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Smart wearable devices in cardiovascular care: where we are and how to move forward

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Abstract | Technological innovations reach deeply into our daily lives and an emerging trend supports the use of commercial smart wearable devices to manage health. In the era of remote, decentralized and increasingly personalized patient care, catalysed by the COVID-19 pandemic, the cardiovascular community must familiarize itself with the wearable technologies on the market and their wide range of clinical applications. In this Review, we highlight the basic engineering principles of common wearable sensors and where they can be error-prone. We also examine the role of these devices in the remote screening and diagnosis of common cardiovascular diseases, such as arrhythmias, and in the management of patients with established cardiovascular conditions, for example, heart failure. To date, challenges such as device accuracy, clinical validity, a lack of standardized regulatory policies and concerns for patient privacy are still hindering the widespread adoption of smart wearable technologies in clinical practice. We present several recommendations to navigate these challenges and propose a simple and practical 'ABCD' guide for clinicians, personalized to their specific practice needs, to accelerate the integration of these devices into the clinical workflow for optimal patient care.

Technological innovations continue to become exceedingly ingrained into everyday life and consumers are beginning to use consumer-grade software and hardware devices to manage their health. Smart wearables are consumer-grade, connected electronic devices that can be worn on the body as an accessory or embedded into clothing. These include smartwatches, rings and wristbands, to name a few, and they all have high processing power and numerous sophisticated sensors that can glean new health insights. An estimated 20% of US residents currently own a smart wearable device and the global market is expected to grow at a compound annual growth rate of 25%, reaching US$70 billion by 2025 (REFS[1,2]). Although the integration of this technology in the clinical workplace is still in its infancy, it has rapidly moved through the Gartner Hype Cycle for emerging technologies[3] and its adoption has further accelerated after the coronavirus disease 2019 (COVID-19) pandemic and the explosive growth of telehealth[4]. In this Review, we summarize the basic engineering principles of common wearable sensors and discuss their applications in cardiovascular disease prevention, diagnosis and management. We also highlight several challenges hindering their widespread adoption and how to move forward as we embark on a new decade of clinical innovation. Finally, we propose a practical 'ABCD' guide for clinicians to handle wearables in routine clinical practice.

Engineering principles of wearable sensors

Activity sensors. Physical activity is inversely correlated to adverse cardiovascular outcomes[5] and all-cause mortality and is recommended by the AHA as one of the 'Life's Simple 7' lifestyle recommendations to promote heart health[6]. The assessment of physical activity levels has traditionally been subjective and recorded only during clinic visits, if at all. This approach is limited by a lack of sufficient detail, recall bias and a failure to objectively assess physical activity in a real-life environment. Common statements such as "I walk five times a week for 30 minutes" do not include important information such as physical activity intensity, distance and sedentary time. Therefore, the subjective reporting of physical activity levels will become obsolete as digital health trends, such as wearables and smartphones, can objectively and accurately assess physical activity and energy expenditure through various sensors.

The triaxial accelerometer is the dominant method of activity monitoring in current wearables and measures

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Key points

- Smart wearables generate a plethora of data through various sensors and software algorithms and understanding their basic engineering principles and limitations can be helpful for clinicians and scientists.
- Evidence supports the use of wearable devices in cardiovascular risk assessment and cardiovascular disease prevention, diagnosis and management, but large, well-designed trials are needed to establish their advantages.
- Several challenges still hinder the widespread adoption of wearables in clinical practice, including a concern for device accuracy, patient privacy and cost, and how to separate actionable data from noise.
- Overcoming these challenges requires that various stakeholders come together to develop comprehensive evaluation frameworks, pragmatic regulatory policies, clinical trials and medical education curricula.
- A practical 'ABCD' guide for clinicians can facilitate the integration of these devices in routine clinical practice.

linear acceleration along three different planes. The other major inertial sensor is the gyroscope, which measures angular motion[7]. The common operation principle of triaxial accelerometers is based on a seismic mass attached to a mechanical suspension system[7]. These devices take advantage of Newton's second law in which mass deflection to the opposite direction of motion with a certain amount of acceleration can be measured electrically. The three most common types of accelerometers are the piezoresistive, piezoelectric and differential capacitive accelerometers, with the differential capacitive accelerometer being the most commonly used in wearables owing to its superior performance[7]. In differential capacitive accelerometers, the seismic mass is suspended between two electrodes and the acceleration of the seismic mass is proportional to the differential capacitance between the electrodes[7]. The advantages of these accelerometers include low power consumption, fast response to motion and superior accuracy compared with the piezoresistive model, which can be undermined by its temperature sensitivity[7]. The placement site on the human body is one of the most important factors that affect the accuracy of accelerometer measurements[7]. A centrally located sensor on the torso (embedded into vests, mounted by straps or attached to the skin) is best suited for detecting posture, acceleration and whole-body movements and offers the least errors compared with other body locations[7]. An ankle-mounted sensor is better suited to measure steps and energy expenditure. However, wrist placement has taken precedence over ankle placement in commercial wearables owing to increased compliance and convenience[8].

Global Positioning System (GPS) and barometers are also included in wearables to more accurately assess physical activity. GPS utilizes a system of 24 or more satellites that are continuously emitting signals to identify their precise orbital position and time based on extremely accurate and stable atomic clocks[9]. With the use of complex equations that include signal emission time and speed of light and account for Einstein's relativistic concepts, the GPS receiver can determine its distance from at least four satellites. The receiver can then trilaterate its position on earth with an accuracy of up to 4.9 m (REF.[9]). However, GPS function is limited by satellite geometry, signal blockage, building reflections, atmospheric conditions and receiver design features[9]. By contrast, barometers utilize a diaphragm mounted on a vacuum chamber that compresses proportional to pressure. The amount of deformation of the diaphragm is converted to electrical signals via a capacitive model that relies either on plates moving closer together or on a piezoresistive strain model in which resistors on the diaphragm change their electrical resistance according to the extent of deformation[10]. The barometer is then able to determine changes in altitude, track stair count and detect falls on the basis of the principle that atmospheric pressure decreases with increasing altitude[10]. However, barometric measurements can be error-prone because the device might mistake natural changes in ambient temperature and pressure as a change in altitude[10]. Although the use of more sensors leads to better estimation of physical activity and energy expenditure, this approach can also put further strain on battery life[11].

Heart rate and rhythm sensors. Heart rate (HR) measurements during rest and exercise can be used to predict the risk of cardiovascular disease. In healthy populations, a high resting HR has been associated with an increased risk of coronary artery disease and all-cause death[12] and is also well recognized as a predictor of adverse outcomes in patients with heart failure (HF)[13]. An impaired HR recovery after exercise correlates with increased adverse cardiovascular events[14]. HR variability (HRV) has also been strongly linked to the risk of adverse cardiovascular events in healthy individuals and in patients with HF with reduced ejection fraction[15].

Commercial wearables measure HR and heart rhythm through electrocardiography (ECG) or photoplethysmography (PPG) by calculating beat-to-beat time intervals and using algorithms to classify heart rhythm. ECG sensors come in various forms and are the gold standard for HR and heart rhythm measurement. Chest-strap monitors and ECG patches provide continuous monitoring of heart rhythm but are less appealing to the average consumer than other options such as smartwatches given their bulkiness, limited functions and long-term inconvenience. Some smartwatches can record a single-lead ECG as needed by placing a contralateral finger on the crown (negative electrode on the side of the watch), with the back of the watch serving

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as the positive electrode[16]. Single-lead ECGs are useful to diagnose simple and common arrhythmias such as atrial fibrillation (AF). However, these single-lead ECGs are often insufficient for the accurate diagnosis of more complex arrhythmias and other conditions such as myocardial infarction (MI) or to detect interval abnormalities unless specific manoeuvres are deployed[17].

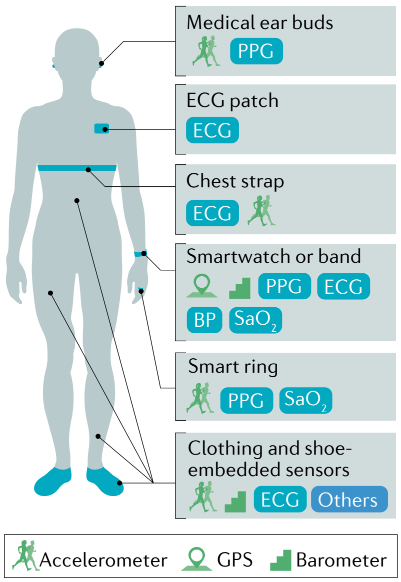
PPG measures changes in microvascular blood volume that translate into pulse waves and a tachogram recording[18]. An emitter sends a continuous pulse of photons through the skin and a photodetector measures the variable intensity of reflected photons from the tissue[18]. Most wearables continuously activate the PPG during exercise whereas, during rest and sleep, PPG measurements occur only intermittently to preserve battery life. PPG tachograms, especially when augmented by single-lead ECG, can also identify arrhythmias[19]. Nevertheless, PPG technology has limitations. The main drawback is that the sensor works best when in direct contact with the skin, which is not always the case with wearables secured with straps. Skin colour, moisture and even tattoos have also been postulated to affect PPG accuracy[20], although one study showed similar device performance across a full range of skin tones[21].

