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Approach to the Postmarket Evaluation of Consumer Wearable Technologies

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IMPORTANCE Consumer wearable technologies have wide applications, including some that have US Food and Drug Administration clearance for health-related notifications. While wearable technologies may have premarket testing, validation, and safety evaluation as part of a regulatory authorization process, information on their postmarket use remains limited. The Stanford Center for Digital Health organized 2 pan-stakeholder think tank meetings to develop an organizing concept for empirical research on the postmarket evaluation of consumer-facing wearables.

OBSERVATIONS The postmarket evaluation of consumer wearables involves broad consideration of an individual consumer's journey from acquisition, intended and unintended use of the wearable, and access to health care resources on receipt of a notification. For individuals who do access the health care system, a wearable's downstream effects can be studied through appropriate clinical evaluation, delivery of guideline-directed treatments, shared decision-making in areas of clinical equipoise, and analysis of clinical end points and patient harms. Effective postmarket research draws from denominators appropriate to the clinical question, with clearly defined parameters for success and failure. Generalizability related to data completeness and reliability should also be considered. As patients increasingly integrate wearables into their health monitoring, cross-platform data sharing with a focus on privacy and data quality can drive patient-centered innovation and identify opportunities to bridge gaps in medical care.

RELEVANCE The think tank identified priorities in postmarket research, comprising the journey from consumer to patient and accounting for patient, clinician, health care delivery system, and societal impacts of consumer wearables. Overall, this approach serves not only to organize the study of consumer wearables but also to act as a guidepost for using real-world data in postmarket research.

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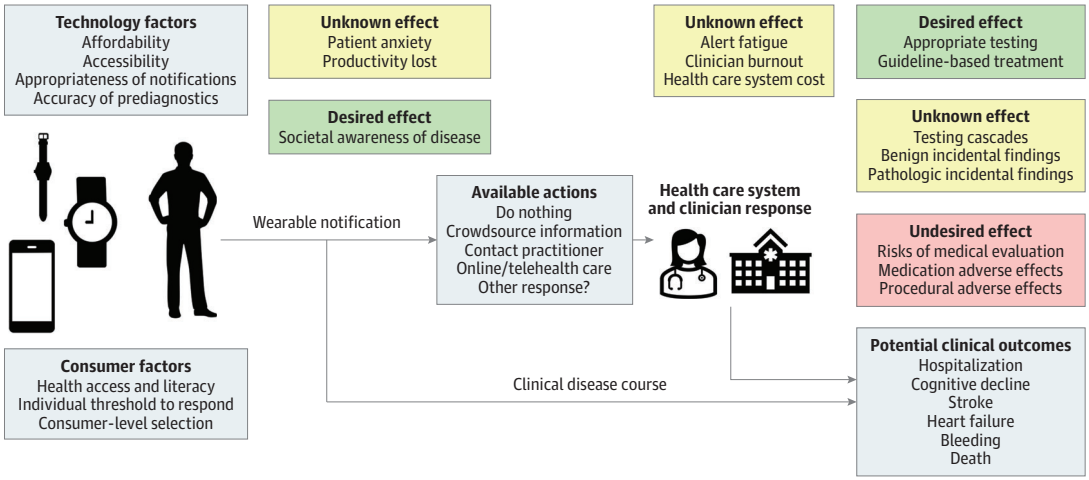
Consumer wearable technologies, including smartwatches, fitness bands, and other trackers, have wide applications for use as wellness products, with the potential for enhancing clinical diagnosis[1] and management of disease. Many of these functions may be considered low-risk general wellness products,[2] which, depending on US Food and Drug Administration (FDA) determination, may not be regulated in the same way as medical devices.[3] However, some of these functions require FDA market authorization, such as those providing notifications based on the data collected by the embedded sensors or software.[2]

Because these wearables are consumer facing and not directly connected to the health care system, there are fewer opportunities to report potential adverse events in the absence of formalized postmarket registries or product safety surveillance mechanisms. Given the high prevalence and incidence of atrial fibrillation (AF)[4] and the wide availability of wearable devices with irregular pulse notifications, AF can serve as an informative case study to highlight challenges and opportunities with consumer wearables. The need for an organizing approach to evaluate the postmarket performance of consumer-facing wearables is summarized in **Figure 1**.

