monitoring of cardiac implantable electronic devices (CIEDs) could serve as a useful paradigm for technology-enabled arrhythmia management. Developed in the late 1990s, remote monitoring of CIEDs has tailored clinician-facing software applications, robust electronic health record integration, mature workflows, stable reimbursement, a large body of observational and trial evidence informing professional society guidelines, and even a career path for allied health professionals, who are a critical constituency of the Heart Rhythm Society.

This playbook may be useful to the maturation of wearables in health care, not just for fitness and wellness. Furthermore, wearables offer a unique opportunity to diagnose, treat, and even predict disease while meeting patients in their daily lives without the geographic, time, or financial disruption of structured health care visits. Indeed, the need for remote monitoring, asynchronous care, and meeting

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patients where they are is more important than ever in our postpandemic world.

The presence of actionable information—data that can be interpreted and acted on in a predictable manner for clinical benefit—is a must. Although not directly analogous to arrhythmia disease and treatment, the use of glucometers in diabetes may provide a helpful framework. Ideally actionable information may require patient-facing components that warrant triage and response by users, such as hypoglycemia necessitating glucose intake or urgent care/emergency department visits, coupled with more detailed clinician-facing data for more complex or longer-term management decisions, similar to using longitudinal blood glucose trends to adjust insulin regimens. For rhythm management, CIEDs largely provide clinician-facing data but have been incorporating certain user alarms for battery decline, device malfunction, or arrhythmia notification. Given their relative nascency, wearables now offer the intriguing opportunity to focus on balancing clinician- and patient-facing data considerations to optimize actionable information as part of their early development.

Finally, unequal access to care significantly contributes to prevalent inequities in cardiovascular health. Therefore, adoption of wearables should address, not amplify, socioeconomic and racial/ethnic cardiovascular health inequities. In particular, the ability to manage personal data in an asynchronous fashion for disease management should be leveraged to mitigate gaps in access to structured health care facilities. However, there also may be disparities in access to technology, including smartphones, according to race/ethnicity or financial status, which should be considered when studying large-scale wearable implementation. Encompassing these principles and as part of the American Heart Association Health Tech and Innovation Strategically Funded Research Network, we and a team at our Stanford Center for Heart Health Technology (H2T) are studying the use of a mobile application with a user data-driven, clinician-guided management algorithm to manage hypertension. The project is centered on actively studying digital health tool adoption and focusing on potentially vulnerable populations, including rideshare drivers. Through the mobile application, the study will help evaluate the effectiveness of an asynchronous management paradigm to meet users during their daily lives to manage hypertension.

The horizon
Wearables research is on the rise. A 2019 analysis of digital health studies registered on ClinicalTrials.gov found 1783 studies, with steadily increasing numbers per year between 2011 and 2017. However, many of the studies were small (only 8% had >1000 patients), and few had reported their findings, making it less likely that they would generate robust evidence. Appropriately powered, high-quality studies are needed. The Apple HEARTLINE study is an ongoing pragmatic, randomized controlled study examining the use of a mobile application paired with the Apple Watch to study AF detection, in addition to cardiovascular outcomes, and adherence to anticoagulation. Among patients without AF, the study aims to assess rates of AF detection and association with cardiovascular outcomes. Among those with AF, the study will assess direct oral anticoagulant adherence.

Conclusion
We are in the first half of the first inning of wearable-guided disease management and asynchronous care. As screening tools, wearables demonstrate clear promise. Their next-stage evolution into robust, evidence-based disease screening and management tools is the next necessary step. The litmus test for wearables as standalone health tools ultimately may depend on whether they can be implemented at scale to provide actionable information, and whether they can be leveraged to avoid amplifying—and potentially improve—health inequities. With a growing body of contemporary evidence for wearables in disease detection and the rising involvement and alignment of major stakeholders (patients, clinicians, medical technology companies, and regulatory bodies), the environment remains primed for a thorough evaluation of the utility of wearables as complex medical-grade tools that can provide meaningful, actionable, asynchronous cardiovascular care.

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