Given the variability in HR accuracy of PPG sensors across different wearable devices, a number of studies have directly compared their performance. One study that investigated the accuracy of the Apple Watch 3 (Apple, USA) and the Fitbit Charge 2 (Fitbit, USA) showed that both devices provided an acceptable PPG sensor HR accuracy (<10% mean absolute percent error) across 24 h and during various activities[22], including sitting, walking, running and activities of daily living (such as chores or brushing the teeth). Over 24 h, the Apple Watch 3 had a mean difference of −1.80 beats per minute and a mean agreement of 95% compared with the gold standard ECG[22]; the Fitbit Charge 2 had a mean difference of 3.47 beats per minute and a mean agreement of 91% compared with the gold standard ECG[22]. Another study evaluated the accuracy of several wrist-worn HR monitors (Fitbit Blaze, Apple Watch, Garmin Forerunner 235 (Garmin, USA), TomTom Spark Cardio (TomTom, Netherlands)) and one chest monitor (Polar H7, Polar Electro, Finland) compared with ECG in patients with established heart disease undergoing phase II or phase III cardiac rehabilitation[23]. The chest strap had the best concordance with the standard ECG during all activities (Lin's concordance coefficient $r_c = 0.99$); the accuracy of wrist-worn devices varied substantially by the type of activity and 5% of HR measurements were substantially inaccurate[23]. These studies highlight that PPG HR readings from wrist-worn devices during activity should be interpreted with caution[20], whereas less convenient, chest-strap monitors are more accurate. Further studies examining newer devices and their performance in diverse populations are needed to further understand the limits of PPG technology and improve its performance.

Blood pressure sensors. Hypertension is a leading cause of morbidity and mortality globally[24]. Incorporating accurate blood pressure (BP) measurement within consumer-grade wearables has the potential to improve screening for hypertension and identify nocturnal or exercise hypertension, which have been linked to worse outcomes[24]. The HeartGuide wristwatch (Omron, Japan), with a built-in cuff, was compared with an ambulatory BP device in office and ambulatory conditions[25]. For office BP measurements, patients were seated and wearing the HeartGuide wristwatch and the standard BP measurement device in the same non-dominant arm and BP readings were taken twice by each device in alternating 30–60-second intervals. For ambulatory BP measurements, patients were given an ambulatory, upper-arm machine that measures BP at 30-minute intervals over 24 h and were instructed to use the HeartGuide device after each ambulatory BP measurement at least 10 times while awake. The mean difference (±s.d.) in systolic BP between both groups was 0.8 ± 12.8 mmHg in the office-based setting and 3.2 ± 17.0 mmHg in the ambulatory setting[25]. These findings are consistent with previously described limitations of wrist-based cuff BP measurements[26]. BP can now be measured without a cuff, increasing the feasibility and ease of monitoring BP throughout the day. This technology uses a combination of PPG and ECG measurements to estimate BP by calculating the pulse transit time, that is, the time required for the arterial pressure wave to travel from the heart to a distant vessel[27]. In a small study, cuff-less BP measurements were compared with ambulatory device measurements[28]. Mean biases between the wearable and ambulatory devices over 24 h were 0.5 mmHg (−10.1 mmHg to 11.1 mmHg) for systolic BP and 2.24 mmHg (−17.6 mmHg to 13.1 mmHg) for diastolic BP, with the mean bias widening over 7 days to −12.7 mmHg for systolic BP and −5.6 mmHg for diastolic BP. Several other variables have been considered to measure cuff-less BP such as pulse wave velocity and propagation in combination with deep learning algorithms; however, most of the studies are limited by small sample sizes and a lack of external validation[29]. Although encouraging, cuff-less BP monitoring is still in its infancy and requires further scrutiny.

Other sensors. Biochemical sensors can measure body fluid electrolytes with the use of electrochemical transducers, offering valuable information about plasma volume status and analyte concentrations[30]. However, the accuracy of these sensors changes with skin temperature, skin contamination with dust, dried sweat or other substances, and hair density. One example of biochemical sensors are the minimally invasive continuous glucose monitors that have been clinically validated but are difficult to embed in consumer-grade wearables and mostly function as a stand-alone product[31]. Non-invasive sensors of sweat and saliva might be more practical to integrate into wearables but still need to be carefully evaluated[32].

Biomechanical sensors incorporated into clothing or shoes, such as ballistocardiograms, seismocardiograms and dielectric sensors, have been developed in an attempt to passively and continuously measure variables such as cardiac output, lung fluid volume and weight[1], which could be beneficial in managing conditions such as HF. Other biomechanical sensors, such as flexible,



Sensors	Measurements	Clinical applications
Activity		
Accelerometer	Step count, impact force, speed, sedentary time, exercise	• Risk assessment in healthy individuals and those with established CVD • Physical activity behavioural interventions in primary and secondary prevention • Cardiac telerehabilitation • Heart failure management
Barometer	Stair count	
GPS	Distance traveled	
	Calories burned estimated from multiple measurements	
Biometric		
PPG	HR, HRR, HRV, cuff-less BP, SaO_2, cardiac output, stroke volume, pulse-based rhythm detection, sleep and its stages	• Risk prediction in healthy individuals and those with established CVD • Hypertension screening and management • Cardiac telerehabilitation • Arrhythmia screening and diagnosis • Acute coronary syndrome diagnosis • Diagnosis of electrolyte abnormalities such as hyperkalaemia • Long QTc diagnosis • Heart failure management • Medication titration such as β-blockers
ECG	Single-lead and multi-lead ECG, continuous or as-needed ECG monitoring, interval measurements such as QTc, arrhythmia detection and electrolyte abnormality changes	
Oscillometry	Wrist cuff BP	
Other		
Biochemical sensors	Invasive for continuous blood glucose and electrolyte monitoring Non-invasive for sweat and saliva electrolytes and hydration status	• Identifying electrolyte abnormalities • Continuous blood glucose monitoring • Heart failure management
Biomechanical sensors such as ballistocardiograms, seismocardiograms and dielectric sensors	Cardiac output, stroke volume, lung fluid volume, body vibrations, weight	

Fig. 1 | **Different smart wearable devices and their cardiovascular applications.** Summary of common commercial smart wearables available on the market, where they are worn on the body, their built-in sensors, and the different types of measurements collected by each sensor and their various cardiovascular clinical applications. BP, blood pressure; CVD, cardiovascular disease; ECG, electrocardiogram; GPS, Global Positioning System; HR, heart rate; HRR, heart rate recovery; HRV, heart rate variability; PPG, photoplethysmography; SaO_2, oxygen saturation.

tattoo-like sensors based on microfluidics, are also promising for non-invasive, haemodynamic, continuous monitoring. However, all these emerging sensors still require extensive clinical validation[33].

FIGURE 1 summarizes common smart wearable devices, their embedded sensors and their applications in cardiovascular care. TABLE 1 lists common wearable products on the market, the published studies on these products and their regulatory status.

Wearables in cardiovascular care

In this section, we discuss the literature supporting the use of wearable devices in cardiovascular patient care, reviewing the critical clinical studies on the most common cardiovascular applications published in the past 15 years (TABLE 2).

Risk assessment and lifestyle interventions. Global cardiovascular disease risk assessment is traditionally based on clinical risk scores that estimate the 10-year risk. However, most of these scores do not capture the dynamic changes in personalized risk that closely follow lifestyle habits. The incorporation of subjective lifestyle behaviours in risk assessment has been challenging; therefore, objective data derived from wearables provide a renewed opportunity to make the assessment of the risk of cardiovascular disease more accurate, comprehensive and dynamic over a lifetime. Several studies have shown wearable-measured physical activity to have an inverse dose-dependent relationship with all-cause mortality[5,34–38]. Moderate-to-vigorous physical activity (MVPA), measured with the use of triaxial accelerometers, was associated with a lower mortality than light physical activity or sedentary behaviour in several US cohorts and in a Swedish population-based cohort[34–38]. Another study of women with a mean (s.d.) age of 72 (5.7) years showed that as few as 4,400 steps per day were significantly associated with a 41% reduction in mortality compared with 2,700 steps per day, but the benefits levelled at 7,500 steps per day[39]. Of note, stepping intensity was not associated with mortality after adjusting for steps per day.

Wearable data also facilitate the application of real-time behavioural change techniques (BCTs) such as just-in-time adaptive interventions, designed to dynamically assess user needs and provide the appropriate amount and type of intervention at the relevant time. Several trials were designed to assess the benefits of wearable-guided BCTs. The mActive trial enrolled 48 outpatients from an academic cardiovascular centre[40]. The prevalence of hypertension, diabetes mellitus and coronary heart disease in study participants was 50%, 23% and 29%, respectively. Trial participants were randomly assigned into two groups, blinded and unblinded

Table 1 | **Number of studies and FDA status of common smart wearable devices on the market**

