12 Wearable Devices in Cardiovascular Medicine

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DEFINITIONS AND OVERVIEW

Wearable technology, commonly referred to as "wearables," represents a broad category of electronic, hands-free devices that are used for the measurement of physiologic signals, diagnosis of physiologic states or medical conditions, and treatment of disease. Eyeglasses, developed in 13th century, are considered to be the first wearable device. The contemporary definition refers to devices with microprocessors and connectivity to smartphones or a network. Colloquially, the term "wearables" more typically refers to technologies that can be directly acquired by the patient or consumer ("consumer-facing") and do not require interaction with the health care system for access. These devices are regarded as an example of the "Internet of Things."[1]

Wrist-worn wearables comprise almost half of the United States and international segments of the wearables market. Early wearables consisted of wristbands with dedicated functions for assessing the pulse rate and were geared toward fitness and wellness consumer markets. With advances in miniaturization, sensor technology, battery longevity, and lower manufacturing costs, these devices have become more complex and packed with a wide range of sensors. Contemporary smartwatches have the sensor capabilities to detect pulse and oxygen saturation (photoplethysmography [PPG]), movement and activity (accelerometer and gyroscope), distance and location (GPS), and sound (microphone) and record an electrocardiogram (ECG). Applications of machine learning and other forms of signal processing to streams of sensor data have enabled assessment of more complex parameters including sleep, 6-minute walk distance, irregular rhythms such as atrial fibrillation, fall detection, heart rate variability, sympathetic tone, and emotional health.

Wearable devices are part of a larger concept in medicine called, "digital health," which is a broad term that describes the application of digital information or data and communications technologies to improve patient health, population health, and care delivery. Digital health is a multidisciplinary domain that includes elements of mobile health, health information technology, wireless or connected health, big data, wearable technologies, telemedicine and remote care, precision and personalized medicine, genetics, and artificial intelligence. Digital health aims to improve all domains of medical care, including disease prevention, prediction, diagnosis, and treatment. Digital health and wearable technologies also offer solutions to improve enrollment and lower costs of clinical trials.

Cardiovascular disease has been a major focus of digital health for a variety of reasons. The sensors measure relevant physiologic parameters (heart rate, ECG), the prevalence and economic burden of disease is high, and evidence-based prevention and treatment therapies exist for a wide variety of conditions.

ACTIVITY AND HEART RATE TRACKING FOR GENERAL CARDIOVASCULAR WELLNESS

The first wearables entered the market in the consumer space for nonmedical use. In the 1970s and 1980s, calculator watches and portable music players first demonstrated the ability of placing microprocessors on compact and wearable devices. In 1987, digital hearing aids were released. In 1994, the first ECG-based smartwatches were released as physician-prescribed event recorders (Fig. 12.1). In 2009, the first major clip-on wearable devices launched and measured step counts, walking distance, and activity using an accelerometer. In the mid 2000s, the field converged to developing wrist-worn devices that embedded more sensor types, including gyroscopes and PPG.

Accelerometers can measure linear acceleration. These sensors have long been used for activity tracking including in implantable pacemakers. However, accelerometers alone are unable to differentiate type of activity. Gyroscopes sense rotation. Used together as an inertia measurement unit (IMU), the two sensors provide greater accuracy to classify gait (walking, running), exercise type, stair climbing, sleep, and even fall detection. IMUs are primarily deployed by smartwatch software for activity and exercise tracking. Built-in or smartphone-paired global positioning systems allow for more accurate estimations of distances traveled compared with pedometer calculations. Accuracy of calorie expenditure estimation is less accurate.

Most wrist-worn wearable devices have heart rate tracking. PPG is an inexpensive optical measurement technique that can estimate relative changes in blood flow. A light source is aimed at the skin, typically underneath the face of the head of the fitness band or watch. An adjacent photodetector measures the reflected light, which can estimate relative changes in blood volume. With continuous sampling, PPG can capture the cardiac cycle and estimate the pulse rate. The peak represents systole, the nadir represents diastole, and the difference approximates the relative pulse pressure. A dicrotic notch from aortic valve closure may also be detected. PPG can also measure oxygen saturation via oximetry, although most consumer watches do not provide the user this information. The core function of PPG remains

FIGURE 12.1 Timeline of wearable devices. (From Vitatron International; BioTelemetry, Inc; Google; AliveCor. Screenshots reprinted with permission from Apple Inc. HeartGuide image courtesy of OMRON Healthcare, Inc.)

measurement of pulse rate. To preserve battery life and accuracy, heart rate sampling is typically noncontinuous and often opportunistic and will increase during exercise modes or with user-initiated measurement. On some watches, users may activate notifications for tachycardia and bradycardia during periods of inactivity (heart rate–activity discordance). The accuracy of PPG-based pulse rate may vary slightly based on the hardware, software, skin color, movement, ectopic beats, and heart rate (e.g., due to decreased ventricular filling in severe tachycardia).

