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# Grains of Sand to Clinical Pearls: Realizing the Potential of Wearable Data

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**ABSTRACT**

Despite the rapid growth of wearables as a consumer technology sector and a growing evidence base supporting their use, they have been slow to be adopted by the health system into clinical care. As regulatory, reimbursement, and technical barriers recede, a persistent challenge remains how to make wearable data actionable for clinicians—transforming disconnected grains of wearable data into meaningful clinical "pearls". In order to bridge this adoption gap, wearable data must become visible, interpretable, and actionable for the clinician. We showcase emerging trends and best practices that illustrate these 3 pillars, and offer some recommendations on how the ecosystem can move forward.

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A 2019 survey by Pew Research estimated that 1 in 5 Americans regularly wore a smartwatch or fitness tracker.[1] The shift toward remote care brought about by the COVID-19 pandemic has only increased wearable adoption,[2] with an 18% growth in international spending on wearables between 2020 and 2021.[3] Common functionalities of consumer wearables include physical activity, sleep, heart rate, and temperature tracking. More recent devices, including the latest generations of Fitbit, Apple Watch, and Samsung Galaxy Watch, offer features including oxygen saturation and single-lead electrocardiogram. There is also a growing panoply of specialized wearables for applications such as glucose monitoring, seizure detection, or alcohol monitoring. These increasingly advanced sensors have given rise to a new modality of clinical data with important diagnostic and prognostic value.[4] Wearable metrics have been shown to emulate formal 6-minute walk tests in patients with heart disease;[5] predict clinical outcomes in oncology patients;[6] and correlate with depression and anxiety symptoms.[7] Qualitative studies suggest that wearables can help to more objectively assess treatment effectiveness, promote adherence to care plans, and may enhance the clinician−patient relationship.[8,9]

Despite this, there remains widespread skepticism around the clinical utility and impact of wearable-based metrics.[10] There is no shortage of pilot care pathways, but there are few examples of adoption at scale or integration of wearables into routine care pathways.[11] There is a complex web of factors behind this adoption gap, ranging from system-level factors such as reimbursement, regulatory

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policy, and liability, down to individual-level factors such as willingness to upload data, data quality, and accessibility of devices.[12] As a consequence, wearable data in most health care settings often remains a disconnected grain of information or, worse still, an irritation to clinicians in a setting of information overload.

Many of the traditional barriers to adoption are now beginning to shift. An increasing number of wearable functionalities have gained regulatory approval from the US Food and Drug Administration (FDA) and European Medicines Agency (EMA)—including the electrocardiogram features of the Apple Watch (in 2018), Fitbit (2020), and the Samsung Galaxy watch (2020).[13] Meanwhile, despite criticisms of ambiguity,[14] the Centers for Medicare and Medicaid Services have consistently trended toward expanding reimbursement codes for remote patient monitoring and interpretation of patient-generated data, with the introduction of 5 new codes in 2022.[15] There is also evidence for a shift in patient attitudes, with the 2019 Health Information National Trends Survey showing that 81% of US adults were willing to share wearable data with their clinicians.[16]

## CLINICAL SIGNIFICANCE

- Wearable data is a rapidly growing data modality that is currently siloed from routine clinical workflows and underutilized in patient care.
- Making wearables more useful for clinicians involves making data visible, interpretable, and actionable.
- Corrie and CHARLI are examples of wearable interventions integrated into cardiovascular care delivery.

As the environment gradually becomes more fertile for wearables as a clinical tool, an overarching question remains: how do we make the data useful for clinicians? How do we transform these potentially irritating and disconnected grains of data into clinical "pearls"? We believe that there are 3 pillars that will support the adoption of wearable data in the clinical mainstream. Wearable data must become: *visible, interpretable*, and *actionable* for clinicians (Figure 1). Below, we review best practices and emerging trends across these pillars, and showcase 2 exemplar use-cases for integrating wearables into care pathways (Boxes 1 and 2). These pillars should be seen as complementary to the more granular implementation science frameworks such as those proposed by