Recognizing the need for an analytical approach to support research on postmarket evaluation of consumer-facing wearables, the Stanford Center for Digital Health organized multistakeholder virtual think tank meetings in March and November 2022. The overarching goals were to (1) identify priorities and challenges in postmarket evaluation of wearables, (2) define an approach to use real-world data (RWD) for postmarket research, and (3) generate insights on using postmarket research to inform clinical practice and innovation. The think tank invited perspectives from patients and patient advocates, clinicians, scientists, regulators, medical and health technology (including wear-

Figure 1. Organizing Approach for Research on Postmarket Evaluation of Consumer-Facing Wearables



Consumer wearable technologies have various wellness functions and sensor-based notifications, but little is known about their postauthorization use and subsequent health care cascades. Studying their effects involves evaluation of desired, undesired, and unknown effects throughout the health care journey.

able manufacturers), and health care system representatives. This white paper synthesizes the content and discussion from the participants who attended the meetings. The views expressed by the participants do not represent new regulatory policy or opinions of their representative institutions or agencies.

Priorities and Challenges in Postmarket Evaluation of Consumer Wearables

AF is the most common sustained cardiac arrhythmia in adults,[4] and even asymptomatic and subclinical AF are associated with an elevated stroke risk.[5,6] Therefore, early detection of AF can potentially have a wide-ranging public health impact on ischemic stroke, heart failure, or other AF-related sequelae.

Large, pragmatic randomized clinical trials (RCTs) have demonstrated the ability of various wearable technologies to identify new AF.[7,8] The Apple Watch Series 4 (Apple Inc) used an irregular pulse notification algorithm to identify AF from photoplethysmography (PPG) databased on pulse irregularity.[1] The Apple Watch Series 5 or later includes software and hardware that record a 30-second single-lead electrocardiography (ECG) rhythm strip to detect AF based on ECG interpretation.[9,10] The AliveCor smartphone-connected single-lead and 6-lead systems (AliveCor Inc) also use ECG interpretation to identify AF. While the Kardia systems (AliveCor Inc) are not typically worn on the body, they are conceptually included as wearables for the scope of this article.[11] More recently, Fitbit (Google LLC) and Samsung, among others, have released watches with FDA-cleared algorithms for AF detection using PPG, ECG, or both.[12,13] However, since authorization, little is known about the postauthorization use of these wearables. Meanwhile, a small study of patients who received notifications of an abnormal pulse raised concern that the studied wearables might cause health care overuse.[14]

In the Apple Heart Study[7] and Fitbit Heart Study,[13] 0.5% and 1% of the study population received notifications of irregular pulse, respectively.[7,13] However, a retrospective study found no significant increase in new AF encounters in the postmarket period after the release of ECG-capable smartwatches.[15] Multiple plausible explanations for this observation exist, including (1) a change in the new AF diagnosis rate that was too small to reliably detect, (2) individuals who receive notifications not seeking care through conventional pathways, or (3) a smaller rate of new AF cases in an unselected, nontrial population.

Regulatory Stakeholder Participant Perspective

The FDA Center for Devices and Radiological Health has published numerous guidances to help promote safe and effective digital health technologies.[16] To this end, close collaboration among health technology innovators, scientists, health care delivery systems, health care professionals, patients, and caregivers can be important in considering benefit-risk trade-offs in developing device technology.

The FDA has also published several guidance documents to address specific uses of wearable and digital health technologies.[16] Guidance documents cover the use of digital health technologies for remote data acquisition in clinical investigations, cybersecurity for medical devices, technologies for data storage and transmission, and the use of artificial intelligence (AI).[17,18] Specific to AI, the FDA has issued guidance on the use of AI in supporting regulatory decision-making for drugs and biological products, which will be increasingly relevant to both preclinical and clinical data streams.[19] The FDA's Medical Device Development Tools program also seeks to promote innovation by qualifying tools such as over-the-counter wearable software to "help evaluate estimates of Afib [AF] burden as a secondary effectiveness endpoint within clinical studies intended to evaluate the safety and effectiveness of cardiac ablation devices."[20]

Patient Perspective

The availability of direct-to-consumer wearables highlights the distinction between consumers and patients. For patients or the consumer-turned-patient, important priorities include (1) accessibility, (2) affordability, (3) adoption, (4) accuracy, and (5) actionability.