ATRIAL FIBRILLATION

Photoplethysmography Detection of Irregular Rhythm

Time series analysis of PPG-derived pulse assessment can identify patterns in the pulse. Quantification of pulse rate variability or machine learning–based algorithms have been shown to successfully discriminate between sinus rhythm and atrial fibrillation using a variety of approaches.[2]

Early approaches to identify atrial fibrillation were based on a conceptual framework similar to ambulatory ECG interpretation, which is to examine a 30-second interval of pulses. This was successfully performed with transillumination of the finger from a smartphone flashlight and detection by the adjacent camera.[3] Eventually, the strategy was applied to watches. As the use cases expanded from fitness and wellness to diagnosis and disease management, these tools required greater regulatory oversight and clearance (Fig. 12.2). An early attempt using third-party software on the Apple Watch had low specificity and positive predictive value.[4] Subsequent approaches for irregular pulse identification were developed for high specificity, using a probabilistic approach of confirmatory pulse checks over hours or days. An algorithm designed for the Apple Series 1, 2, and 3 watches (Apple Inc, Cupertino, CA)[5] intermittently and passively measures pulse over 1 minute to generate a beat-to-beat pulse tachogram (Fig. 12.3). If this tachogram meets irregularity criteria, then the algorithm temporarily increases the sampling frequency. If five out of six consecutive tachograms met irregularity criteria, then the algorithm notifies the user of an irregular rhythm. Therefore, unlike the classical ECG definition of AF, which requires a consecutive duration of only 30 seconds, this PPG-based algorithm is probabilistic, requiring multiple episodes to meet criteria (see Fig. 12.3), and is therefore considered less sensitive, especially for very short AF episodes, but much more specific.

The Apple algorithm was tested at scale in a single-arm, unblinded, investigational device exemption study.[6] Inclusion criteria included age ≥22, possession of compatible Apple watches and phones, no prior history of AF, and U.S. residency. Over an 8-month period between 2017 and 2018, the study enrolled 419,297 U.S. participants. Overall 0.52% of participants received an irregular rhythm notification. Among 450 participants with notifications who received ambulatory ECG patch monitoring, AF was a detected on that patch in 34% (97.5% CI 29% to 39%). The positive predictive value for an irregular rhythm notification was 0.84 (95% CI 0.76 to 0.92). Because only notified participants received "gold standard" ECG monitoring, the study was unable to assess sensitivity or specificity.

Studies similar in design have been performed to test similar PPG-based algorithms on other smartwatch platforms. The Huawei Heart Study enrolled 246,541 participants in China to evaluate a fitness band and smartwatch and had directionally similar results, although a lower proportion receiving notifications, possibly due to a younger population or greater algorithm specificity.[7] In May 2020, Fitbit launched its own study to evaluate an algorithm on their device platform with target enrollment of 100,000 participants (https://clinicaltrials.gov/ct2/show/NCT04380415, accessed September 5, 2020).

Although these studies indicate the promise for undiagnosed AF detection in an at-risk population, the FDA views this class of algorithms as *prediagnostic* tools, rather than serving as more definitive

Measurement		Notification threshold	Use case
Active HR measurement (smartphone camera)		Low or high	Third-party solutions No uptake
Active irregular rhythm (phone camera, accelerometer)		Normal or atrial fibrillation	Third-party solutions No uptake
Passive HR sampling (every few seconds to minutes)		Low or high	Consumer experience **No FDA clearance**
Passive irregular rhythm notification		Single vs. repeated confirmation	Consumer-facing **FDA clearance as "prediagnostic"; not traditional screening**
Ad hoc ECG		Varies (FDA) Normal sinus vs. atrial fibrillation	Prediagnostic and disease management **FDA clearance**
Blended HR-ECG model (trained HR sensor)		To prompt ECG	Disease management **FDA clearance**

FIGURE 12.2 Evolution of consumer-facing photoplethysmography pulse measurement. (From Google, AliveCor. Screenshots reprinted with permission from Apple Inc.)