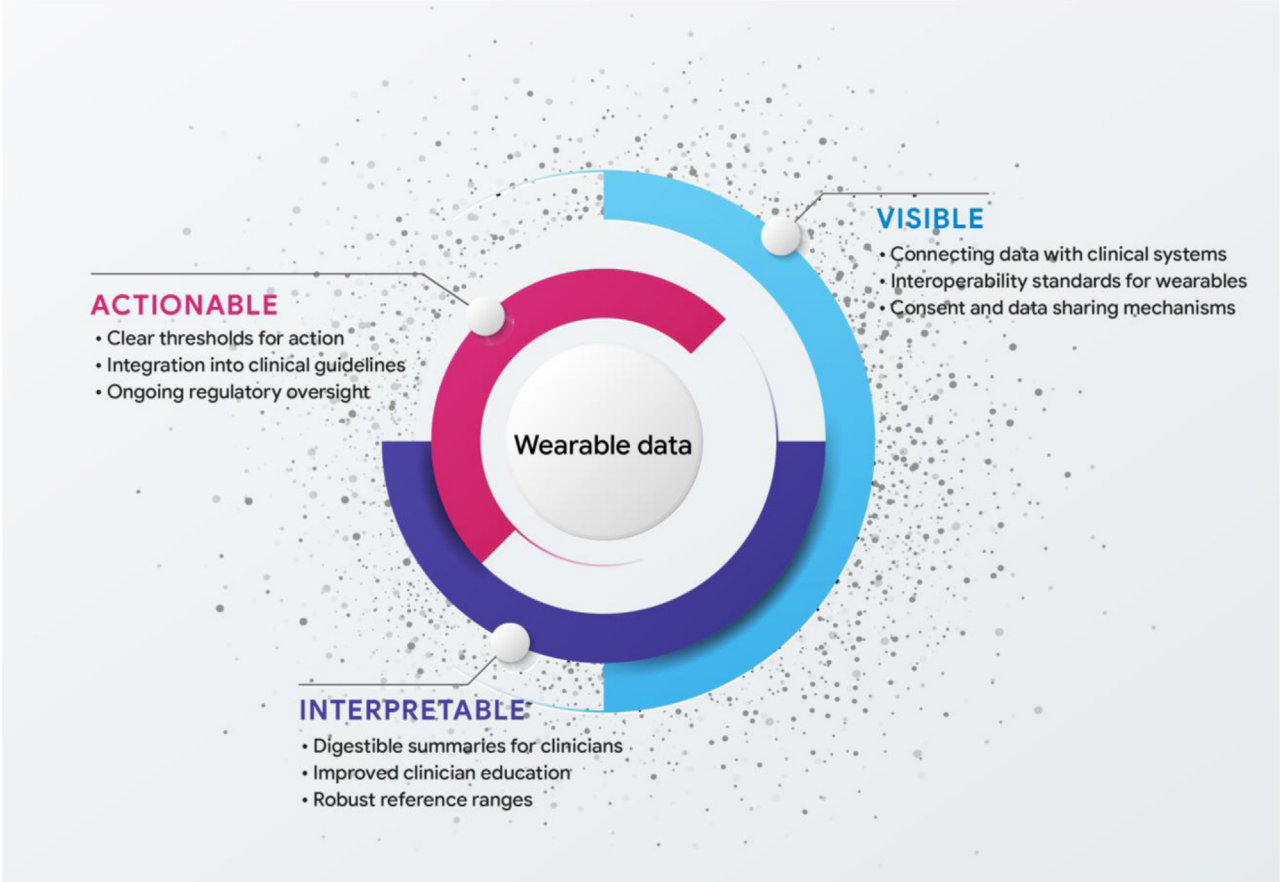


**Figure 1** Grains of sand to clinical pearls—strategies for making wearable data more useful for clinicians.

**Box 1 CORRIE**

Inspired by patient needs and persistent inequities in cardiovascular disease outcomes, the Corrie ("Cor" means heart in Latin) Health Digital Platform was created as the first cardiology app built with Apple CareKit to empower patients in guideline-based cardiovascular disease prevention.[41,42] The intervention was clinically validated in the Myocardial infarction, COmbined-device, Recovery Enhancement (MiCORE) trial.[43] Across 4 US hospitals, hospitalized patients with acute myocardial infarction were offered the Corrie program for use while in the hospital and at home. The program included a smartphone application ("app") with a daily care plan, educational videos, medication tracking, blood pressure management, physical activity tracking, mood assessment, and follow-up appointment management, paired with a cooperative Apple Watch and blood pressure monitor (Figure 2). The MiCORE trial found that Corrie participants had high levels of patient activation and a propensity-adjusted 52% lower relative risk of all-cause unplanned 30-day readmissions compared with patients in the control group who received standard of care. An economic analysis showed approximately $10,000 savings per patient using Corrie based on reduction in 30-day readmission cost savings.[44] The program was available to patients whether they could afford technology or not by offering a technology loaner program.[45] The MiCORE trial supports the promise of digital health to enhance patient engagement, reach diverse and underserved patients, and support guideline-directed care to improve outcomes. Guided by human-centered design and the goal of health equity, the Corrie intervention has been further developed into a Virtual Cardiac Rehab program, to support phase 1 to 4 cardiac rehab. Corrie Virtual Cardiac Rehab is entering a randomized controlled trial as part of the American Heart Association's Strategically Focused Research Network on Health Technology and Innovation.

