

REVIEW ARTICLE

WEARABLE DIGITAL HEALTH TECHNOLOGIES IN MEDICINE

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Key Issues as Wearable Digital Health Technologies Enter Clinical Care

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WEARABLE DIGITAL HEALTH TECHNOLOGIES (DHTS) OFFER THE POTENTIAL to affect health care by making behavioral and physiological patterns in daily life outside the clinic visible to patients and medical professionals. Our series to date has covered areas of clinical care in which there are reasonably robust clinical trial data showing the value of these technologies: diabetes¹ and two types of cardiovascular disease.² These trials have shown that enabling more personalized data-driven interventions and objective measurement of treatment effects can lead to results that are in many cases superior to those achieved with the use of intermittent clinical data, which is the current basis for the standard of care. We have also highlighted areas showing the nascent effect on patients and clinicians of wearable DHTs that measure movement and sleep for the management of depression³ and wearable DHTs that use artificial intelligence (AI) to monitor patients for seizures, improve seizure quantification, reduce injuries, and lower the risk of sudden unexpected death from epilepsy.⁴ The evidentiary basis for the broad clinical effect of wearable DHTs in these areas is in its infancy, but our series has shown the potential for real-world medical benefits. Well-designed longitudinal trials will show which of these transformative aims can be realized.

In this final review in the series on wearable DHTs, we highlight important challenges that must be met to integrate the devices into clinical guidelines and practice. We have deliberately grounded our narrative in what is possible today, but we also speculate about specific uses of wearable DHTs in the future. As Figure 1 shows, we identify six interlocking and vexing issues at the foundation of delivering DHT-informed care: data ownership; patient trust, literacy, and access; standards and interoperability; integration of DHTs into clinical care; patient empowerment and agency; and reimbursement and a return on investment for health care systems.

DATA OWNERSHIP

Who owns the raw and derivative data obtained from wearable DHTs? Ownership can be unclear, since data collection involves multiple stakeholders, including patients, device manufacturers, app providers, and data aggregators. Raw sensor data typically reside with the device provider, whereas medical summary information and trends derived from processed raw data may reside with the health care delivery system and provider. In some jurisdictions, patients are generally considered owners of their health data, and most jurisdictions control access to it. Health

KEY POINTS

Integrating Digital Health Technologies into Clinical Care

- Wearable digital health technologies (DHTs) are devices that record behavioral or physiological data for use in medical decision making about the wearer. This article covers issues that are common to the use of wearable DHTs to manage a range of conditions.
- As wearable DHTs progress from experimental applications to routine use in clinical care, data ownership and the right to control the data must be addressed.
- To derive full value from the devices, patients must be able to access their data, achieve data literacy, and gain trust in the systems for managing the information.
- Data standards and interoperability must be established and used consistently.
- As wearable DHTs are integrated into routine clinical care, the volume of the data generated will pose workflow challenges that must be addressed, including incorporation into electronic health records.
- If patients feel empowered by the use of wearable DHTs, they will have a sense of agency in controlling some aspects of their disease management.
- Patients and health care systems will need to be reimbursed for wearable DHTs in a way that yields a reasonable return on investment.