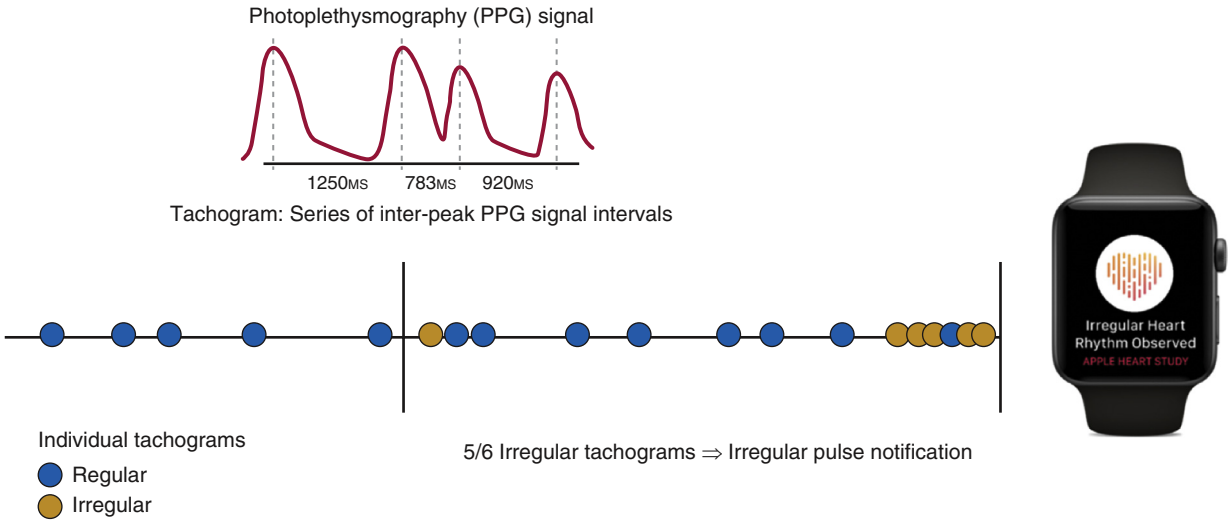

FIGURE 12.3 Irregular pulse detection algorithm. (From Perez M, Mahaffey KW, Hedlin H, et al. Large-scale assessment of a smartwatch to identify atrial fibrillation. *N Engl J Med*. 2019;381[20]:1909–1917.)

diagnostic tests. On the Apple platform, consumers must opt in to enable these features on their watches. In doing so, they receive onboarding that includes education. Because the sensitivity of these tests is not known and because they are enabled by the user rather than by a clinician as a public health intervention, these tools do not meet the classical Wilson-Jungner criteria for screening tests. Presently, there are no professional society or U.S. Preventative Services Task Force recommendations for their use for AF surveillance, screening, or diagnosis.

Electrocardiogram

More recent smartwatch models (Apple Watch Series 4 or higher, Samsung Galaxy Watch 3) have FDA-cleared single-lead ECG capability (see Fig. 12.1). The user actively records a 30-second lead I (right arm [–] to left arm [+]) ECG on the watch by pressing the crown with a finger of the hand opposite the hand with the watch body electrode. However, the first major smartphone-connected ECG was released in 2013 (AliveCor, Mountain View, CA). The Kardia device has two electrodes (one for each hand) and communicates wirelessly to a smartphone. A new six-lead consumer version (Kardia 6L) is now available that uses the right leg for additional limb and derived ECG leads.