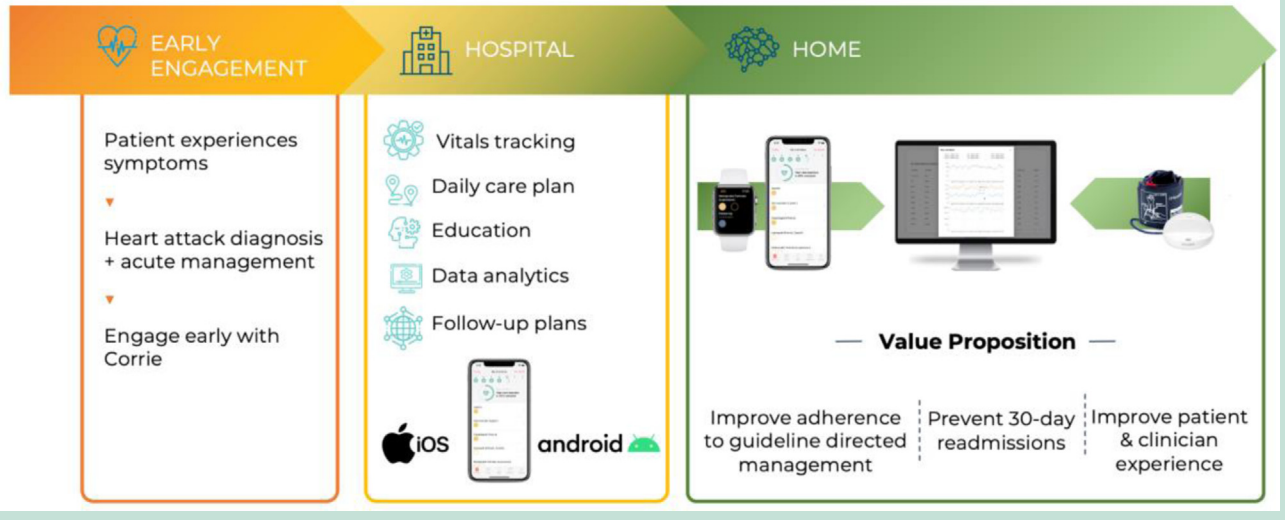


**Figure 2** The Corrie program uses a wearable and patient-facing app to optimize recovery post myocardial infarction.

Smuck et al[17] and Bayoumy et al,[13] and the review of clinical use cases by Gupta et al.[4] Those frameworks can guide clinicians on how to deploy specific wearables in the day-to-day care of patients. Here we take an ecosystem view, offering broad principles for how both health systems and industry stakeholders might make existing wearable data streams more useful for clinicians.

## VISIBLE

First, a patient must be able to make their wearable data visible to their treating clinician, if they choose to do so. Historically, the data collected by wearables has been siloed from other clinical datasets.[18] Some have proposed standardized templates in electronic health record (EHR) documentation to help clinicians input patient-reported wearable data.[4] In much of the research literature, custom interfaces have been developed on top of the EHR to visualize wearables data.[19,20] However, there is now a growing trend toward direct EHR integrations, which will greatly accelerate clinician adoption.[21] One mechanism for this involves on-device data sharing between a wearable app and an EHR patient portal app. Genes et al,[22] for example, used this method to allow patients to upload asthma symptom data. A second mechanism involves cloud application programming interfaces (APIs). Most of the smartwatch providers have launched APIs that enable wearable data to be queried with user consent; however, these are typically

## Box 2 OHOM & CHARLI

The *Our Hearts Our Minds* (OHOM) program is a preventive cardiology program that draws on the principles of the EUROACTION trial[46] and the subsequent MyAction Westminster program.[47] A multidisciplinary team supports patients at high cardiovascular risk to adopt healthy lifestyle behaviors, optimize cardioprotective medications, and improve their psychological health. Initially rolled out in 2019 in the Western Health and Social Care Trust in Northern Ireland, it had to rapidly transition to a fully virtual program during COVID, including the provision of Fitbit devices. The OHOM team were able to track their patients' physical activity in real time on a dashboard pushing them tailored motivational messages via the Fitbit app (Figure 3). Analysis of the outcomes after 1 year showed equivalent clinical outcomes as the face-to-face program[48] and the patient feedback was overwhelmingly positive. The OHOM team have now built on this experience using a participatory design approach with patients and a technology partner Connected Life to develop the Cardiovascular Health Application and Real Life Integration (CHARLI) platform. CHARLI consists of 1) the Fitbit smartwatch; 2) a patient-facing app where patients can log their weight, blood pressure, diet, and relevant symptoms; and 3) a clinician-facing dashboard to view patient-reported and Fitbit data in real time. The platform allows 2-way communication between team and patient as well as easy visualization of progress and achievement of targets.