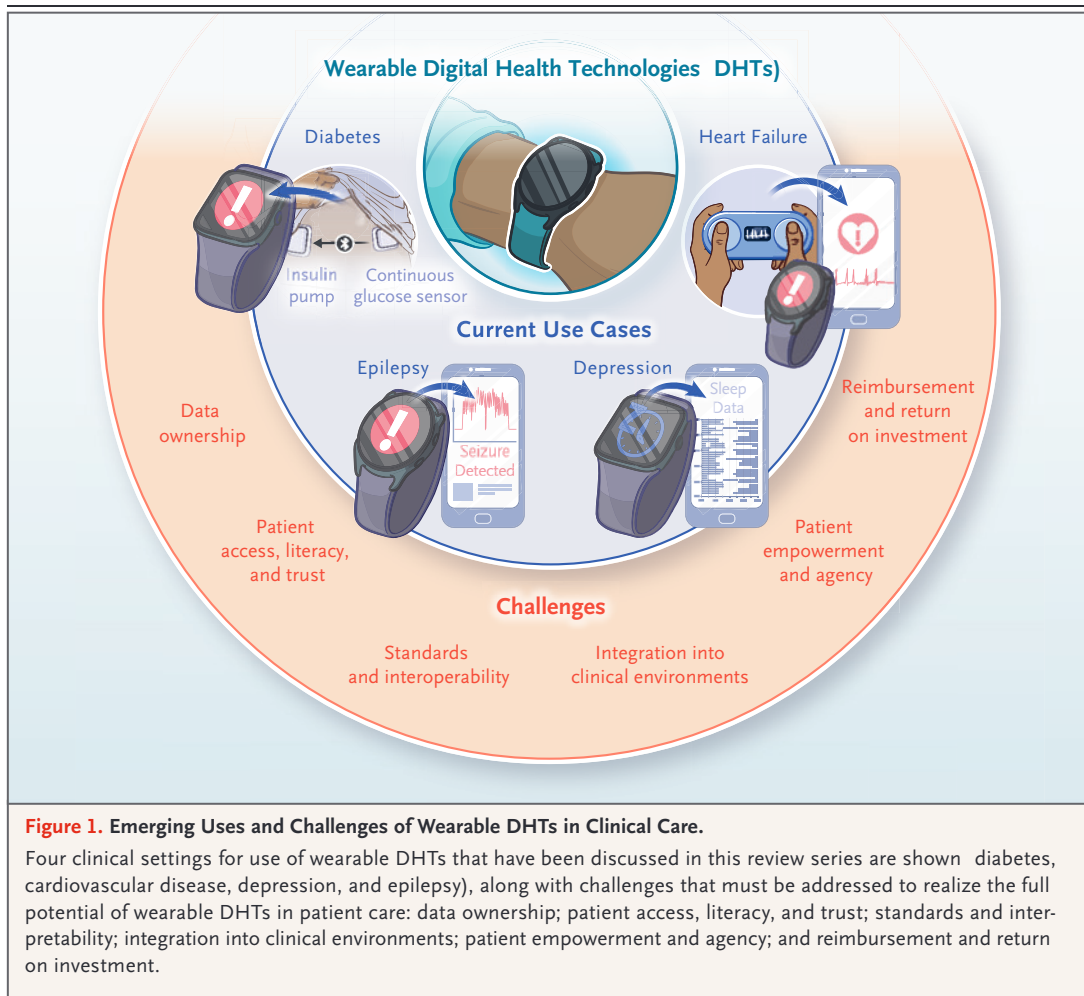
care systems claim ownership of health data generated in their systems or collected during patient visits (including by means of telemedicine). When patients have been given access to their data, it has led to some improved medical outcomes. For example, patients with diabetes who use an open-source, community-built smartphone app that captures glucose and insulin-pump data from commercial devices have been shown to improve insulin control by adjusting their insulin levels more frequently.⁵

We believe persons should understand the terms of use and privacy policies associated with the devices and apps they use. Transparency regarding the policies and principles for the use of wearable DHT data by patients, researchers, and medical professionals is essential in order to allow patients to provide fully informed consent in sharing their data. This information should be provided in a short, easy-to-understand paragraph rather than a lengthy legal document. Since data use and other policies for wearable DHTs are evolving, there may be a need, at least temporarily, for a “digital health counselor,” akin to a genetics counselor, who is a member of a health care team dedicated to assisting both patients and clinicians with the integration of technology. The counselor’s duties could include facilitating access to technology, teaching digital literacy skills, supporting telehealth visits, recommending health apps, troubleshooting technical issues, and interpreting clinically relevant data sourced from health apps.⁶

Health data from wearable DHTs are valuable not only for individual patient care but also for population health research, public health initiatives, and the development of new approaches to health care. Challenges arise in determining how patient data can be aggregated and used for secondary purposes while respecting privacy. One scenario is for users of wearable DHTs to provide consent for deidentified data aggregation and secondary use for research, which is how electronic health record (EHR) data are now used by researchers. Patients would be able to opt in or opt out of sharing their data for research or other purposes. Assuring patients that only their deidentified data will be shared may be insufficient, since reidentification is possible when deidentified data are shared and paired with other data sources. To foster transparency, consideration should also be given to enacting policies that empower patients with access to their health data and the right to manage and control the data collected by means of wearable DHTs.