Consumer-based ECG devices entail substantial limitations. Compared with medical 12-lead systems and patch-based ECG monitors, smartphone-connected and smartwatch ECG devices tend to have significantly more artifact. To counter this, aggressive filtering and baseline drift correction may be applied, which may obscure important ECG features. For example, a smartwatch algorithm incorrectly labeled a tracing of atrial tachycardia as atrial fibrillation (Fig. 12.4). Careful review shows that atrial tachycardia P waves have been attenuated due to filtering, which was clearly present on the medical 12-lead ECG. However, ST changes during acute coronary syndromes as measured by the Apple Watch in all 12 lead positions have shown good agreement with medical grade systems.[8]

Another major caveat is that consumer-based ECG systems also do not provide comprehensive prediagnostic information across a variety of rhythms compared with medical grade systems. Numerous examples of incorrect diagnosis, including of sustained ventricular arrhythmias, have been documented. Moreover, a ventricular rate that is out

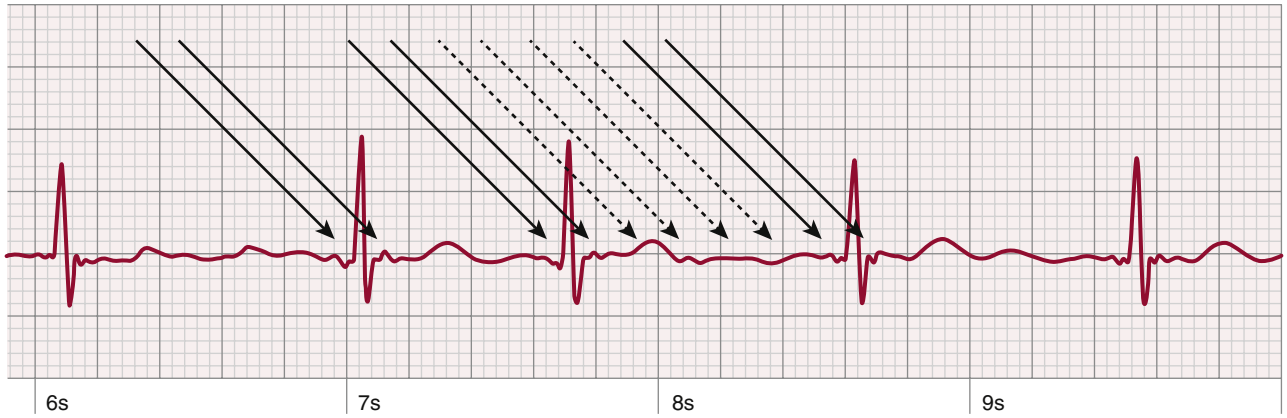

FIGURE 12.4 Atrial tachycardia misdiagnosed as atrial fibrillation due to filter attenuation. Careful observation of this Apple Watch electrocardiogram (ECG) rhythm strip identifies discrete organized atrial activity denoted by the solid arrows. The dashed arrows indicate atrial activity that appears attenuated due to filtering. A 12-lead ECG identified a macro-reentrant stable atrial tachycardia. Watch sampling was 513 Hz with 10 mm/mV gain and 25 mm/sec paper speed.

of range (<50 or >100) prevents automated ECG interpretation on the Apple Watch.

HYPERTENSION

There are hundreds of smartphone applications that allow the user to enter his or her blood pressure and track it and other vital signs over time. However, smartwatch applications and hardware that enable the device to measure blood pressure are relatively new. There are many unregulated smartphone apps that provide a blood pressure measurement based on pulse transit time derived from the PPG tracing. One such app has been found to be highly inaccurate, despite almost 150,000 paid downloads.[9] Many smartwatches available on online retail stores claim to measure blood pressure but do not have FDA clearance.

One smartwatch with FDA clearance for blood pressure uses traditional oscillometric measurement by using an inflatable cuff on the watch for blood pressure measurement (Omron Healthcare, Kyoto, Japan) (see Fig. 12.1). This watch connects to smartphones for transfer of information. A watch that uses PPG-derived pulse information to estimate blood pressure has received regulatory approval in South Korea (Samsung, South Korea) (https://news.samsung.com/global/samsung-launches-the-samsung-health-monitor-application-with-blood-pressure-measurement, accessed September 7, 2020). The device's artificial intelligence algorithm is trained and calibrated to an individual user's cuff readings. After sufficient training, the algorithm can be used to directly estimate blood pressure from the PPG data. The device is not yet approved in the United States.