Company	Product name	Biological measurement	All studies on PubMed[a]	Number of clinical trials[b]	Number of cardiovascular clinical trials[c]	FDA status[d]
Watches						
Adidas	miCoach Fit Smart	HR, PA	0	1	1	Not cleared or approved
Apple	Apple Watch	HR, PA, falls, sleep and ECG	135	49	18	Cleared
Biobeat	BB-613WP	HR, PA and cuff-less BP	0	9	3	Cleared
Fitbit	Flex, One, Charge	HR, PA and sleep	612	530	40	Cleared
Garmin	Vivoactive, Vivofit, Forerunner	HR, PA and sleep	51	55	12	Not cleared or approved
Huawei	Huawei Watch GT, Huawei Band	HR, PA and SPO_2	6	0	0	Not cleared or approved
Karacus	DIONE, TRITON	HR and PA	0	0	0	Not cleared or approved
Omron	HeartGuide	HR, PA, sleep and cuff BP	3	2	2	Cleared
Samsung	GearFit 2	HR, PA and sleep	0	2	1	Not cleared or approved
SmartCardia	INYU	HR, PA and ECG	0	0	0	Not cleared or approved
TomTom	TomTom Spark	HR and PA	3	1	1	Not cleared or approved
Withings	Steel HR, Move, Move ECG, Pulse HR	HR, PA, sleep, ECG and SPO_2	20	3	2	Not cleared or approved
Google	Wear OS on different hardware manufacturers	HR, PA and sleep	3	0	0	Not cleared or approved
Patches						
iRhythm	Zio Patch	HR and ECG	23	18	18	Cleared
Preventice Solutions	BodyGuardian	HR and ECG	4	4	4	Cleared
Corventis Inc.	Nuvant MCT	HR and ECG	3	2	2	Cleared
Bardy Dx	BardyDx CAM	HR and ECG	0	0	0	Cleared
BioTelemetry	BioTel Heart	HR and ECG	0	0	0	Cleared
MediBioSense	MediBioSense MBS HealthStream	HR and ECG	0	0	0	Cleared
Huinno	MEMO Patch	HR and ECG	0	0	0	Not cleared or approved
Samsung	S-Patch Cardio	HR and ECG	1	0	0	Not cleared or approved
Bands						
AliveCor	KardiaBand (commercially discontinued)	HR and ECG	3	1	0	Cleared
Microsoft	Microsoft Band	HR, PA and sleep	49	7	1	Not cleared or approved
Nike	FuelBand (commercially discontinued)	PA	18	2	1	Not cleared or approved
Under Armour + HTC	UA Band	HR, PA and sleep	0	0	0	Not cleared or approved
Xiaomi	Mi Band	HR and PA	3	11	4	Not cleared or approved
Fitbug	Fitbug ORB	PA and sleep	1	1	1	Not cleared or approved
Rings						
Motiv	Motiv Ring	HR, PA and sleep	0	0	0	Not cleared or approved
Oura	Oura Ring	HR, PA and sleep	7	7	0	Not cleared or approved

Table 1 (cont.) | **Number of studies and FDA status of common smart wearable devices on the market**

Company	Product name	Biological measurement	All studies on PubMed[a]	Number of clinical trials[b]	Number of cardiovascular clinical trials[c]	FDA status[d]
Miscellaneous						
AliveCor	KardiaMobile	HR, single-lead and 6-lead ECG	28	13	11	Cleared
Omron + AliveCor	Complete™	HR, BP and ECG	0	0	0	Cleared
SonoHealth	EKGraph	HR and ECG	0	0	0	Not cleared or approved
BioSensive Technologies	Joule Earrings	HR and PA	0	0	0	Not cleared or approved
GraphWear	GraphWear epidermal sensor	Blood glucose and lactic acid measurement	0	1	0	Not cleared or approved
Abbott	Freestyle Libre	Continuous blood glucose measurement	166	106	3	Approved
Jabra	Sports Pulse Wireless Headphone	HR and PA	1	1	0	Not cleared or approved
Komodo Technologies	AIO Smart Sleeve	HR, PA, ECG and sleep	0	0	0	Not cleared or approved
Zephyr	BioHarness 3 clothing	ECG, HR, PA, respiratory rate and skin temperature	22	0	0	Cleared
Polar	Polar H7 strap	HR and PA	129	8	3	Not cleared or approved
Total	–	–	1,291	833	128	15

The information is current as of October 2020. BP, blood pressure; ECG, electrocardiogram; HR, heart rate; PA, physical activity; SPO_2, arterial oxygen saturation. [a]Search terms used on PubMed.gov included "wearable device name"; all article types included. [b]Registered at ClinicalTrials.gov; search terms included "device name" in the 'other terms' search tab. [c]Registered at ClinicalTrials.gov; search terms included "device name" in the 'other terms' search tab and "heart" in the 'conditions' search tab. [d]FDA clearance means that a class I or II medical device has demonstrated substantial equivalence to another (similar) legally marketed device through a 510(K) premarket submission; FDA approval means that a class III device has demonstrated safety and efficacy after submitting a premarket approval application, the most stringent regulatory category of medical devices.

to their Fitbug ORB (Fitbug, USA) activity, and evaluated in two phases[40]. The initial phase involved the use of only the tracking device and the second phase entailed the use of smart texts with BCTs for the unblinded group. The smart texts were automated and personalized (coaching SMS messages designed by the physician investigators and informed by real-time activity from the device). The messages were divided into positive reinforcement messages, when participants were on track or had already attained their goal of 10,000 steps per day, or boosting messages to motivate participants who were not on track to reach their goal. The text messaging group increased their daily steps by 2,534 compared with the no-texting unblinded group and by 3,376 steps compared with blinded controls[40]. Gamification, another type of BCT, leverages competition between members of a shared activity network to encourage lifestyle modifications. In the BE FIT Framingham trial[41], involving 200 participants from 94 families, participants in the gamification group were more likely to achieve step goals and had a significant increase in mean daily steps from baseline compared with the control group (1,661 versus 636 increase; adjusted difference 953, 95% CI 505–1,401)[41]. Another gamification study randomly assigned participants to either a Fitbit-only group or a Fitbit plus MapTrek (a virtual global racing platform) group to promote physical activity[42]. Participants with MapTrek had an average of 1,455 more steps per day and 89.6 additional active minutes per week than the Fitbit-only group[42]. A 2 × 2 factorial randomized trial examined whether goal setting (adaptive versus static goals) and rewards (immediate versus delayed financial incentives) had an effect on step count and MVPA with the use of a Fitbit Zip in 96 participants[43]. The trial showed that adaptive goals outperformed static goals and small, immediate rewards outperformed larger, delayed rewards, suggesting that adaptive goals with immediate rewards should be preferred to promote physical activity. However, some researchers have questioned the value of activity trackers for health promotion[44,45]. A four-arm trial from Singapore randomly assigned 800 participants to control (no tracker or incentives), Fitbit Zip, Fitbit Zip plus charity incentives or Fitbit Zip plus cash incentives[44]. The trial showed that a cash incentive was most effective at increasing MVPA at 6 months, but this effect was not sustained 6 months after the removal of incentives. Moreover, despite the improvement in MVPA at 12 months with activity tracking, with or without incentives, these findings did not translate into an improvement in health outcomes, such as weight and BP reduction, at 12 months. The encouragement of physical activity is a cornerstone of primary and secondary prevention; therefore, cardiovascular specialists should familiarize themselves with BCT platforms that have been proven to work and recommend them to their patients, particularly those who have failed to follow traditional counselling for the promotion of physical activity.

Frequent wearable-generated HR measurements, such as resting average HR, HR recovery and HRV, can

Table 2 | **Summary of cardiovascular clinical applications of wearable devices and key studies**

Cardiovascular applications	Wearable device measurement	Wearable device	Key clinical outcome studies	Summary
Risk assessment	Step counting and stepping intensity	Triaxial accelerometers including, ActiGraph AM-7164 (ActiGraph, USA), activPAL (PAL Technologies, Scotland), ActiGraph GT3X (ActiGraph, USA)	Prospective cohort studies[34–39]	Objectively measured PA levels, categorized into sedentary behaviour, light PA and MVPA, can be used to assess the risk of cardiovascular and all-cause death
	Heart rate and step counting	Fitbit (Fitbit, USA), Apple Watch (Apple, USA), Wear OS (Google, USA)	Retrospective study[59]	A machine learning algorithm using heart rate and step count was able to classify cardiovascular risk factors such as high cholesterol levels and hypertension
Physical activity interventions	Step counting and active minutes Interventions: text messaging, gamification, adaptive goals, financial incentives	Fitbug Orb (Fitbug, USA), Fitbit Flex and Fitbit Zip (Fitbit, USA), Fitbit Zip + MapTrek platform	Randomized controlled trials[40–43]	PA interventions, including texting, gamification and social or financial incentives, can promote PA
	Step counting, MVPA time, clinical variables, including weight and BP Interventions: activity tracking with or without cash or charity incentives	Fitbit Zip and Fitbit One (Fitbit, USA)	Randomized controlled trials[44,45]	PA interventions did not show long-term behavioural changes or did not improve clinical outcomes
AF and other arrhythmias	PPG tachograms or notification algorithms and single-lead and multi-lead ECG	Apple Watch (Apple, USA), AliveCor Kardia Band and KardiaMobile (AliveCor, USA), Zio Patch (iRhythm Technologies, USA)	Prospective cohort studies[19,51–53,55–57], randomized controlled trials[50,58]	AF screening via ECG patches in selected high-risk individuals is feasible and clinically valuable[50]
				AF screening through PPG has shown variable accuracy depending on the algorithms and devices used[19,51,52]
				AF screening through PPG coupled with ECG is feasible and practical; no clinical studies available; the HEARTLINE study aims[54] to examine this application and its effect on clinical outcomes
				The IPED trial[58] showed that a single-lead ECG monitor can improve outpatient arrhythmia detection in patients who present to the emergency room with palpitations or presyncope and no clear aetiology
				Wearables can be used to assess AF burden; rhythm-guided anticoagulation is a feasible approach in some patients with AF; no clinical studies exist but a trial examining smartwatch-guided anticoagulation therapy is under development
				Wearables were used in one study to confirm persistent AF before admission for cardioversion[53]
				Wearables can be used to guide rate control in patients with permanent AF; no clinical studies available
Coronary artery disease	Heart rate, step counting and single-lead ECG	Apple Watch	Prospective cohort study[76], case report[17]	In patients with type I myocardial infarction, the MICORE study[76] showed that a mobile app platform (including a smartwatch) improved secondary prevention management by reducing hospital readmissions and cost
				Wearables can be used to guide β-blocker titration in patients with chronic coronary syndrome; no available clinical studies
				Single-lead ECG wearables can be manipulated to acquire a 12-lead ECG for acute coronary syndrome diagnosis, as shown a in case report[17]