PATIENT TRUST, LITERACY, AND ACCESS

Patient trust is another major factor required for adoption of wearable DHTs (Fig. 2). Fear that personal health data may be compromised or misused, especially with the increasing use of AI, is one of the most important trust issues. Health professionals should be aware of the data

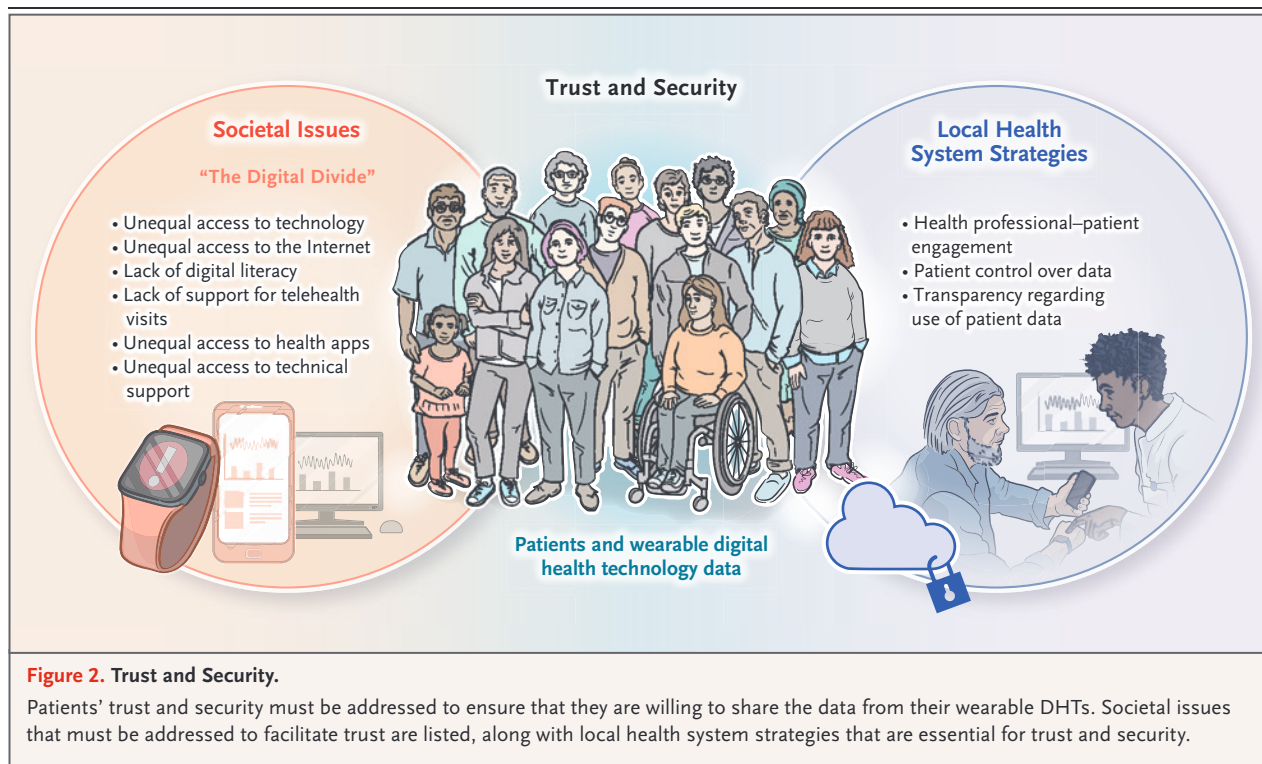


security protocols in place at their institutions and ideally should be able to communicate to their patients how their data are used, stored, and shared. Clinicians can reasonably expect that security procedures will be continually updated in clinical practice guidelines. Giving patients control over their data may increase trust.