CARDIAC REHABILITATION AND HEART FAILURE

Activity sensing and heart rate detection have been applied as measurement tools for heart failure and cardiac rehabilitation. Smartphone-based 6-minute walk assessments have shown high accuracy across a range of devices, applications, and disease states, including heart failure[10] and peripheral arterial disease.[11] Smart devices may have application programing interfaces to access step counts and distance traveled recorded by the watch rather than needing to access the raw data to derive these counts. Behavioral science and gamification have been incorporated into digital cardiac rehabilitation platforms. Although telehealth cardiac rehabilitation has proven at least as effective as center-based rehabilitation,[12] there remain relatively sparse randomized data on the efficacy of using mobile technology.[13]

In heart failure, mobile technology applications have focused on identifying patients at risk of heart failure and disease management (see also Chapter 11). Deep learning techniques applied to single- and multi-lead ECGs can identify systolic dysfunction with high discrimination (c-statistic 0.93),[14] although this has not been deployed in practice at scale. A pragmatic trial is ongoing (NCT04000087). Sensor technologies to assess pulmonary congestion (thoracic impedance) and cardiac filling and emptying (ballistocardiography, seismocardiography) appear feasible but require larger trials.[15] Machine learning–based detection of obstructive hypertrophic cardiomyopathy using wearable-derived PPG has shown high discrimination.[16]

CARDIAC ARREST AND SUDDEN CARDIAC DEATH

Without reliable continuous blood pressure, ECG monitoring, or the ability to deliver therapy, treatment of cardiac arrest from a wearable sensor is challenging. Fall detection on wearable devices can be configured to call emergency medical services. Assessment of hemodynamics or circulatory arrest, if accurate, could be used to trigger medical response and bystander cardiopulmonary resuscitation.[17]

EVALUATION OF WEARABLE DATA AND NOTIFICATIONS

Ancillary Information to the History

In patients with symptoms concerning for arrhythmia, pulse rate data may be useful to correlate heart rate at time of symptoms, similar to ambulatory ECG monitoring (Fig. 12.5A). A patient can be asked by the clinician if they may view the data together on the patient's phone. It is recommended that the phone be kept by the patient and that the clinician directs him or her to access the data. This method ensures transparency and also serves to teach patients to navigate their health information on their smartphone.

If tachycardia or bradycardia is found, the activity or exercise measurement and time of day may provide useful clues as to the arrhythmia trigger and reliability of the tracing (see Fig. 12.5B). Pulse rate data may also be useful to assess ventricular response in atrial fibrillation. However, PPG may significantly and unpredictably underestimate (or overestimate) ventricular rate, especially during rapid atrial fibrillation or in the presence of structural disease such as aortic stenosis. In patients with tachycardia during AF, only 15% of earlier generation Fitbit devices and 60% of Apple Watch readings were within 10 beats of the actual ventricular rate.[18] The use of pulse rate data during syncope can be useful but must be interpreted with caution because a fall can create mechanical artifact that may create spurious readings. Patients with smart ECG devices can be counseled to immediately take an ECG if and when they have recurrent symptoms.

Heart Rate and Rhythm Notifications

Based on the positive predictive value of 0.84, a smartwatch irregular rhythm notification in a patient with no prior history of AF must