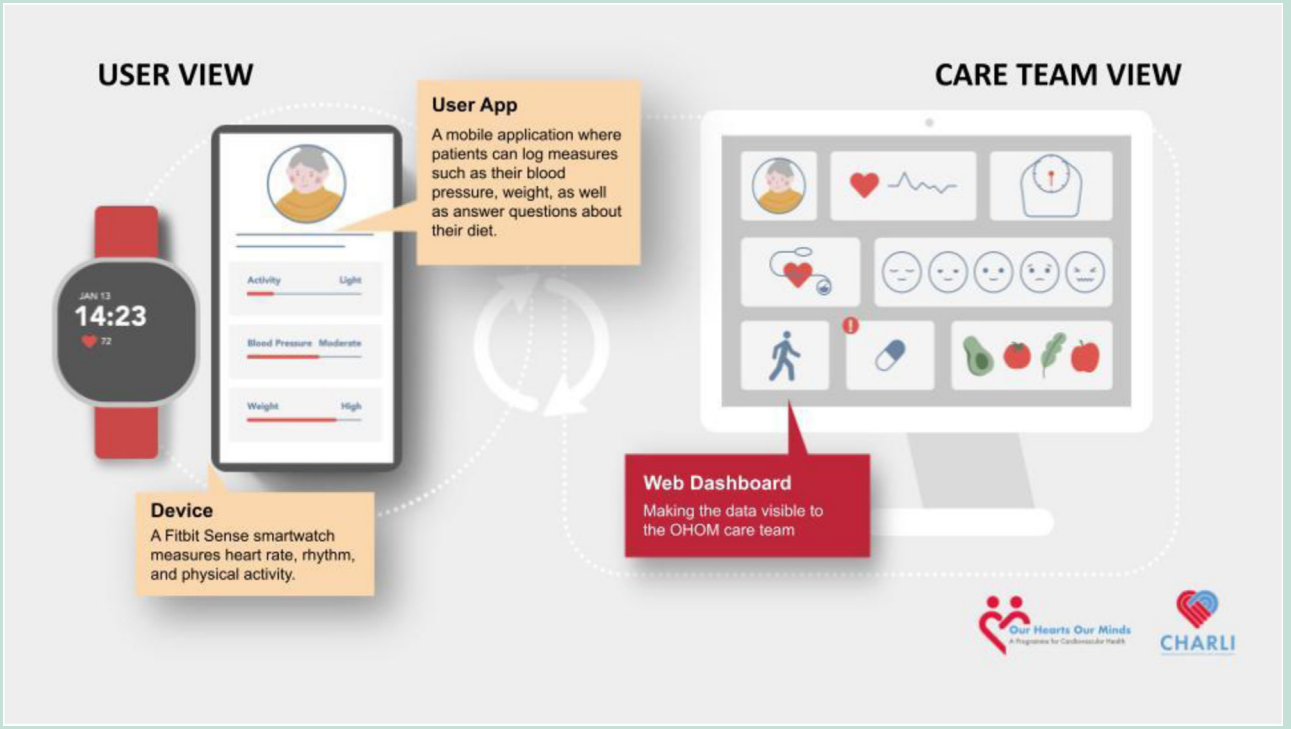


**Figure 3** The Cardiovascular Health Application and Real Life Integration (CHARLI) program consists of a wearable, patient-facing app and a clinician-facing dashboard for optimizing cardiovascular risk factors.

not Fast Healthcare Interoperability Resources (FHIR) based, and so require custom adaptors for direct EHR integration or visualization.[23]

The 21st Century Cures Act in the United States has endorsed the FHIR data model.[24] Use of FHIR is not as mature in the wearable data space as it is for traditional EHR data. Sayeed et al[25] introduced SMART Markers—a framework for encoding patient-generated data built upon the SMART (Substitutable Medical Applications and Reusable Technologies) on FHIR specification. Further development of the FHIR ecosystem for wearable use cases (via profiles and implementation guides) will be critical. Heralding a major shift toward FHIR APIs, in 2021 Apple launched a data-sharing feature that enabled users to share data from the watch, including heart rate and falls, with treating clinicians.[26] The feature works with a range of EHRs, but only at participating health systems via an FHIR API endpoint that must be specifically configured.[27] The data appear in a SMART on FHIR WebView within the EHR and are not written back to the EHR database.[28]

It is important to note that making data visible is not just a technical problem—it also relies on patients being motivated to share these data. This requires not only a robust infrastructure for managing consent (including granting and withdrawing access permissions), but also a shared understanding of the clinical benefits. The future of wearables as a clinical modality will rely on an open dialogue between clinicians and patients on how these data are used in clinical decision-making.