Low digital literacy levels in certain patient populations, particularly patients with limited technology exposure, can lead to mistrust and impede effective adoption and use of wearable DHTs. At a minimum, education and training programs are likely to be needed to enhance digital literacy among patients and health care professionals.

Supporting patients from diverse groups in their digital experience, facilitating access, and providing education will be of paramount importance for the successful integration of wear-

able DHTs into clinical care and for reducing “the digital divide” and resulting health inequalities. The digital divide refers to unequal access to technology and Internet connectivity, which results in uneven adoption of wearable DHTs. Disparities in access to digital resources and in the ability to afford the associated costs disproportionately affect marginalized populations, which exacerbates existing health care inequalities, as noted in two of the articles in this series.^{1,2} Reducing costs or providing reimbursement for wearable DHTs and ensuring affordable data plans and reliable networks in underserved areas can reduce disparities in access. Collaborations between the public and private sectors — particularly, strategic partnerships between health care systems and manufacturers — may facilitate affordable options, subsidies, or reimbursement programs that promote equitable access.⁷



STANDARDS AND INTEROPERABILITY

Although the broad field of DHTs, which includes EHRs and telemedicine, has adopted data standards, the field of wearable DHTs, which is characterized by ongoing development, lacks such standards. The Institute of Electrical and Electronics Engineers (IEEE) has developed standards for wearable DHTs, particularly those used for monitoring health and wellness, to ensure that these devices are safe, effective, and interoperable. However, these standards have not been widely adopted. The Food and Drug Administration (FDA) has provided guidelines for determining which “mobile medical applications” qualify as medical devices and require regulatory oversight.⁸ The FDA can demand removal of products that make medical claims without having obtained formal FDA clearance or approval. The Federal Trade Commission and the Office of the National Coordinator for Health Information Technology also provide oversight for wearable DHTs and have already penalized firms for sharing information without consumer consent.⁹ We believe that a clear set of interoperability standards should be established for

wearable DHTs and that patients are not well served when each manufacturer establishes its own data standards¹⁰⁻¹³ (Fig. 3).

INTEGRATION INTO CLINICAL ENVIRONMENTS

Integrating wearable DHTs into clinical care presents several workflow challenges that can affect both health care professionals and patients (Fig. 4). One of the biggest challenges is the sheer volume of data generated by wearable DHTs, which can be overwhelming. As the field evolves, efforts are being made to distinguish between cases in which raw data should be transmitted to health care systems and cases in which summary data are sufficient. Approaches to sorting and analyzing data efficiently, deriving insights, and making them clinically useful are evolving (particularly since the advent of AI). Although some wearable DHTs can collect and deliver data in real time, most of the data received by clinicians will not have been delivered in real time. Finally, the temporal (and dense) data from wearable DHTs must somehow be incorporated into EHRs, which probably means

transforming the data into standard and interoperable data outputs, as discussed above, for facilitating the exchange of data within and between clinical systems. The most effective manner in which wearable DHT data are presented to health care professionals and to patients is an area of ongoing investigation.

Ensuring the accuracy and reliability of data collected by wearable DHTs is essential for clinical decision making. As the scope of clinically actionable data provided by wearable DHTs expands, we expect a maturation that will reduce false alarms, as described for continuous glucose monitors.¹ Some manufacturers of wearable DHTs have begun using rigorous testing and validation to ensure the accuracy and reliability of these devices, which has allowed them to make medical claims or provide data to support medical decisions as a result of regulatory clearance by the FDA.^{1,2,4}

Wearable DHTs are used primarily to collect data outside the clinical setting, and some of those data, such as step counts, may seem to be nonmedical. Yet changes in step counts may herald changes in a diverse set of medical issues, from heart failure to depression, that are useful for clinicians in assessing the clinical status of their patients. Data collected by wearable DHTs also pose privacy issues. Most wearable devices use wireless data to communicate with a smartphone or nearby station, and the transmitted data might be intercepted. It is important to ensure that a given patient's data, if intercepted, cannot be easily read.