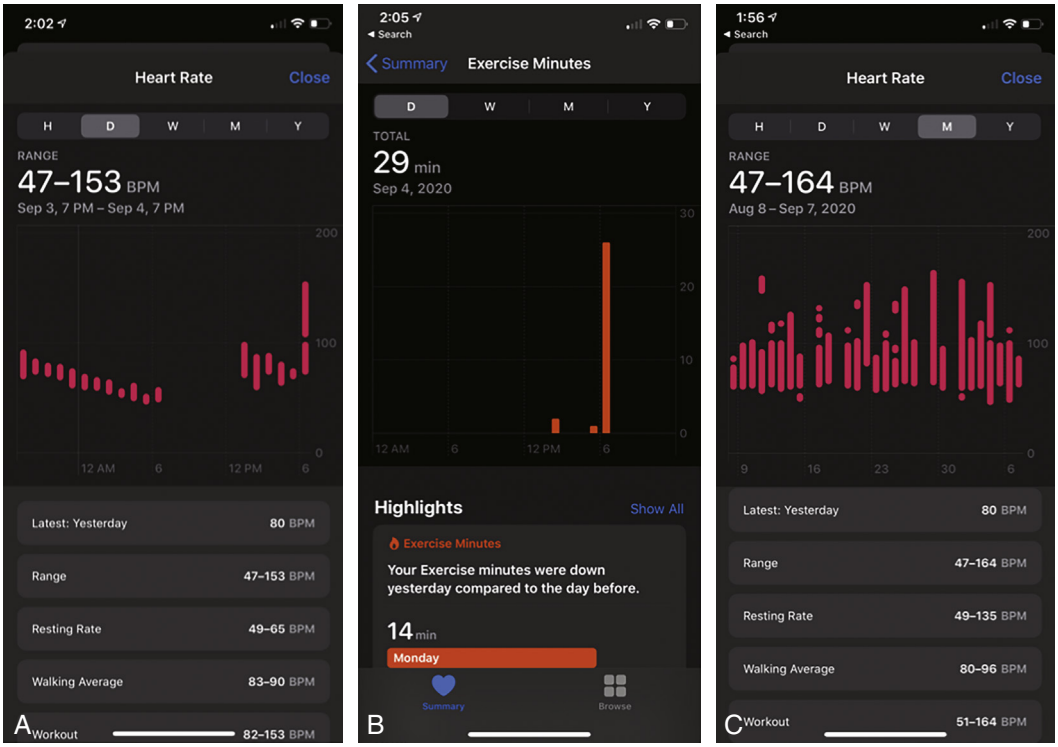

FIGURE 12.5 Pulse and activity data from a smart phone app. Data shown are pulse rate data in the Apple Health app on iPhone, which shows the pulse rate data sampled from the paired Apple Watch (Apple Inc, Cupertino, CA). **A**, Day level data show an abrupt rise in heart rate at 6 PM. **B,** Corresponding rise in activity (exercise), which is the likely cause of the tachycardia. **C,** Month level display of heart rates, which can be useful in the assessment of rate control of atrial fibrillation. (Screenshots reprinted with permission from Apple Inc.)

be taken seriously (Table 12.1). **Confirmation by an ECG is essential; the irregular rhythm notification alone is insufficient for clinical diagnosis.** The notification should prompt the clinician to ask a series of questions in the history no different than for subjective complaints: date, time, place, and context of what the patient was doing at the time of the notification. The patient should also be asked of prior notifications that were silenced or ignored. The smartphone app can also be used to collect more details and search for prior notifications.

In 25% of Apple Heart Study participants that received a notification, AF was present throughout the entire ambulatory ECG recording.[6] Therefore, an ECG taken by the patient on their watch or smart device may, with clinician verification, provide an immediate diagnosis (see Table 12.1). If AF is not present at the time of ECG, then ambulatory ECG monitoring of a minimum of 7 days and preferably 14 should be performed. If these two tests do not reveal AF, then consideration may be given for repeat ambulatory ECG monitoring or to counsel the patient to take an ECG if another notification is received. **Irregular rhythm notification alone does not suffice to make a clinical diagnosis of AF without ECG confirmation.** The feature is also not FDA cleared for use for AF disease management.

If non-AF arrhythmias are detected with ECG testing, then the clinician should inquire about symptom-arrhythmia correlation because many of ambulatory ECG findings such as infrequent atrial or ventricular ectopy could be inconsequential (see Table 12.1). Frequent or sustained non-AF rhythms could trigger irregular rhythm notifications. An appropriate work-up for these rhythms may be indicated.

Patients may also present with tachycardia or bradycardia notifications (see Table 12.1). On the Apple Watch, these are opt-in notifications where the user may set a specific threshold to be notified if the heart rate is greater than (default >120 beats/min) or less than (default <40 beats/min) specific rates while being inactive for a period of 10 minutes. Again, clinical attention should be given to the context and history. Watching sports or a movie, for example, could trigger tachycardia, and bradycardia during sleep may be normal. These features are not likely to detect exercise-induced or transient arrhythmias.

Activity, Exercise, and Sleep

The movement tracking features may be useful to provide a general sense of baseline level of activity and exercise. However, automated exercise logging, step counts, and sleep can be inaccurate, and these data are used best together with a history and patient report of activity.

LIMITATIONS

Despite the rapid innovation and incorporation of hardware and software into consumer wearables, progress has been slow to develop these tools into durable, disease management solutions. Electronic health record (EHR) integration is not robust or widely available; patients often communicate with their doctors or care team with their wearable data by electronic mail or messaging. In contrast, remote monitoring of cardiac implantable electronic devices (pacemakers, defibrillators, heart failure sensors) have tailored clinical software applications, mature workflows, stable reimbursement, clinical trials, professional society guideline recommendations, and a career path for allied health professional education.