Table 2 (cont.) | **Summary of cardiovascular clinical applications of wearable devices and key studies**

Cardiovascular applications	Wearable device measurement	Wearable device	Key clinical outcome studies	Summary
HF diagnosis and management	Heart rate, step counting and single-lead ECG	PhysioMem (PM 1000, GETEMED Medizin und Informationstechnik AG, Germany), unidentified wrist ECG sensors	Randomized controlled trials[66–70]	TEN-HMS, TIM-HF and BEAT-HF trials showed that a remote telemonitoring intervention did not reduce HF hospitalizations and all-cause mortality[68–70]
				The TEMA-HF1 and TIM-HF-2 trial showed that telemonitoring reduced days lost owing to HF hospitalizations and reduced all-cause mortality[66,67]
				More studies are needed to assess the value of telemonitoring and remote sensors in HF management; wearables can be used to objectively and frequently assess HF prognosis via 6-minute walk tests or measuring heart rate variables such as heart rate recovery or variability; no clinical studies available
				Wearables can be used to detect high-risk arrhythmias and stratify patients who might need a defibrillator; no clinical studies available
Cardiac rehabilitation	Step counting and heart rate	BioHarness 3 (Zephyr Technology, USA), Garmin Forerunner (Garmin, USA), Senswear mini armband (commercially discontinued), Yamax pedometers (Japan), Fitbit Charge, My Wellness Key accelerometer (commercially discontinued), Gex sensor (commercially discontinued)	Randomized controlled trials, a systematic review and a meta-analysis[85,86]	Home-based cardiac telerehabilitation using wearable sensors is equivalent or better than centre-based rehabilitation and can increase access to cardiac rehabilitation and reduce the cost
QT interval measurement	Single-lead or 6-lead ECG	BodyGuardian (BG-Preventice Solutions Group, USA), KardiaMobile 6-lead ECG	Prospective cohort study[78], retrospective study[79]	Single-lead or 6-lead ECG was able to reasonably measure the QTc interval but with clinically significant variability; further studies are needed before clinical adoption
Hypertension diagnosis or management	Oscillometric or cuff-less BP	None	None	No clinical studies available (only BP measurement validation studies)
Hyperkalaemia diagnosis	Single-lead ECG	AliveCor investigational device	Retrospective study followed by prospective validation[82,83]	Hyperkalaemia detection via wearable ECG is feasible but has high false-positive rates; further studies are needed before clinical adoption
Peripheral vascular disease management	Step counting and heart rate	Fitbit Charge, Fitbit One, Fitbit Zip, StepWatch 3 (Modus, USA), Nike + FuelBand (commercially discontinued), Yamax pedometer, Pam personal	Randomized controlled trials[88–90] and a systematic review[91]	Randomized trials showed that wearable-guided exercise prescriptions improve walking ability, speed and oxygen consumption[88,89]
				Other trials showed no improvement in walking ability or quality of life but improvement in exercise frequency[90,91]

AF, atrial fibrillation; BP, blood pressure; ECG, electrocardiogram; HF, heart failure; MVPA, moderate-to-vigorous physical activity; PA, physical activity; PPG, photoplethysmography.

potentially be incorporated in cardiovascular risk scores given their correlation with cardiovascular disease, as described in previous sections. Moreover, longitudinal HR data can establish what is normal for an individual and, subsequently, recognize important deviations in lifestyle earlier, before cardiovascular disease develops[46]. HR-guided training has also been gaining popularity[47]; however, no clinical trials have examined the benefits of this training.

Screening and diagnosis

Hypertension. Initiating hypertension screening in young adulthood is widely recommended to prevent cardiovascular disease[24]. Oscillometric or cuff-less wearables that accurately measure BP and are continuously worn on the wrist might be more convenient in the ambulatory setting than traditional upper arm BP devices for the screening of hypertension, the self-monitoring of BP and the titration of antihypertensive drugs[48]. However, dedicated studies on the use of these wearable wrist devices for hypertension screening and management are needed. Continuous wearable BP measurements using novel sensors will potentially facilitate the measurement of BP during sleep or activities such as exercise when oscillometric measurements are not practical. Future studies are needed to determine whether these continuous BP data have any clinical significance[33]. For example, the continuous measurement of BP can have the potential to detect cardiac arrest or haemodynamic shock, thus saving lives.

Atrial fibrillation and other arrhythmias. The global burden of AF and its association with stroke, HF and mortality have been well established[49]. Wearables might be a convenient tool to diagnose asymptomatic or symptomatic AF[20]. The mSToPS study[50], which included both a randomized trial and a prospective cohort, evaluated the effect of immediate versus delayed continuous ECG monitoring with the use of a Zio patch (iRhythm Technologies, USA) on new AF diagnosis at 4 months and 1 year. The study showed that ECG monitoring led to a higher rate of new AF diagnosis at 4 months and 1 year and was associated with the increased initiation of anticoagulation therapy and outpatient cardiology and primary care visits in patients without previously known AF[50]. The Apple Heart study[19], the largest remotely conducted study to date, enrolled 419,297 participants in the USA over 8 months to ascertain whether a PPG-enabled device could detect AF in individuals without a known history of the disease. Once an initial tachogram met irregularity criteria, the algorithm scanned for PPG irregularities during periods of minimal arm movement. If four subsequent irregular tachograms were confirmed, the participant was notified of an irregular pulse via a notification on the Apple Watch and study app. The positive predictive value for AF detection was 84% and 71% for the irregular notification algorithm and individual tachograms, respectively[19]. In a proof-of-concept study involving the use of Apple Watch-based PPG sensor data, a deep neural network (DNN) algorithm trained with heuristic pretraining showed excellent prediction of AF (C-statistic 0.97) against the gold standard 12-lead ECG[51]. Another study that assessed the use of the Huawei Band 2 (Huawei, China) PRO AF algorithm showed a positive predictive value of 99.6% and a negative predictive value of 96.2%[52]. KardiaBand (AliveCor, USA), now commercially discontinued, coupled with the SmartRhythm 2.0 DNN was compared with implantable cardiac monitors in a study that collected >31,000 h of continuous heart rhythm data and showed a sensitivity of >97% for detecting AF episodes lasting ≥1 h (REF.[53]). However, the KardiaBand experienced difficulty in interpreting up to 33.3% of recordings in another analysis[53]. The ongoing HEARTLINE trial[54] is the first randomized trial to investigate whether detecting symptomatic and asymptomatic AF with the use of an Apple Watch 4 or a newer model (with combined PPG and ECG) improves clinical outcomes[20]. The trial aims to recruit 150,000 US residents aged ≥65 years and evaluate whether AF detection with a wearable device would improve clinical AF diagnosis, reduce hard outcomes and increase compliance with anticoagulation therapy.

The diagnosis of symptomatic arrhythmias has also moved from burdensome strategies, such as the use of bulky Holter monitors, to more convenient wearable monitors. Wearable monitors can provide continuous, single-lead ECG monitoring, such as the Zio patch, or continuous PPG heart rhythm monitoring coupled with as-needed ECG such as the Apple Watch. Although most of these devices are only single lead, they can be as effective or even exceed the ability of conventional Holter monitoring to detect arrhythmias owing to their convenient usability over longer periods of time[55,56]. A DNN that used single-lead, ambulatory ECG data was able to classify 12 rhythm classes with a high diagnostic performance similar to, and perhaps exceeding, practicing cardiologists[57]. This technology could be applied to wearables in the future. The IPED study[58] was a multicentre, randomized trial that recruited 243 patients who presented to the emergency department with palpitations and presyncope without a clear aetiology. Participants in the IPED study were randomly assigned to an intervention group with KardiaMobile SL (AliveCor, USA) or to standard care. At 90 days, a symptomatic rhythm was detected in 55.6% of participants in the intervention group compared with only 9.5% in the control group. The mean time to symptomatic rhythm detection in the intervention group was 9.5 days compared with 42.9 days in the control group[58]. Although KardiaMobile is not considered a wearable device, wearables with single-lead ECG can be similarly used to diagnose arrhythmias in patients with palpitations or presyncope.

Other diagnostic applications. For risk factor screening, a semi-supervised learning algorithm, developed from >57,000 person-weeks of data from Fitbit, Apple Watch and Wear OS (Google, USA), classified high cholesterol levels and hypertension with high accuracy (area under the curve (AUC) 0.7441 and 0.8086, respectively) using HR and step count data available from these commercial wearables[59]. In another study, a convolutional neural network developed with a training dataset of 35,970, 12-lead ECGs and validated in an independent dataset of 52,870 ECGs classified ventricular dysfunction with good accuracy[60]. After a median follow-up of 3.4 years, patients with a false positive (those without ventricular dysfunction by echocardiography but classified by the machine learning ECG algorithm as having left ventricular dysfunction) were at fourfold increased risk of developing ventricular dysfunction in the future compared with patients with a true negative (those without ventricular dysfunction by both echocardiography and the machine learning algorithm)[60]. Of note, these 12-lead ECG prediction algorithms need to be validated with the use of single-lead ECGs before incorporation into wearable devices.