Table 1. Overview of Potential Outcomes in Postmarket Research of Atrial Fibrillation (AF)

Outcome type	Considerations
Consumer to patient transition	• Which consumers are choosing to use wearables? What is the impact of socioeconomic factors? • How frequently do consumers receive notifications? • What is the notification threshold for consumers to engage with care? • Is there anxiety or stress associated with receiving notifications?
Health care system access and utilization	• How do patients contact health care professionals? • What is the conversion rate on health care visits? • What is the delay from patient contact to clinical assessment?
Clinical evaluation	• What is the scope of care utilization (ie, 12-lead ECG, ambulatory ECG monitoring, echocardiography, cross-sectional imaging, or invasive procedures)? • Do differences in geographic location, health care system, care pathway, or clinician specialty lead to variation in care?
Treatment decisions in patients without clinical equipoise	• Do patients with high AF burden, long episodes (ie, >24 h), persistent AF, or high clinical stroke risk receive guideline-concordant care? • Is there variation in care based on geographic location, health care system, care pathway, or clinician specialty?
Treatment decisions in patients with clinical equipoise	• What diagnostic and therapeutic decisions are made for patients without established clinical guideline support (low-risk AF, ventricular ectopy, non-AF tachycardia)? • Is there variation in care based on geographic location, health care system, care pathway, or clinician specialty?
Hard clinical end points	• Stroke, hospitalization, heart failure, bleeding, or death can be considered as hard clinical end points; in an ideal clinical scenario, detection of AF could lead to improved cardiovascular risk stratification, initiation of oral anticoagulation, and prevention of major cardiovascular events that may have otherwise been the initial trigger for AF diagnosis, although in the general population with many low-risk individuals, it may be difficult to demonstrate significant differences in major cardiovascular outcomes
Potential harms	• Anticipated harms include procedural complications, incidental findings, and treatment-related complications • Unanticipated harms include psychological distress or financial stress • What is the added impact of harms in individuals with false-positive data, who may glean no foreseeable benefit from such interventions?
Effect on clinicians and health care systems	• How do notifications impact clinician stress or burnout? • What is the net effect of an additional pathway of care on the total capacity to provide care? • How are clinician efficiency and throughput affected? • What is the total resource utilization in a health care system?
Shared decision-making	• When incorporated correctly, shared decision-making has the potential to improve patient satisfaction, patient engagement, treatment adherence, and clinical outcomes; well-validated measures of shared decision-making can be both informative and impactful in improving patient care

Abbreviation: ECG, electrocardiography.

Table 2. Proposed Approach to Postmarket Research for Consumer Wearables

Area	Approach
Denominators for analysis	• Consumer-level wearable use, to generate insights into the potential statistical bias of distribution; this denominator may require closer collaboration with digital health companies as many of these individuals are not captured in the health care system • Patients with defined treatment guidelines, including those with high AF burden, long episodes (ie, >24 h), persistent AF or high clinical stroke risk • Patients without defined treatment guidelines, such as those with AF episodes <6 min in duration or minimal risk factors
Defining successes and failures	• Patients for whom there are established clinical treatment guidelines; successes and failures of therapy are predefined • For patients without established treatment or intervention guidelines, comprehensive descriptive analyses can lay the foundation for data scientists and clinicians to understand which pathways of care provide a net benefit to the patient and health care system
Generalizability of findings	• Intentional efforts to adjust for variability in different factors can improve generalizability to other health care systems; however, acceptable risk of error in one system could overwhelm the capacity of a different system • Even if not generalizable, an alert as an individual classifier still has value in treatment decision-making for a specified population with known disease prevalence
Completeness and reliability of data	• Combining data sources may be a useful solution to address the data completeness challenge, especially with complex clinical questions • Small prospective clinical trials, where appropriate, may provide data bridges that ultimately come together to answer important clinical questions
Patient empowerment	• Knowledge generated by postmarket research can help patients understand the synthesized data from their wearables • Mirroring patient-level synthesis, health care systems can be equipped to quickly incorporate and interpret findings, optimally through a system that bypasses clinician interpretation and provides asynchronous response
Deconstructing complex challenges	• For complex clinical questions, the entirety of a question may not have to be answered with 1 study or data set; with high-quality data at each level, one could separately answer questions on (1) signal validity, (2) pursuing clinical care, (3) health care decisions, and (4) long-term clinical outcomes
Opportunities to bridge gaps in care	• Data ascertainment that considers multiple data sources, health care systems, and avenues of care can provide insights into care disparities in low-resource areas or for historically underserved populations • Effective data ascertainment can serve as a vehicle to generate insights on technology-based approaches to reduce disparities • Where available, unified repositories of health data may help in improving care in different populations