The FDA now imposes cybersecurity requirements for digital platforms and devices that have been cleared for medical use.^{16,17} Manufacturers of FDA-regulated wearable DHTs increasingly must have robust privacy and security measures, including data encryption, access controls, and

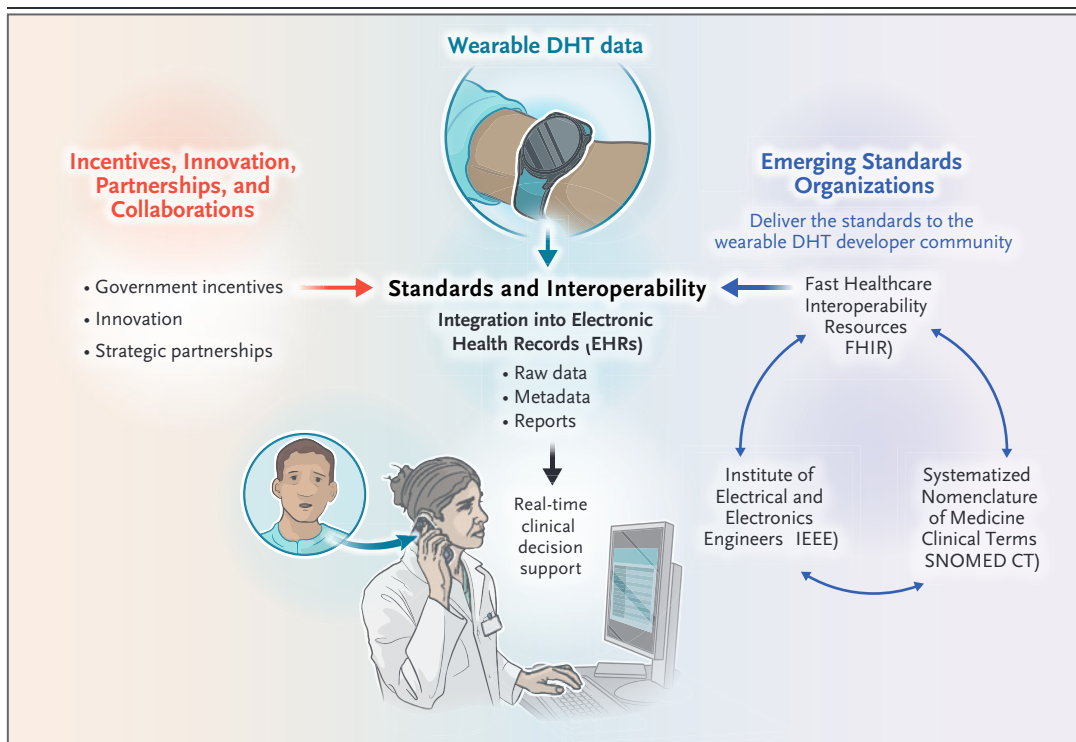


Figure 3. Standards and Interoperability.

Interoperability of data collected from wearable DHTs makes possible the integration of the data into electronic health records (EHRs) as raw data, metadata, and reports. Integration of these data and reports with clinical decision support in real time allows health professionals to gain insights that can inform decision making. Government incentives, innovation, and strategic partnerships could lead to partnerships and collaboration and facilitate the development of data standards and interoperability. Emerging standards organizations should cooperate in delivering the standards to the DHT developer community.^{14,15}

compliance with relevant regulatory standards. The FDA requires device providers to have protocols in place for addressing and reporting vulnerabilities, especially data breaches, and conducts audits of businesses, examining multiple levels of procedures. In addition, the FDA requires testing of usability by the intended users. In contrast, the manufacturers of consumer devices without FDA clearance are not required to follow any of these practices. Although clinicians first and foremost should use data from FDA-cleared devices, data from other consumer devices may have clinical value as well, if used to generate a hypothesis about a patient's condition that could be tested. Overall, it seems prudent for health

care systems to adopt an overarching implementation framework and strategy to ensure that integration of wearable DHTs into their clinical environments allows straightforward, confidential use and interpretation of the data gathered to improve patient care.