Cobos Gil proposed a novel method to use the Apple Watch 4 to obtain standard and precordial leads by manipulating the placement of the watch back crystal and crown on the arms, legs and chest[17]. Although this approach might have limitations, it could be pragmatic as a diagnostic bridge for acute coronary syndromes when a standard ECG cannot be obtained such as in remote rural areas.

The current processing power and battery life of wearables might constrain the use of sophisticated machine learning algorithms. Therefore, Sopic et al. created a unique, two-level classification system for MI[61]. This system included an initial screening level, which considered only a few features to detect if any ischaemic abnormalities needed further evaluation, followed by a second-level classifier, which was more computationally demanding but more accurate compared with the screening level. The algorithm was tested on SmartCardia INYU devices (SmartCardia, Switzerland) and achieved a clinically relevant accuracy of 90% for classifying MI[61]. These multi-layered algorithms require extensive validation before being considered for clinical use.

Management of patients

Heart failure. In patients with HF, common wearable data, such as physical activity levels, HR, HR recovery and HRV, can be used for risk stratification. For example, one study showed that administering the 6-minute walk test through a pedometer is feasible and can be used to predict HF severity and death[62]. HRV in patients with mildly symptomatic HF can help to identify individuals with limited benefit from cardiac resynchronization therapy[63]. Therefore, the use of wearable-measured HRV might be beneficial in predicting the response to cardiac resynchronization therapy in patients with HF. Emerging biomechanical sensors, such as dielectric sensors, are also promising for HF management but require careful evaluation before clinical adoption.

Several randomized trials have assessed the value of remote invasive and non-invasive telemonitoring interventions in HF, with mixed results[64]. One of the landmark trials on remote telemonitoring[65] randomly assigned patients with NYHA class III HF to either a treatment group, in which clinicians had access to pulmonary artery pressure readings from an implanted CardioMEMS Heart Sensor (CardioMEMS, USA), or to a control group, in which clinicians had no access to this information. After a mean follow-up of 15 months, the telemonitoring group had a 39% reduction in HF-related hospitalization compared with the control group[65]. The TIM-HF2 trial[66] randomly assigned 1,571 patients with NYHA class II–III and a left ventricular ejection fraction (LVEF) of ≤45% (or an LVEF of >45% if receiving oral diuretics) to usual care plus remote management or to usual care only. The structured remote intervention consisted of a multicomponent system comprising a three-channel ECG (PhysioMem PM 1000, GETEMED Medizin und Informationstechnik AG, Germany), a BP device, a weight scale and an oxygen saturation device. The intervention, compared with usual care, was associated with a smaller proportion of days lost from unplanned HF-related hospital admissions and had a lower all-cause mortality (HR 0.70, 95% CI 0.50–0.96) after 393 days of follow-up[66]. In the TEMA-HF1 trial[67], 164 patients with HF and a mean LVEF of 35 ± 15% were randomly assigned to intensive follow-up facilitated by telemonitoring (daily BP, weight and HR measurements with the use of electronic devices) or usual care. The intervention group had a significantly lower all-cause mortality (absolute reduction of 12.5%) and a lower number of follow-up days lost to death, hospitalization or dialysis. However, this effect might have been due to the thorough follow-up and not necessarily to the use of remote devices[67]. Although certainly promising, other trials have not shown the same favourable outcomes. The TEN-HMS home telemonitoring trial[68] used wearable and non-wearable non-invasive monitors (home BP monitor, weigh scale and single-lead ECG on a wrist band) in patients with an LVEF of <40% and a recent hospital admission for HF and showed no significant differences in days lost owing to hospitalization or death compared with nurse telephone support or usual care at 240 days, although the telemonitoring group had a lower mean duration of hospital admission by 6 days. The TIM-HF trial[69] randomly assigned 710 patients with an LVEF of ≤35%, NYHA class II–III and a history of HF decompensation within the previous 2 years to telemonitoring (weight, BP and heart rhythm data transmission) compared with usual care and found no differences between the groups in cardiovascular and all-cause mortality or in hospitalizations at a median follow-up of 26 months. One of the largest trials on telemonitoring in HF, the BEAT-HF study[70], randomly assigned 1,457 elderly patients hospitalized for HF (median LVEF of 43%) to usual care or to remote care after hospital discharge consisting of telemonitoring (daily collection of BP, HR, symptoms and weight data) combined with telephone-based coaching. The trial had low adherence rates in the remote-care group; only 61.4% and 55.4% of patients assigned to this group were >50% adherent to telephone calls and telemonitoring, respectively, within the first 30 days. Moreover, the remote care intervention did not lower the rate of hospital readmission for any cause at 30 days or 180 days after hospital discharge[70]. Other smaller studies have shown mixed results[52,64]. Trials on HF telemonitoring have considerable differences in inclusion criteria and trial design such as the types of remote devices used and variables collected, thereby limiting the reproducibility and generalizability of these studies. In addition, most trials had a risk of bias due to the lack of blinding. Larger trials with more standardized protocols that utilize validated devices and ensure higher adherence rates might shed further light on the true value of wearable sensors in HF management.

Established atrial fibrillation. We have discussed the use of wearables to diagnose symptomatic or asymptomatic AF in previous sections; in this section, we now focus on the applications of wearables in individuals with established AF. Non-invasive, continuous heart rhythm data generated by wearables have the potential to shift the definition of AF from a categorical to a continuous and quantifiable entity, opening new frontiers in anticoagulation and rhythm control strategies. Wearables can further empower patients with AF in their care through a targeted approach to anticoagulation coinciding with the episodes of AF[71]. A study of patients with AF who underwent catheter ablation showed that twice-daily pulse checking and the initiation of direct oral anticoagulants when a pulse irregularity was detected was a feasible practice[72]. The REACT.COM pilot study[73] recruited patients with an implantable cardiac monitor to initiate anticoagulation if the patient developed an AF episode of ≥1 h. This study showed a 94% reduction in anticoagulation use compared with chronic anticoagulation treatment[73], with a saving of approximately US$800 per patient over 3 years[74]. Similarly, the iCARE-AF study[71] randomly assigned patients with paroxysmal AF to continuous or as needed anticoagulation according to KardiaMobile-generated ECG recordings. The study demonstrated the feasibility of this approach but patient compliance was a concern compared with an implanted monitor[71]. Utilizing wearables to tailor anticoagulation regimens holds great potential but should be judiciously used in select patients according to their individual compliance and risk of stroke. Turakhia et al. are currently developing a large ($n=5{,}000$) trial of rhythm-guided treatment with direct oral anticoagulants with the use of smartwatches (M.P.T., unpublished work). The trial will be powered for superiority for major bleeding events and non-inferiority for ischaemic stroke. Wearables might also be used to confirm persistent AF in patients before presenting for elective cardioversion, thereby preventing unnecessary hospital visits and costs[53]. Finally, this technology might have value in optimizing the ventricular rates at rest and during exercise in patients with permanent AF[75].

Coronary artery disease. Strategies for the secondary prevention of coronary artery disease aim to prevent recurrent events by improving the control of modifiable risk factors. The MiCORE study[76] enrolled 200 patients with type I MI across four US hospitals who received a guideline-driven, self-management programme comprising a mobile application integrated with an Apple Watch and a Bluetooth BP cuff. Preliminary results from 164 patients showed a 43% lower likelihood of hospital readmission at 30 days among participants receiving a guideline-driven, self-management programme than among participants in a propensity-matched, historical comparison group ($n=695$)[76]. Furthermore, a cost-effectiveness analysis concluded that as much as US$6,000 per patient were saved by implementing this intervention[77]. Randomized trials examining the benefits of these platforms have the potential to revolutionize care in patients with MI. Although not yet studied, wearables can also potentially be used to titrate β-blocker dosage in patients with chronic coronary syndrome and to screen for atrial or ventricular arrhythmias after MI, especially in patients with a reduced ejection fraction.

QT interval measurement. A prolonged QT interval can predispose patients to life-threatening arrhythmias. However, monitoring this abnormality is difficult and requires a 12-lead ECG. The single-lead ECG patch BodyGuardian (Preventice Solutions Group, USA) was compared with 24-h, 12-lead Holter monitoring in 25 patients with congenital long QT and in 20 healthy individuals and the mean of the Bland-Altman plot was almost 0 with a small standard error (-1.4 ± 1.8 ms)[78]. Another study applied a convolutional DNN, trained from >560,000 manually annotated QTc intervals on 12-lead ECGs, to analyse prospectively collected, manually annotated lead I and II data from a standard 12-lead ECG and from the KardiaMobile 6-lead ECG in 145 patients with prolonged QTc[79]. The mean difference in the algorithm-predicted QTc from the KardiaMobile 6-lead ECG versus the annotated 12-lead ECG was 4.90 ms but with a large s.d. of 21.58 ms. The use of single-lead ECGs embedded in most wearables might not be practical for accurate QTc measurement, but accurate QTc measurement might be possible with innovative approaches such as device manipulation to record multi-lead recordings[17] and advances in artificial intelligence (AI) algorithms.