## INTERPRETABLE

With cars come traffic jams. So too, with the rise of wearables comes the information overload problem of ever more granular wearable data streams that must be ingested, stored, and interpreted by clinicians. Efforts to summarize wearable data into interpretable, digestible insights will be key. Fitbit Wellness Reports are one such effort—providing a summary, which users can show to their treating clinician, that clearly visualizes week-to-week trends in areas including physical activity, heart rate, and sleep.[29]

There has been a wealth of literature on developing and prospectively validating algorithms for arrhythmia detection using smartwatches—notably the Apple Heart and Fitbit Heart studies for atrial fibrillation.[30,31] These algorithms can be seen as examples of converting continuous monitoring data into interpretable insights. Another recent example is a real-time alerting system for COVID infection using activity and heart rate metrics from a smartwatch,[32] which showed signals a median of 3 days prior to symptom onset. The future of wearables will rely on the development of a library of metrics and algorithms to distill voluminous, noisy, continuous monitoring into meaningful insights. There will also need to be accompanying clinician literacy around these insights, for example, by incorporating wearable data types into medical curricula and continuous professional development programs.

Another element of interpretability is having robust reference ranges. Despite validation of proprietary metrics in specific subpopulations or controlled environments, wearable metrics may behave differently in real-world settings and clinical populations. It will be critical to better understand population distributions for metrics such as heart rate variability and active zone minutes in order for them to become mainstream. The National Institutes of Health *All of Us* Research Program, which aims to collect longitudinal health data from 1 million patients to power observational research, has introduced a linkage with Fitbit to enable participants to sync Fitbit data with their profile.[33] Meanwhile, the Scripps Institute is distributing 10,000 Fitbits as part of an *All of Us* collaboration.[34] Initiatives like these will help clinicians and researchers to better understand the distribution of wearable metrics across diverse populations.

## ACTIONABLE

Finally, insights from wearable data must be actionable—that is, clinicians (and patients) should have some defined care pathways that are triggered by wearable-derived insights. In a survey of clinicians' views toward patient-generated health data, Adler-Milstein and Nong[11] identified actionability as the primary barrier to clinician adoption. Many clinicians reported feeling unclear on the clinical significance of activity or heart rate fluctuations, and were uncertain about the relevant thresholds at which to intervene. A meta-analysis of wearables for remote patient monitoring across a range of disease areas found that interventions associated with clear care pathways and tailored coaching had the highest chances of success.[35] Similarly, a survey of cardiologists on how to respond to a wearable alert for atrial fibrillation found that a majority of respondents called for consensus guidelines on how to manage such an alert—that is, which sequence of follow-up interventions should be triggered.[36] The Fitbit "provider page" is one example of clinician-facing education that outlines how wearable-generated metrics can be used in practice.[37]

Increased engagement from regulators, as seen in the FDA's *Digital Health Innovation Action Plan*[38] and the EMA's *Medical Device Regulation*,[38,39] is shining a spotlight on these actionability questions, as wearable applications seeking regulatory approval must submit clear indications of use. The field would also benefit from greater involvement of clinical consensus bodies on how to translate wearable data into practice guidelines. To date, for example, wearable devices have not been integrated into atrial fibrillation screening guidelines,[40] despite promising evidence as a screening modality.[30,31] In parallel, the research community should prioritize the inclusion of patient-generated data in clinical trials, which can help to gather the foundational data required to design actionable guidelines and local protocols. In the future, for example, might primary care screening pathways for cardiovascular disease include active heart zone minutes in addition to traditional scores like the Framingham risk score?

## CONCLUSIONS

Wearable data is a rapidly growing modality that is currently siloed from routine clinical workflows and underutilized in patient care. As wearable data become more widespread and the regulatory and reimbursement environment becomes more favorable, the ecosystem (including both health systems and industry stakeholders) must invest in making wearable data more useful for clinicians—namely, making these data visible, interpretable, and actionable. Two successful examples of integrating wearables into care delivery are showcased in Boxes 1 and 2. In this way, with appropriate patient consent, wearable data can be integrated into the fabric of clinical workflows and realize its potential as a diagnostic and prognostic tool.

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