PATIENT EMPOWERMENT AND AGENCY

For patients to have agency and empowerment in using data from their wearable DHTs, the challenges of control over the data, an understanding of how the data can be used effectively, and trust in the systems managing the data will need

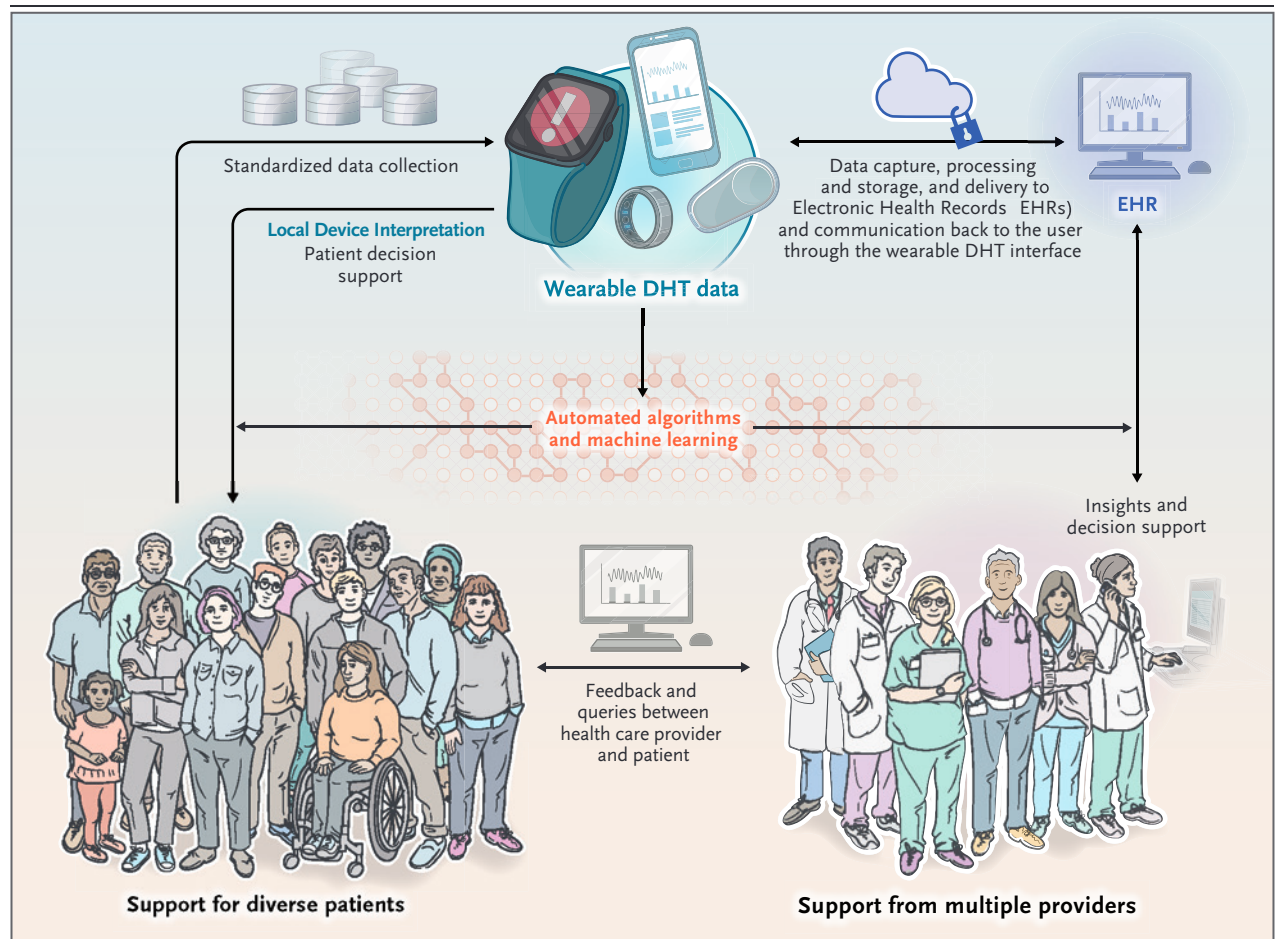


Figure 4. Integration into Clinical Environments.