Hyperkalaemia. Hyperkalaemia is a common cause of life-threatening arrhythmias in patients with cardiovascular disease, especially in individuals with underlying renal insufficiency[80]. ECG monitoring has been touted as a method to recognize the arrhythmogenic effects of severe hyperkalaemia such as peaked T waves, QRS widening, PR shortening and bradycardia. However, evidence is conflicting as to whether these findings are reliable, especially in patients with chronic hyperkalaemia[81]. A study evaluated the performance of an established DNN[82] for the detection of hyperkalaemia in 10 patients undergoing haemodialysis who also underwent 4 h of ECG recording with the use of an investigational AliveCor device and concurrent blood testing[83]. A total of 5.4 h of data in a hyperkalaemic state and of 44.1 h otherwise was recorded. The sensitivity by duration of hyperkalaemia was 94% and the specificity was 74%, suggesting that this AI algorithm is a viable and non-invasive option for the screening of hyperkalaemia at home[83]. However, caveats such as high false-positive and false-negative rates and the need for continuous ECG monitoring curb the current enthusiasm supporting the use of available off-the-shelf wearables to diagnose hyperkalaemia. However, novel advances in sensors and software algorithms over the next few years might improve our ability to detect hyperkalaemia or other electrolyte abnormalities via ECG or, even better, with biochemical sensors.

Cardiac rehabilitation. Cardiac rehabilitation is a mainstay in the management of many cardiovascular conditions because it provides a structured exercise programme together with comprehensive guideline-directed secondary prevention. Telerehabilitation programmes supported by real-time wearable data might revolutionize home-based rehabilitation and relieve the inconvenience and cost associated with centre-based programmes that currently lead to low participation rates. A meta-analysis of 23 randomized trials, including a total of 2,890 patients undergoing cardiac rehabilitation after MI, revascularization or HF diagnosis, showed that a home-based form of cardiac rehabilitation was as effective as centre-based rehabilitation in improving clinical and health-related quality-of-life outcomes[84]. However, most of these studies did not use wearable devices. A non-inferiority, randomized trial comparing REMOTE-CR — a real-time, remote telerehabilitation platform that includes the use of a chest-worn wearable sensor (BioHarness 3, Zephyr Technology, USA) — with a centre-based programme showed that REMOTE-CR was associated with less sedentary time at 24 weeks and was more cost-effective than the centre-based programme[85]. The REMOTE-CR platform leveraged social cognitive theory to improve self-efficacy and self-determination (essentially, the belief that they can exercise more) in patients in the REMOTE-CR group[85]. Furthermore, a systematic review and meta-analysis of nine trials of patients with cardiovascular disease demonstrated that wearable monitors of physical activity that included exercise prescription or advice were superior to no device in improving fitness and step count in the maintenance phase of cardiac rehabilitation[86]. Although virtual home-based telerehabilitation is already available, additional high-quality and generalizable randomized clinical trials could usher in a future that will greatly expand access to this evidence-based intervention.

Peripheral vascular disease. In patients with peripheral vascular disease, the first-line treatment for intermittent claudication is a supervised exercise programme of gradually increasing intensity. A pilot study randomly assigned 37 patients with peripheral vascular disease to use a feedback-enabled Nike FuelBand (Nike, USA; now commercially discontinued) and a supervised exercise programme (intervention group) or to a supervised exercise programme without the band (control group)[87]. Instead of exercise prescriptions guided by the number of steps, 'fuel points' were used to estimate overall activity. These fuel points were reviewed at follow-up visits and customized exercise prescriptions were programmed into the devices of patients in the intervention group. The study showed significant increases in maximum walking distance, claudication distance and quality of life, sustained over 12 months, in the intervention group compared with the control group[87]. Two randomized trials of >100 patients with peripheral vascular disease, each utilizing the ankle-based accelerometer StepWatch 3 (Modus, USA), showed that wearable-guided exercise prescriptions were associated with a significant improvement in walking ability, speed and peak oxygen consumption[88,89]. Conversely, a wearable activity monitor combined with telephone coaching did not improve walking ability or quality of life but improved exercise frequency in a trial of 200 patients with peripheral vascular disease[90]. Other studies have shown variable results[91]. Although we need to continue to study the role of wearables in peripheral vascular disease, we must consider the use of the devices and exercise protocols that have proven benefits in this patient population.

Challenges and future directions

Understanding the triggers and barriers of wearable devices requires close collaboration between medicine and technology as well as knowledge of how the technology will be adopted and accepted through different stakeholders, from clinicians to regulatory bodies to users. Today, several challenges are still hindering the widespread adoption of wearable devices in clinical practice, the most important of which we discuss in this section (TABLE 3). Creative evaluation frameworks, pragmatic regulatory policies and simple clinician guides are needed to accelerate the integration of these devices in routine practice and propel us toward a new decade of health democratization.

Hardware and software accuracy and validity. Consumers, fuelled by the hype of trendy but often unproven technologies, are pushing for the rapid adoption of wearables in clinical practice but we, as a scientific community, must tread with caution. Inaccurate data is more harmful than no data. Many validation studies have questioned the accuracy of raw sensor data and software algorithms[92–94]. The heterogeneity in wearable data quality can be attributed to the lack of consensus on the development and design of digital health products and the obscurity of regulatory oversight policies. At the beginning of 2020, Coravos et al. developed a timely evaluation framework to test the accuracy and validity of connected sensor technologies, which included wearables[95]. In this comprehensive framework covering both the hardware and software components of these technologies, the authors outline the potential resources, evaluation criteria and target thresholds for five dimensions: verification, analytical validation and clinical validation (V3); data security and privacy; data rights and governance; utility and usability; and economic feasibility[95]. Meticulous scrutiny of these devices through such structured frameworks ensures that they are worthy of clinician and patient trust by the time they reach the market.

The absence of clear regulatory oversight policies governing commercial wearable devices has also led to the emergence on the market of numerous products of unknown safety and efficacy. Medical-grade sensors such as wearables with ECG are usually regulated by regulatory agencies such as the FDA risk-based medical device policy in the USA, which is the most rigorous agency and often labels these sensors as class I or II medical devices. The FDA often clears these sensors through the accelerated 510(k) pathway if the applicant can show substantial equivalence to a US legally marketed predicate device[96]. Rarely do these devices receive approval for a new indication label, which requires randomized trials showing clinical efficacy (TABLE 1). Owing to these policies, the performance of medical-grade sensors tends to be more consistent across various wearable manufacturers compared with non-medical sensors, such as activity or PPG sensors, which do not undergo FDA evaluation. Clinicians and patients must exercise caution when interpreting data from unregulated sensors. For example, abnormal PPG HR measurements are often error-prone and should be interpreted in the context of device placement, user activities and symptoms.

Software algorithms that deploy AI to analyse sensor-collected data continue to evolve in breadth and complexity, allowing the efficient processing of large amounts of data that greatly exceed human cognitive capacity. Augmented AI is expected to complement traditional data analytics and clinical care to improve patient outcomes and lower costs. However, the performance of AI algorithms in medical tasks still faces considerable technical and ethical challenges such as the ability to detect confounding variables in inadequately labelled datasets, the difficulty of integration in clinical workflows, bias and non-representative population data, risk of aggravating health disparities, interpretability of 'black box' unsupervised algorithms, and uncertain regulatory and tort environments[97]. In addition, the lack of transparency and reproducibility of AI computational algorithm methods and code in many published

Table 3 | **Challenges and recommendations for wearable use in clinical practice**

Theme	Challenges	Recommendations
Accuracy and validity	Inaccurate data is more harmful than no data	Develop comprehensive evaluation frameworks such as the one developed by Coravos et al.[95]; create standards by medical societies to evaluate these devices; define clear and unified regulatory policies for these devices, many of which contain a number of sensors and constantly evolving software algorithms
Meaningful use criteria and clinical evidence	Paucity of meaningful use criteria and robust clinical evidence; very few trials have examined the superiority of wearables for clinical outcomes compared with no wearables	Build an extensive body of evidence that proves efficacy and rules out harm; define meaningful use criteria that separate actionable data from noise; the tech industry should follow the steps of the pharmaceutical industry in investing in large and well-designed randomized clinical trials with long follow-up to improve patient and clinician trust; include wearable teaching modules within telehealth curricula in schools and postgraduate training programmes across different health disciplines
Behavioural change	Enacting and maintaining behavioural change is difficult; some studies question the value of wearables in guiding behavioural change	Standardize the methods used to create behavioural change technique tools, such as the framework proposed by Hekler et al.[104]; develop tools to pre-empt the problem of non-adherence, such as that developed by Zhou et al.[105]; develop novel social and financial incentives that capitalize on behavioural economics and cognitive psychology; insurance rewards programmes[106] must guarantee data privacy, voluntary opt-outs without negative consequences and protect those who cannot afford wearables or have low digital literacy
Hardware cost and payment models	Wearables might emerge as a new health disparity; up to threefold difference in wearable use between high and low socioeconomic status	Studies are needed to assess whether wearables will create a new health disparity; manufacturers should consider developing low cost clinical-grade wearables; in the USA, the Centers for Medicare and Medicaid Services and private insurance companies should continue to incentivize wearable data use by expanding reimbursement to include data such as physical activity and include lifestyle interventions; as value-based reimbursement for wearables grows, providers should consider giving wearables to their patients through loaner programmes[109] or for a reasonable co-pay
Data security and governance	Sensitive wearable data is subject to breaches; sharing wearable data for research or clinical purposes is difficult; unrealistic patient expectations for data handling	De-identification of wearable data might not be sufficient, and next-generation cybersecurity tools such as blockchain should be developed and encouraged; outdated HIPAA/HITECH policies need to be recalibrated to cope with the increasing availability and heterogeneity of patient engagement technologies; rather than opt-out systems to waive rigid security standards, opt-in systems with transparent privacy policies might improve patient engagement[112]; set clear expectations between patients and their clinicians through next-generation data user agreements; openly address patient privacy concerns to gain their trust
Data management	Data interoperability, provenance and storage	Develop policies that incentivize semantic interoperability between wearables and other platforms; develop policies that govern data storage and provenance; use novel technologies such as blockchain to transform secure data provenance