Abbreviation: AF, atrial fibrillation.

Accessibility, Affordability, and Adoption

Technologies that require prescription by a physician or need to be acquired directly from a manufacturer are less accessible for many consumers and patients than those that can be picked up off the shelf at a retailer or directly purchased online. Another barrier for many patients may be cost. If wearables are not affordable or covered by health plans, their adoption may be limited and skewed toward those of higher socioeconomic status. Even when technologies are available to patients, unconscious perceptions of an individual's digital literacy, technology access, and attitudes toward use may influence a clinician's willingness to enroll and engage these individuals with digital health care tools. Additionally, certain types of disability may hinder technology use for some patient groups, creating a loss of point-of-care options for these individuals. If these challenges are not carefully navigated, the technologies could unintentionally widen the digital divide in the United States.

Accuracy and Actionability

Consumers and patients may inherently trust products by virtue of their widespread availability without understanding the appropriate use of the wearable and the level of risk or indications for use. During premarket review, the FDA purview is to ensure safety and effectiveness of the evaluated devices or functions.

Health Technology Perspective

Most consumers who use wearables are not necessarily patients and may not be diagnosed with a related condition; however, it is a priority to users that when they use a health-related feature, they have a clear path or feature to share the relevant information with a health care professional for abnormal findings. This has implications for applications in terms of their accuracy, safety, effectiveness, and subsequent appropriate clinical management. Therefore, there is alignment of interest in postmarket research between consumers, clinicians, health care delivery systems, and health technology to (1) develop and implement effective care pathways initiated by these wearables, (2) delineate the net effects on clinical outcome measures, (3) develop technology based on user, clinician, and health system feedback, and (4) iteratively improve guidance about what to do with collected information.

Clinician Perspective

For clinicians, a major challenge with wearable technologies is understanding whether and how to incorporate newly available information and alerts into clinical practice. These are important gaps in knowledge and crucial needs for clinicians in caring for patients with notifications from consumer wearables. However, prior established studies and guidelines can provide a bridge for studying AF notifications.[21] These cases may then be used as a reference point to compare with the less understood cases (ie, subclinical or low-burden AF in young patients with minimal risk factors).

To be useful in clinical decision-making, actionable data need to be transmitted to health care professionals through electronic health record (EHR) interfaces efficiently, promptly, and in an understandable way with patient permission that addresses privacy requirements and data protection. Information overload is a rising challenge for clinicians and a contributor to burnout.[22] Therefore, clinicians and health care systems may wish to provide specific guidance to patients around how and when to transmit data from wearables, set expectations on response time (ie, 24-48 hours based on usual expectations for patient messages), and separate symptoms or rhythm abnormalities (ie, syncope, very rapid heart rates) that would typically be evaluated urgently or emergently.

Outcome-Based Approach to Postmarket Research

Drawing from the insights of each stakeholder group, the think tank provides a broad overview of outcomes and adverse events in the postmarket research of AF, detailed in **Table 1**.

Given the role of consumer wearables in medical care and the priorities discussed herein, there is reason to study the consumer-to-patient transition and understand how and when consumers use wearables, when they seek health care, and the mental health impact of owning these technologies. A recent retrospective study demonstrated that patients with AF using wearable monitors had higher degrees of symptom preoccupation and AF-specific health care use.[23] Patient satisfaction and patient-reported outcomes, such as anxiety resulting from an abnormal notification or delayed care due to a false-negative reading, are also important when evaluating the potential net benefit and risk of wearables. For consumers who become patients, understanding how they seek care and their subsequent clinical evaluation can identify important avenues to reach high-risk patients while streamlining other, low-risk patients to low-contact pathways of care.