THE FUTURE

Despite these limitations, rapid and sustained clinical adoption is likely. Large randomized trials that aim to evaluate hard outcomes are emerging. The HEARTLINE study (NCT04276441) aims to randomize 150,000 persons age ≥65 years to a smartwatch with AF detection capabilities and a study app for digital health engagement. Outcomes include clinical diagnosis of AF, anticoagulation adherence, and incidence of a composite cardiovascular outcome. Other studies are in various stages of development.

The introduction of new reimbursement codes in the United States for remote patient monitoring is expected to catalyze adoption by clinicians, practices, and health care systems. The dramatic post-pandemic shift to telehealth, including virtual visits and asynchronous care, has created new unmet needs for at-home complex cardiac diagnostics

TABLE 12.1 Management of Wearable and Smartwatch Pulse Notifications

For All Notifications		
• Obtain a full detailed history for context (date, time, place, symptoms) surrounding the notification • Ask the patient if you may view the data together on the patient's smartphone or watch; it is recommended that the patient hold the phone while the clinician directs him or her to access the data if needed • On the phone or watch, examine the heart rate, activity, and exercise data for useful clues (time of day, whether exercising, and heart rate before and after the notification) • Ask if this is the first notification or if there were others. The notifications can usually be found on the notification history on the connected smartphone • Determine if the patient's watch has an ECG feature or if the patient may have other smartphone ECG devices		
Tachycardia Notification	**Irregular Rhythm Notification**	**Bradycardia Notification**

• Several watch manufacturers can notify users of HR-activity discordance
• Algorithm will notify user if HR exceeds user-defined threshold (usually >100–150 beats/min) for more than 10 min while not active (based on embedded accelerometer or gyroscope)
• Assess if heart rate is appropriate (stress, anxiety, pain, dehydration, pregnancy, systemic illness, fever, deconditioning). If appropriate sinus tachycardia, then no further arrhythmia evaluation may be needed
• Examine pulse and obtain a medical-grade ECG
• Pursue appropriate diagnostic cardiac evaluation
  • Consider ambulatory ECG monitoring of 7–14 days or event recording of up to 30 days
	• An irregular rhythm notification alone should not be used to make the diagnosis of AF without ECG confirmation
	• The irregular rhythm notification feature is not cleared by the FDA for disease management or surveillance of established AF
	• As of January 2021, this notification is only available in the United States on the Apple watch series of products. Other hardware may access similar algorithms via the use of third-party software.
	• Determine if the patient has a history of documented arrhythmias that could explain these findings
	• Ask and look for whether a smartwatch-based ECG was taken at or near the time of notification. Counsel patient to do this when a notification is received, even in the absence of symptoms.
	• Examine pulse, and obtain a medical-grade ECG
	• If AF is not present, then perform ambulatory ECG monitoring of 7–14 days
	  ○ Consider repeat ECG monitoring based on clinical suspicion if initial test if negative
	  ○ If non-AF rhythms are identified, then inquire about symptom-arrhythmia correlation as these may be inconsequential
	• If arrhythmias are identified then pursue work-up with appropriate diagnostic evaluation
		• Algorithm will notify user if HR is less than a user-defined threshold (<40–50 beats/min) for more than 10 min
		• Examine pulse and obtain a medical-grade ECG.
		  • If there is sinus rhythm, then determine if response is normal and physiologic (high vagal tone) or secondary (medications, hypothyroidism, sleep apnea, other illnesses)
		  • If rhythm is not sinus, then evaluate for structural heart disease and primary electrical disease
		  • If symptoms are associated with bradycardia (presyncope, syncope, exercise intolerance), then consider ambulatory ECG monitoring and evaluation for structural heart disease
		  • If there are no symptoms, then consider ambulatory ECG or diagnostic tests to look for chronotropic incompetence (exercise treadmill testing)

ECG, Electrocardiogram.

and remote monitoring. In the future, sensor technologies may move away from a wearable framework and toward contactless sensing. Sensors in the home may detect and differentiate changes in vital signs, cardiac rhythm, activity, habits, medication adherence, and psychometrics for each household member. Behavioral incentives for good health may be embedded outside of traditional health care and insurance services and on to platform technologies in computing, retail, and social media. Low-cost, minimally invasive microsensors and microimplantables may also have a role where greater sensor fidelity is needed.

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