HIPAA/HITECH, The Health Insurance Portability and Accountability Act of 1996/Health Information Technology for Economic and Clinical Health Act.

studies threatens scientific progress and discovery, which require that independent scientists are able to scrutinize and reproduce results[98]. The US National Academy of Medicine issued a reference document for the responsible development and maintenance of AI in the clinical setting that provides a guiding framework for all stakeholders, including AI developers and the medical community[99]. Furthermore, regulatory agencies such as the FDA have realized that the fast iterative and dynamic development of medical software technologies is vastly different from hardware. The FDA new digital health innovation plan promises a pragmatic risk-based approach to regulate software as a medical device through a pre-certification programme that aims to look first at the software developer rather than at the product[100]. The FDA then leverages the International Medical Device Regulators Forum risk categorization framework to help the pre-certified company determine the appropriate premarket pathway for its product. Finally, post-marketing surveillance of real-world data is used to verify the software's efficacy and safety. As this novel strategy enters its pilot phase, the FDA should continue to solicit feedback from all stakeholders, including clinicians, scientists, technologists and industry leaders, and learn from the proposed comprehensive software and hardware evaluation frameworks such as that by Coravos et al., which could improve this programme[95]. Other global regulatory agencies can closely monitor the implementation of the FDA plan and improve on it to facilitate the rapid introduction of high-quality and low-risk devices into clinical care.

Meaningful use criteria and building clinical evidence. Defining meaningful use criteria for wearables requires building an extensive body of evidence that unequivocally proves benefit and rules out harm. This approach requires that we separate noise, which might be anxiety-provoking for both patients and clinicians, from actionable and meaningful clinical information. For example, does long-term, continuous ECG monitoring in asymptomatic young individuals provide any meaningful clinical information? In TABLE 1, we summarize the number of completed or ongoing studies listed on PubMed.gov and ClinicalTrials.gov examining the clinical applications of wearables. Small, proof-of-concept studies are abundant but the larger, well-designed randomized trials, such as those examining wearables in peripheral vascular disease or AF, set a worthy example for others to follow. The technology industry should learn from the veteran pharmaceutical industry that a continued investment in evidence generation, particularly randomized clinical trials, increases patient and clinician trust and maximizes the return on investment if a new label indication, not only clearance, is granted by a regulatory agency.

Given that wearable software and hardware components are validated through evaluation frameworks and regulatory pathways, the duty of our medical community and US federal agencies, such as the Centers for Medicare and Medicaid Services, will be to agree on the best practice clinical guidelines and meaningful use criteria for these devices. For example, the Apple Heart Study sparked a debate on how a small false-positive rate can increase downstream medical testing and costs if screening is applied to the entire general population. Alternatively, false negatives can have detrimental consequences, especially in symptomatic or high-risk patients in whom false reassurance can delay anticoagulation therapy and increase the risk of stroke[101]. Therefore, cardiology society guidelines have not yet endorsed the use of the Apple Watch for AF screening. However, the ongoing HEARTLINE trial[54] aims to further evaluate whether the newer Apple Watch models, augmented by a single-lead ECG sensor, can improve screening accuracy and clinical outcomes, which could potentially change guideline recommendations. Finally, as several colleges and postgraduate training programmes across different health-care disciplines are in the process of developing telehealth curricula to cope with the COVID-19 pandemic[102], these curricula should incorporate structured learning modules about common wearables, their current clinical applications and the potential to improve remote patient care.

Enacting and maintaining behavioural change. Despite the promise of wearable-guided BCTs, their ability to maintain long-term behavioural change remains a concern. As mentioned previously, a trial with 800 participants questioned the value of wearables in sustaining long-term behavioural changes and improving clinical outcomes[44]. In another small study, 67 participants with overweight or obesity received a Fitbit One to wear and 50% of the participants were randomly assigned to receive text message prompts[45]. The group receiving the text message intervention showed an increase in the number of steps. However, this effect was not sustained over the 6-week study period. Heterogeneity in the design and implementation of BCTs has been a considerable challenge and efforts have been made to standardize the methods to create these tools[103]. Hekler et al. proposed a framework for the use of digital BCTs, such as just-in-time adaptive interventions, to encourage and maintain health[104]. The merit of this framework is that it recognizes the personalized health needs of the participants. This framework highlights the importance of the 'state-space', essentially the readiness to respond to an intervention according to intrinsic factors (state) and contextual factors (space). For a real-world example, the framework of a behavioural intervention might use GPS and time of day to identify when a person is at work versus at home to deliver the correct amount of encouragement to engage in physical activity. However, digital models often require programming for a strict definition of the desired outcome and the type and amount of intervention proposed and are in constant flux to tailor interventions[104]. Zhou et al. produced a tool to pre-empt the problem of non-adherence with use of a Discontinuation Prediction Score[105]. The researchers utilized data from the mPED study, which enrolled women who were physically inactive, and randomly assigned participants to physical activity interventions (counselling or app-based), creating a score that would predict the risk of relapse in the following week with the use of accelerometer data. The score had an AUC of 0.9 with high accuracy (>80%) and specificity (>80%). A simulation was then performed in which financial incentives were allocated based on an individual's predicted exercise adherence, resulting in a theoretically greater adherence compared with a random incentivization scheme. Therefore, the use of behavioural economics and cognitive psychology to develop novel social and financial incentives can potentially sustain good habits, especially when initiated at a very young age[44]. For example, some wearable companies have launched a connected lifestyle coaching platform for insurance plans, employers and health-care systems that leverages inherent reward programmes and financial incentives to promote healthy behaviours in individuals and families[106].

Although two-thirds of millennials in one survey agreed to share their wearable data with insurance companies[1], applying financial and non-financial rewards with penalties raises several ethical questions. Can consumers simply opt out of these programmes without consequences if they choose not to share their data? How are these programmes managed for individuals who cannot afford a wearable device or for those with low digital literacy? Are there clear data user agreements that govern data sharing with third parties? Future post hoc analyses of these programmes will shed light on their value in enacting long-term behavioural changes, particularly in challenging populations such as in elderly people and individuals with low digital literacy.

Hardware cost and payment models. The cost of wearables varies substantially and the cost–utility ratio is subject to the full range of health and non-health features unique to each device. A survey among 4,272 US adults reported a threefold difference in wearable use between individuals earning ≥US$75,000 and those earning <US$30,000 (REF.[107]). Therefore, the use of wearables in standard clinical practice might emerge as a new health disparity, with individuals unable to afford the device being subject to substandard health care. Interestingly, a study examining low-cost fitness trackers (defined as <US$105) on the market showed no correlation between the cost of the device and the number of BCTs incorporated. Some of these behavioural intervention strategies might not be cost-prohibitive for individuals or unprofitable for the manufacturer, which is encouraging[108].

Reimbursement from health insurance will be crucial to narrow the financial disparity. In 2018, the American Medical Association introduced new CPT (Current Procedural Terminology) codes to incentivize the adoption of remote monitoring in clinical practice. These codes were included in the 2019 Centers for Medicare and Medicaid Services physician fee schedule and are reimbursed by private insurers. In light of COVID-19, insurers have even expanded remote monitoring to include acute as well as chronic conditions. Reimbursement for services, such as reviewing vitals, is currently more straightforward than other services such as reviewing physical activity levels or delivering wearable-guided lifestyle interventions. Payers, in the USA and around the world, should consider expanding reimbursement to include the review of various forms of wearable data and the prescription of wearable-guided BCTs. Providers might then be incentivized to use wearables regularly in their practice and even hand them to their patients for free, through loaner programmes[109] or for a reasonable co-pay.

Data security and governance. Three major issues exist in relation to wearable data privacy, especially in an era when big data collection and analysis is sought after by different stakeholders and can yield unprecedented breakthroughs. First, how do we protect sensitive wearable data from undesired data breaches? Although de-identification is a possibility, the meta-data associated with the user can be theoretically used to re-identify them[110]. Given the sensitivity of wearable data, next-generation cybersecurity tools, such as blockchain[111], should be considered because data breaches are expected as an eventuality rather than a mere possibility and because the data constantly move from one platform to another.

Second, how do we facilitate wearable data sharing for research and clinical purposes when desired by the patient? In the USA, HIPAA/HITECH (The Health Insurance Portability and Accountability Act of 1996/Health Information Technology for Economic and Clinical Health Act) privacy and security bureaucratic requirements are, to an extent, considered outdated and might need to be amended to cope with the increasing availability and heterogeneity of technologies that personalize and promote patient engagement[112]. Some institutions currently allow patients to waive rigid security standards for sharing health information but this opt-out system involves additional costs and is biased towards the most engaged patients. Opt-in systems with transparent privacy policies might be better equipped to improve patient engagement while maintaining autonomy[112]. Ultimately, trading off rigid protection for a flexible but secure system that facilitates technology adoption will depend on societal principles. We envision a future in which patients approach their health information as they approach their financial data today; but to make this transition, we must openly address patient privacy concerns and gain their trust.

Third, the plethora of data available from consumer-grade wearables necessitates that expectations are set between patients or consumers and their medical providers. Next-generation data user agreements and e-consents should transparently state details about data transmission medium and frequency, the frequency of data review, the personnel reviewing the data, and the preferred method of communication about actionable or urgent data[113].