The data and information flows from wearable DHTs are shown. Data are collected from patients, and local interpretation of data or trends can help guide patients in making some decisions themselves. Data sets are captured centrally in the health care system to allow for integration into the EHR and to provide support to health providers in developing insights from the data and making evidence-based decisions. Artificial intelligence, machine learning, and automated algorithms can facilitate this process.

REIMBURSEMENT AND RETURN ON INVESTMENT FOR HEALTH CARE SYSTEMS

to be addressed. Patients should understand and have a say in who has access to their data and how the information is used. Wearable DHTs are designed to serve multiple roles; for example, patients may want useful real-time information and guidance on how to interpret and act on it, whereas the clinical and research community may want better insights into treatments and responses and efficient, lower-cost health care. At present, there is a gap between use of the devices to gather data that can guide patients in making lifestyle decisions and use of the devices to help clinicians make decisions about medical interventions.

As exemplified in this series, wearable DHTs are beginning to modify the roles of patients and health care providers. For example, a patient with type 2 diabetes who is not yet insulin-dependent can modify diet and exercise in real time in response to the data from a continuous glucose monitor.¹ Wearable DHTs also enable persons to have access to real-time data about their health and well-being, including metrics such as heart rate, activity levels, and sleep patterns. These data have the potential to provide them with a better understanding of their health and to help them be proactive in meeting health goals. However, there are trade-offs. For example, smartwatches that monitor heart rhythm may set off a false alarm for atrial fibrillation, leading not only to anxiety on the patient's part but also to an unnecessary medical evaluation.^{18,19} AI methods have shown promise in reducing false alarms, especially with the use of large, high-quality data sets for training.²⁰

Wearable DHTs may also be used to provide personalized health recommendations based on a patient's specific data, with the potential to motivate the patient, modify behavior,²¹ and tailor medications and treatment plans. At the same time, patients and providers need to understand the limitations of wearable DHT data, be able to discuss their accuracy and reliability, and recognize the possibility of overreliance on technology for health care management. Self-awareness, self-management, and active participation in health care are beginning to drive a new sense of agency and empowerment for some persons that ultimately can contribute to adherence to treatment plans, participation in research, health literacy, and improved health.

Reflecting the likely benefits of wearable DHTs in improving clinical outcomes and operational efficiency, there is now a set of Current Procedural Terminology (CPT) codes for remote patient monitoring with wearables (e.g., CPT codes 99453, 99454, 99457, and 99458), which cover FDA-cleared or FDA-approved devices, their setup and patient education, remote patient monitoring, data reading, and patient consultations, with some restrictions. Devices and procedures that do not meet existing CPT definitions still present serious challenges in securing reimbursement. These challenges stem from the need for evidence of clinical effectiveness and cost savings, a complex and evolving landscape of regulatory requirements, and imperfect paradigms for integration of these technologies into existing health care delivery models. As a result, health care systems sometimes struggle to justify financial investment in wearable DHTs.

Although regulatory clearance by the FDA indicates sufficient evidence of claimed medical functionality and several kinds of safety, health insurance companies often require evidence of cost equivalence or cost reduction before they reimburse patients for wearable DHTs. Drivers of inequitable access, such as heterogeneous coverage by public payers and high-deductible insurance plans, provider bias, and limited English proficiency, considerably restrict the availability of wearable continuous glucose monitors and seizure monitors,^{1,4} and similar barriers apply to most new wearable DHTs. Comparative effectiveness research and, in some cases, randomized clinical trials are needed to provide evidence that wearable DHTs provide benefits with respect to long-term health outcomes, health care utilization, and effects on health care costs. Such studies pose extra challenges for small manufacturers, which already face substantial hurdles in meeting the quality levels and extra procedures required by the FDA. Evidence-based guidelines that define the specific conditions in which these devices are effective can help payers determine reimbursement criteria. In the meantime, it is likely that consensus

guidelines developed by health care professional societies, device manufacturers, researchers, and regulatory bodies will be required for the appropriate use of and reimbursement for wearable DHTs.