Once patients have entered the health care system, the effectiveness and appropriateness of care can be studied by researchers within the following domains: (1) treatment decisions in patients without clinical equipoise, (2) treatment decisions in patients with clinical equipoise, (3) hard clinical end points, and (4) potential harms. Within this paradigm, treatment decisions can be appraised in the context of published clinical guidelines when appropriate, while creating separate denominators for less clear cases. When studying harms, collaboration among investigators with patients and interdisciplinary teams is important in identifying unanticipated negative effects that may nonetheless affect patients.

Finally, in reviewing the care journey of patients with wearable notifications, researchers can understand large-scale effects on clinicians and health care systems, ranging from stress and burnout to resource utilization and overall efficiency. Shared decision-making is an important consideration in how these systems should be evaluated and, in certain clinical contexts, may be a satisfactory end point on its own.

Using RWD for Postmarket Research

RWD is defined as data derived from a source other than a traditional RCT, such as postmarket studies, EHRs, or wearables. The RWD from different data sources can inform both innovation and regulation in development of pragmatic research.

Regulatory Guidance

The FDA has published examples of regulatory decisions that were made based on RWD[24] to demonstrate how (1) regulatory decisions can be driven by different data sources and (2) RWD can be leveraged for different regulatory purposes across a device's total product life cycle, from premarket to postmarket stages. These guidelines can serve as an anchor for the evaluation of wearables.

In 2017, the FDA published guidance outlining criteria for assessing reliability and relevance of real-world evidence (RWE) for regulatory use for medical devices.[25] The FDA "will consider the use of RWE to support regulatory decision-making for medical devices when it concludes that the RWD used to generate the RWE are of sufficient quality to inform or support a particular regulatory decision."[25] Moreover, the RWE should have relevance, described as "adequate for evaluating the performance of a device in the identified regulatory context,"[25] and reliability, which encompasses "how the data were collected (data accrual), and whether the people and processes in place during data collection and analysis provide adequate assurance that errors are minimized and that data quality and integrity are sufficient (data assurance)."[25] One cited example of RWD is the National Cardiovascular Data Registry's Percutaneous Coronary Intervention Registry, which captures the characteristics and outcomes of patients undergoing catheterization procedures and measures adherence to practice guidelines and appropriateness of revascularization.[25] In some cases, a clinical end point (ie, stroke, heart failure) can be directly associated with an exposure. This association is less straightforward for devices intended to detect AF,

which may require large prospective studies to determine the association between device-detected AF, potential surrogate markers, and subsequent clinical outcomes in a cohort of patients with longitudinal follow-up.

Outcomes Research and Data Science Perspective

The optimal use of wearables may result in outcomes that are different from what is accomplished in a real-world setting. This can have multiple contributors—the response of a patient to a notification, the knowledge and resources of the clinician responding to the patient's notification, and the ability of the health care delivery system to support the downstream clinical management. Interpreting a success or failure in care based on a wearable notification should then be able to differentiate the effects of the wearable on the patient, clinician, and health care delivery system.

High-quality RWD could potentially help achieve the goals of outcomes researchers while serving as a bridge between patients, manufacturers, and health care professionals. However, current medical ontologies, including the *International Classification of Diseases*, SNOMED, *Current Procedural Terminology*, and Logical Observation Identifiers Names and Codes, do not have mechanisms to capture consumer wearable use or clinician interpretation of data from wearables. One potential solution that can be developed is to apply validated natural language processing or other text-processing methods to unstructured data to identify instances in which wearables led to interaction with the health care delivery system. When applied to large, automatically extracted, and deidentified data repositories from EHRs, typical outcomes research methods can then be used to identify health care utilization, treatment decisions, guideline adherence, and long-term clinical outcomes. Automated data extraction and processing could also allow frequent monitoring and evaluation of secular trends in wearable use and clinical outcomes. Available FDA guidance also recommends capture and reporting of sex differences since "[c]ertain medical products elicit different responses in women compared to men,"[26] as evidenced by differences in outcomes with ventricular assist devices and cardiac resynchronization therapy devices. The end goal would be longitudinal and complete data sets with high sensitivity and specificity for health outcomes.