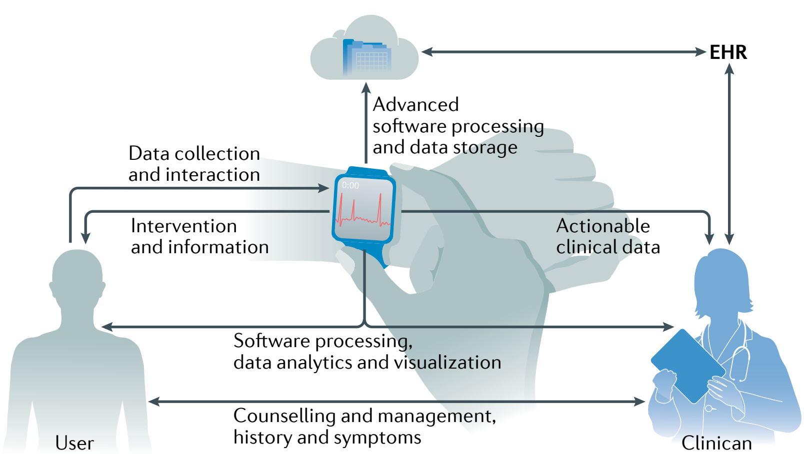


Fig. 2 | **Smart wearable data workflow and integration in clinical practice.** Schematic representation of how wearables can be optimally integrated in patient care. Raw and processed wearable data can provide actionable clinical information to health-care professionals that can help them with cardiovascular disease risk assessment, diagnosis and management. In addition, wearable data can be processed to develop personalized, real-time and adaptive health coaching interventions delivered directly to the patient. Finally, wearable data can be continuously stored in secure, personal health clouds or electronic health records (EHR) for advanced data processing and visualization and to share the data with third parties and research studies through transparent data user agreements.

Data management. Patient records are generally dispersed in data silos across multiple platforms and health-care facilities that are not easily accessible, thereby exposing patients to safety concerns. Unleashing the full potential of wearables in patient care and research requires attaining semantic interoperability with other platforms such as electronic health records and patient portals (FIG. 2). Rather than being handicapped by scepticism[114], contemporary policies should be devised to incentivize hospitals, industry and other stakeholders to achieve smooth interoperability without compromising the patients' privacy or accessibility to their data. Big data storage and provenance (the process of tracing data origin and the movement of data between databases) also require careful attention, especially when terabytes of medical data are expected to be generated over an individual's lifetime. Novel technologies, such as blockchain, should be considered in its implementation[111].

A practical ABCD guide for clinicians

As consumers continue to push the use of wearable data in clinical care and as health-care leaders and policymakers sift through all the challenges mentioned above, clinicians, in the meantime, would benefit from a pragmatic guide to evaluate commercial wearables and integrate them into their clinical practice. We recommend a simple ABCD guide that clinicians can utilize in their daily practice (TABLE 4). Through this guide, clinicians can assess the device's accuracy, clinical utility and validity, regulatory approval status, price, and any existing best-practice guidelines. Clinicians can then determine whether the device benefits their patients and clinical practice in terms of quality of care, efficiency, convenience and cost-effectiveness. After the device is deemed to have reasonable accuracy and clinical utility, clinical workflow integration needs to be established. This workflow includes integration with electronic health records, establishing logistics for patient onboarding and staff education, setting parameter alarms and expectations for the frequency of data review, and the development of reimbursement or payment structures. Finally, clinicians must institute data rights and governance procedures through state-of-the-art data user agreements and privacy policies that maintain patient confidentiality and trust. This simple guide can potentially accelerate wearable integration in cardiovascular practice and usher a new era of connected remote patient care.

Table 4 | **A clinician's ABCD guide to wearable device use in clinical practice**

ABCD guide	Topics	Questions clinicians need to ask	Examples of how to answer these questions (based on an ECG smartwatch)
A	Assess the device Assess the literature Assess regulatory approvals Assess price Assess best practice guidelines for the use of these devices	What data (raw or processed) is generated by the device and what is its clinical utility? Are the hardware sensors accurate and clinically valid? Are the software algorithms accurate and clinically valid? What is the price of the device? Is the device FDA or CE approved for its specific indication? Is clinical evidence available to support the use of the device for a specific clinical application?	This device generates heart rate, physical activity and single-lead ECG data; the hardware has been clinically validated and FDA cleared; single-lead ECG has limitations compared with 12-lead ECGs such as the inability to diagnose acute coronary syndromes; the software algorithms for AF detection have been validated in some of the devices[19,53]; regulatory approval or clearance status can be found on each regulatory agency's website or in press releases; no randomized clinical trials are available showing that ECG smartwatches improve outcomes; some trials, such as HEARTLINE[54], are currently ongoing
B	Benefit to patients Benefit to clinical practice	Does the device help me with the patient's clinical care or saves them money or inconvenience through remote monitoring? Does the device assist me with patient care by facilitating remote patient management and improving my clinical workflow and cost-effectiveness?	ECG-based devices can help me manage patients with established AF remotely, thereby improving convenience and reducing costs; I can use the device to assess AF burden in my patients; I might be able to use the device to manage anticoagulation if future trials show benefit; seeing stable patients with AF remotely while reviewing their recorded ECGs allows me to fit new patient consults within my schedule
C	Clinical workflow integration	What are the logistics of integrating the device in my clinic, such as consent or electronic health record integration? Who will teach patients how to use the device and link their data with the clinic? Who will teach the other health-care staff (such as nurses or assistants) how these devices work? What are my patients' expectations for the frequency of reviewing wearable data? How will my patients be informed of abnormal findings and who will inform them? What parameter thresholds will be set to notify me or my patients? Can I bill for the device initial setup? Can I bill for reviewing the data? What data can I bill for and how frequently? What are the billing codes?	Reimbursement for virtual visits and remote monitoring requires patient consent; some smartwatches can share patient ECGs to electronic health records, for example, Apple Watch-derived ECGs can be shared to some electronic health records such as EPIC; if a patient has a smartwatch ECG, my trained assistant or myself will teach them how to acquire and transmit an ECG; I might invest in buying a model smartwatch for demonstration to my staff or medical trainees; if the patient records an ECG for a new episode, they will share the ECG with me through the electronic medical records and will notify my assistant about the episode; otherwise, we will review regularly acquired ECGs during our in-person or virtual visits; future software platforms might allow the clinician to set customizable alarms (for example, alert me if more than five episodes of AF per month or when episodes of rapid ventricular response occur); discuss with my billing department the codes that can be used to bill for remote monitoring set up and data review (for example, in the USA, CPT codes 99453, 99454, 99457 and 99091 can be used)[115]
D	Data rights and governance Data storage and privacy	Who owns the rights to the data? Can I use these data for research? Do I have data user agreements or privacy policies in place? Can I send these data to a third party and how does this affect patient care and trust? Where are these data being stored and are they HIPAA secured?	The patient must consent to the rights for using their data in research or sharing the data with third parties; the wearable ECG devices will be only accessible through HIPAA-compliant electronic medical records; the patient should be aware that cybersecurity breaches are a possibility, especially if non-secure platforms are used

AF, atrial fibrillation; ECG, electrocardiogram; HIPAA, The Health Insurance Portability and Accountability Act of 1996.

Conclusions

A new age of consumer-driven health has arrived, with great future benefits in cardiovascular disease prevention, diagnosis and management. Currently, several challenges hinder the widespread use of wearable technologies in clinical practice. As sensor and computing technologies continue to evolve, wearables will acquire more complex functions and become an integral part of our cardiovascular practice armamentarium. These devices must be regulated through comprehensive evaluation frameworks and adequate regulatory oversight policies to ensure safety and efficacy. Moreover, a practical ABCD clinician's guide can facilitate the integration of these devices into the clinical workplace. As COVID-19 has launched us at rocket speed into a new era of remote and decentralized patient care, this is a golden opportunity to shake off our scepticism and embrace wearable technologies in our clinical practices for the benefit of our patients.

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Author contributions

K.B., M.G., M.P.T., K.T. and M.B.E. researched data for the article, made substantial contributions to discussions of the content, wrote the article, and reviewed and/or edited the manuscript before submission. A.E. and O.M. researched data for the article, made substantial contributions to discussions of the content and wrote the article. E.H.D., F.A.M., S.S.M. and E.D.M. provided substantial contributions to the discussion of content and reviewed and/or edited the manuscript before submission.

Competing interests

F.A.M. and S.S.M. are co-founders of and hold equity in Corrie Health. Under a licence agreement between Corrie Health and the Johns Hopkins University, the University owns equity in Corrie Health, and the University, F.A.M. and S.S.M. are entitled to royalty distributions related to technology described in the study discussed in this publication. This arrangement has been reviewed and approved by the Johns Hopkins University in accordance with its conflict of interest policies. S.S.M. has received consulting and advisory fees from 89bio, Akcea, Amgen, Astra Zeneca, Esperion, Kaneka, Novo Nordisk, Quest Diagnostics, Sanofi, Regeneron and REGENXBIO and funding from Amgen. M.P.T. has received funding from Apple, AstraZeneca and Boehringer Ingelheim, consulting fees from Abbott, Biotronik, Cardiva Medical, Johnson and Johnson, Medtronic and Novartis, and is an editor for *JAMA Cardiology*. K.G.T. reports advisory board and consulting roles in AliveCor, Janssen Pharmaceutical, and Medtronic. M.B.E. is a co-founder and holds equity in EMBER Medical, a telemedicine company. The other authors declare no competing interests.

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