For health care systems to effectively adopt wearable DHTs, investment in infrastructure, interoperable data solutions, cybersecurity measures, staff training, data analytics, and workflow integration will be required. Equity in the use of wearable DHTs will also necessitate investment in addressing the digital divide. Together, these investments have the potential to improve health outcomes in several ways, including detection of medical conditions in a more timely and actionable way.¹⁻⁴ For example, a seizure detector can alert a caregiver to attend to a patient having a convulsive seizure, preventing injury.⁴ Such investments also promote interventions based on personalized data, which may lead to reduced hospitalizations, reduced administrative burdens, streamlined health care processes, improved resource allocation, and improved overall patient well-being.¹⁻⁴ For example, the cardiovascular article in this review series showed how remote monitoring for heart failure, enabled by wearable DHTs, reduces rehospitalization, increases efficiency in the delivery of care, and is likely to reduce costs associated with preventable complications.² Although alerts from a wearable DHT might prompt more people to see their physicians, driving up health care utilization and billing,²² this proactive approach may help to slow or arrest the progression of chronic diseases. A promising current example is the use of wearable DHT monitoring for atrial fibrillation to reduce the probability of stroke.^{21,23}

Promptly reported, deidentified wearable DHT data on health and behavior may also contribute to population health management. Health care systems could leverage these data to identify trends, monitor public health risks, and design targeted interventions to improve population health outcomes. The coronavirus disease 2019 (Covid-19) pandemic provided use cases for outbreak detection, contact tracing, and education on health behaviors for patients using apps and wearable DHTs.²⁴ Health care systems investing in reducing the digital divide and building end-user trust have the potential to foster patient en-

gagement and satisfaction.²⁵ Empowering patients with access to their health data and the ability to actively participate in their own health management may enhance patient satisfaction and strengthen the patient-provider relationship.²⁶ Although false positive signals may have the unintended consequence of incurring additional office visits and costs, satisfied and engaged patients may be more likely to adhere to treatment plans, which in turn may lead to better health outcomes and reduced health care costs in the long run. Finally, wearable DHTs may promote decentralized decision making and reduce the need for some office or hospital visits; consequently, the overall assessment of return on investment is complex.

Earlier interventions, more proactive disease management, and a greater emphasis on preventive measures have the potential to reduce the burden of chronic conditions, prevent costly hospitalizations, and make the best use of resources.²⁷⁻²⁹ Wearable DHTs may play an important role in all these improvements if initial investments are made for their appropriate use.

CONCLUSIONS

Our premise is that in the realm of medical innovation, wearable DHTs are likely to shift the way health and disease are observed and managed. As engineers know, better controllability comes with better observability: operators of vehicles drive better when they can see. Data sets from wearable DHTs provide observations of physiological and behavioral patterns in real life, which have previously been unavailable to clinicians. These new data insights may help to foster a proactive and adaptive health care framework that can better fit an individual patient, providing earlier prevention and tailored treatments in line with the vision of precision health. Expanded use of wearable DHTs has started to catalyze a redefinition of traditional health care roles. Patients are inspired by their data to be better personal health managers, and providers can receive health-relevant objective data about patient activities outside the clinic.

As we contemplate the opportunity and potential promise of wearable DHTs, however, new challenges arise. Providers are largely unequipped to manage or understand the massive new sets

of data. They will need to understand the benefits and limitations of AI-generated outputs, as well as the extent to which insights from wearable data are clinically meaningful, since some device alerts may cause superfluous use of health care. Investments are needed to educate clinicians and patients in the appropriate handling of data from wearable devices. Most important, work must be done to keep wearable DHTs from widening the digital divide. Addressing disparities in access and in proficiency with these technologies is paramount if we are to advance health equity while improving the quality of health care. Quantifying the return on investment for wearable DHTs, in terms of both clinical outcomes and economic efficacy across

the whole health ecosystem, remains a vital task. To address and solve these challenges will require the collective will and collaboration of a large stakeholder community, including health care providers, users, and wearable DHT developers, if we are to realize the full promise of data from wearable DHTs in facilitating early interventions and advancing precision health care for all people.

Neither the *Journal* nor the Massachusetts Medical Society endorses any specific digital health technology. Examples of such technology appear in this article for illustrative purposes only and do not constitute an endorsement.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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