Health Care Delivery System Perspective

Health care delivery in the United States takes many forms and is increasingly delivered through large systems with shared resources or integrated health care delivery systems with closed payer models. Many of these systems already have limited resources that are being distributed to various types of remote patient information or asynchronous care. Effective incorporation of data from wearables into clinical practice could be supported by a strong evidence base on how to use incoming patient data, which can inform automated processes for clinical response. Aligning these processes further with existing patient care guidelines can potentially improve clinical outcomes and both quality and efficiency of care.

Machine Learning and Data Science Perspective

When using RWD with machine learning, there are real concerns about the validity and reliability of the observations since data are not collected using the same standards or protocols or under the same care regimens. Therefore, considerations for traditional RCTs can still apply to RWD, including data quality, noise, missingness, and representativeness. There is also potential for statistical bias if RWD do not come from the target patient population for reasons such as differences in distribution of technologies at the patient level.

The timeline of a patient's clinical journey may be long, often involves many modalities of care, and may include the integration of multiple data concepts—many of these are not available for clinician review or scientific evaluation. Contemporary use of data relevant to patient prediction involves comorbidities, disease risk factors, clinical findings, imaging results, diagnosis codes, medication orders, laboratory testing, reported demographic features, and occasionally biometric data or other objective pieces of information. However, when incorporating additional information, such as data from a wearable, there are important concerns regarding whether the data can be ascertained, the provided data have high quality and fidelity, and techniques can be automated to process and interpret data to avoid further burden to health care delivery.

Combined perspectives and recommendations on the approach to postmarket research for consumer wearables are summarized in **Table 2**.

Building an Effective Data Source

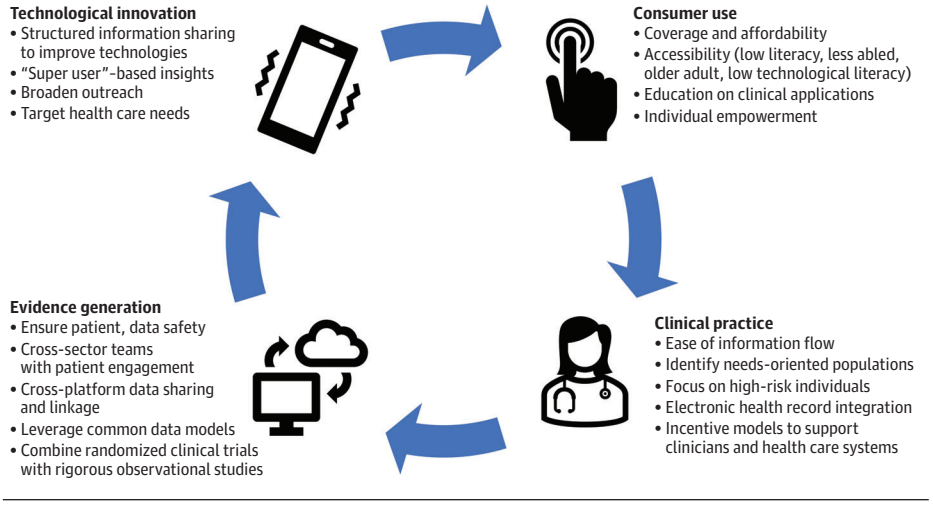
An intentional and stepwise approach to information gathering can lead to building an effective data source for postmarket research. First, a data set should be built on trust by protecting access, following institutional and government regulatory protocols, and accounting for representativeness. Since this can be an early point of entry for data bias, incorporating input from a variety of stakeholders, including patient advocates, and promoting their involvement in advisory boards or steering committees can help to offset these effects. Next, since health data are captured and stored in multiple locations and formats, data-sharing agreements and high-fidelity data linkage can empower cloud-based research infrastructures that reflect the whole spectrum of health care. Notably, for devices that include a device software function, software, or programmable logic, the FDA now provides guidance on cybersecurity considerations to protect patients and improve the safety and effectiveness of devices.[27] Third and most important, consistent patient engagement will help improve confidence in the integrity of the data, focus scientific questions on patients' highest priorities, and improve the overall likelihood of success.

An overview of challenges and opportunities in the clinical integration of RWD and research findings from wearables, and the shared responsibility and potential incentives to drive postmarket wearable research, are summarized in **Figure 2**.

Consumer Wearables in Clinical Practice

A primary challenge in the clinical integration of data from wearables is the high burden of information currently facing clinical care teams. This challenge can be addressed by data readouts from wearables that are well summarized, quickly digestible, interpretable by any care team member, and efficiently integrated into the EHR. To further refine system efforts, monitoring tied to specific health care

Figure 2. Building an Effective Data Source for Postmarket Research to Inform Clinical Practice and Innovation



An effective data source would allow safe data flow between patients and clinicians while facilitating evidence generation and innovation through encrypted and deidentified data summaries to improve care and the end-user experience.

conditions or treatments can optimize the time investment. At scale, such a model of integration of data from wearables might also support the next generation of clinicians who are likely to face larger target patient populations.

Patient Empowerment Over Their Health

Consumer wearables have the potential to bridge gaps in care by empowering patient involvement in their health and allowing closer monitoring of individuals with barriers to access to care. However, there are important obstacles to wearable use, including cost, health care and digital literacy, trust in digital technology firms, and language comprehension. Potential ways to address these obstacles include developing systems that (1) lower the threshold for technology (ie, through insurance or health care system–based incentives), (2) provide education for consumers and patients with a broad spectrum of literacy, language, and comprehension skills, and (3) use postmarket research to critically evaluate wearable use patterns to identify existing or widening digital gaps. Other helpful approaches could include evaluating how or why individuals may underuse health features of their wearables and playing an active role in developing targeted education campaigns.

Clinical Reimbursement

Financially, while consumers and patients increasingly expect their clinicians and health care systems to incorporate data from wearables into medical management, current reimbursement models are not aligned with remote monitoring. *Current Procedural Terminology* codes most closely aligned to such remote monitoring are 99091 (interpretation of remote monitoring data) and 9945x (remote patient monitoring including the initial setup, remote monitoring, and patient-physician communication). When used for remote monitoring, payers require that technologies be FDA cleared or approved as medical devices.[28] However, review of data from consumer wearables for arrhythmia monitoring is not currently reimbursed as remote patient monitoring. For clinicians and care teams with limited time and resources, the lack of reimbursement can pose a barrier in devoting the effort needed to adequately review data from a wearable.

At a health systems level, potential remote monitoring workflows for wearables can incorporate a rules-based approach in which the data from a wearable are used to inform patient risk and the type of health care encounter needed. For example, an irregular heart rate notification through wearable remote patient monitoring in a middle-aged individual with no cardiovascular disease may require an outpatient or telehealth visitation, while the same finding in a stable patient with heart failure could warrant pathways to understand whether AF or another arrhythmia is present.[29] RWD for how specific conditions are managed using wearables that capture patient and clinical workflows, resource utilization, and health care outcomes could be helpful for various purposes. Such an approach could be a pathway to creating population health quality and revenue cycle management models and could support development of technologies that are both safe and effective in at-risk individuals and those with chronic conditions.

Summary of Key Strategies

We propose the following key strategies to organize the study of consumer wearables and use RWD in postmarket research. First, postmarket research of wearables optimally should reach beyond traditional analytic approaches to consider preclinical consumer access, technological literacy, typical and atypical use of wearables, and access to health care institutions. Second, studying a broad range of outcomes can inform the health impact of outcomes from wearables, including guideline-concordant diagnostics and treatment, shared decision-making, and net effect on clinicians and health care system resources. Third, the use of RWD can be particularly impactful when stemming from structured information sharing with a focus on patient safety, cross-platform data linkage, data quality, and AI-based approaches that may broaden insights through unstructured data. Fourth, the most effective clinical and scientific integration of consumer wearables will likely stem from readily digestible data summaries streamlined into EHRs, combined with clinical care pathways and reimbursement mechanisms.

Conclusions

This report summarizes the perspectives and recommendations of think tanks held to develop an organizing approach for postmarket research on consumer-facing wearables. Wearables are becoming an integral part of patient care, and their RWD can help inform patients, clinicians, and regulators. Overall, this approach provides a guidepost for using RWD in postmarket research, which is necessary for supporting innovation in consumer wearables. The views expressed by the participants do not represent new regulatory policy or opinions of their representative institutions or agencies.

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