

REVIEW ARTICLE

WEARABLE DIGITAL HEALTH TECHNOLOGIES IN MEDICINE

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Wearable Digital Health Technology for Epilepsy

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THIS REVIEW ARTICLE PRESENTS TWO TRUE-LIFE CLINICAL VIGNETTES that illustrate how digital health technology can aid providers caring for patients with epilepsy. Specific information that would identify real patients has been removed or altered. The vignettes are followed by a discussion of how these methods were used in the care of the patients.

PATIENT 1: SAM

Sam, who is 17 years old, received a diagnosis of juvenile myoclonic epilepsy at 14 years of age. He has had myoclonic seizures every week, with an average of two generalized tonic-clonic seizures per year, typically after poor sleep or missed medication. Sam's parents have worked with him to develop his independence by, among other things, adhering to his medication regimen and maintaining good sleep hygiene. They purchased a wrist-worn seizure detector and encourage him to use it day and night. One evening, Sam returned home and went to his second-floor bedroom. His parents were asleep in their third-floor bedroom. At 4 a.m., his parents were awoken by a seizure alarm on their phones. They found Sam lying face down on his bedroom floor. They provided immediate aid but were overcome by the realization that their son could have died if he had not been wearing his seizure detector or if they had not responded quickly. How can they encourage Sam's independence yet keep him safe with his convulsive seizures?

PATIENT 2: JULIE

Julie is a 35-year-old woman who has had epilepsy since adolescence; she lives alone in an apartment. For years, she has reported good seizure control with carbamazepine. Recently, however, her new partner has observed episodes of unresponsiveness, with hand automatisms of which she was unaware. Julie and her medical team are considering an additional antiseizure medication. However, they are concerned that if her nonconvulsive seizure frequency cannot be quantified, they will be unable to accurately assess her response to treatment. Could a wearable digital health device help?

THE NEED FOR WEARABLE DIGITAL HEALTH DEVICES TO MANAGE EPILEPSY

For people living with epilepsy, as well as their families and caregivers, epilepsy is an unpredictable, challenging, and often frightening disorder, especially for the

Table 1. Risk of Sudden Unexpected Death in Epilepsy According to the Frequency of Generalized Tonic–Clonic Seizures and Living Situation.*

Living Situation	No. of Seizures in Preceding Year					
	No Seizures		1–3 Seizures		≥4 Seizures	
	<i>no. of cases/no. of controls</i>	<i>odds ratio (95% CI)</i>	<i>no. of cases/no. of controls</i>	<i>odds ratio (95% CI)</i>	<i>no. of cases/no. of controls</i>	<i>odds ratio (95% CI)</i>
Shared household and bedroom	8/138	1.00 (reference)	16/50	15.89 (6.05–41.78)	8/21	19.85 (6.37–61.84)
Shared household but not bedroom	4/287	1.10 (0.30–4.02)	18/50	31.34 (11.22–87.53)	27/61	33.55 (12.21–92.18)
Living alone	26/260	3.92 (1.69–9.13)	72/50	65.90 (27.72–156.65)	76/48	81.81 (33.60–199.15)

* Data are from Sveinsson et al.⁷ Odds ratios have been adjusted for age and sex (matching variable). CI denotes confidence interval.

one third of people with epilepsy who have ongoing seizures despite medical treatment.¹ The paroxysmal nature of Sam's seizures makes it difficult for his parents to allow him the usual independence of a teenager. They fear he will have a seizure when no one is around to keep him safe. These fears are valid. Seizure-related injuries and accidents are most often associated with generalized tonic–clonic seizures, and up to 25% of people with such seizures have had at least one severe injury in their lifetime.^{2,3} Furthermore, generalized tonic–clonic seizures are the strongest risk factor for sudden unexpected death in epilepsy, the leading cause of epilepsy-related death.⁴ The average risk of sudden, unexpected death for a person living with epilepsy is 1% per decade. Thus, each year, sudden, unexpected death claims 1 in 1000 lives among people with epilepsy; the risk is 1 in 250 for those with severe forms of epilepsy.^{5,6} The risk of death increases with the frequency of generalized tonic–clonic seizures but is modified by living conditions. Living alone or sharing a household but not a bedroom is associated with an increased risk of sudden death; a person who sleeps alone and has frequent tonic–clonic seizures has the highest risk⁷ (Table 1).

For Julie and her health care providers, subtle seizures of which she is unaware limit the assessment of therapeutic efficacy. Julie faces two challenges that Sam does not. She lives alone, and her subtle seizures lack the robust physiological markers on which seizure detection is based. Therefore, a wearable device has limited benefits. For people living alone, as Julie does, even convulsive seizures may go undetected,

especially if the seizures occur during sleep or are followed by amnesia. Seizure reports maintained by people with epilepsy are often unreliable, failing to document more than half of all seizures and more than 85% of nocturnal seizures confirmed by video-encephalography, the current clinical standard for seizure diagnosis.⁸ For children with epilepsy, parental reports of seizures are also unreliable, and up to 50% of seizures may be unrecognized.⁹ Challenges with seizure recognition contribute to diagnostic delays, inaccurate diagnoses and classification of epilepsy and seizures, and under- and overtreatment of underlying disorders.¹⁰ Underdiagnosis of seizures can endanger the person with epilepsy and others if the person with epilepsy is driving (if that is allowed in the jurisdiction where the person resides) or working in a dangerous setting. Inaccuracies in the clinical history and seizure reporting can also lead to overdiagnosis, resulting in unnecessary treatments and limitations on driving and work, as well as a reduced quality of life.

Wearable digital health technology (DHT) may fill several critical gaps in epilepsy care. Accurate seizure-detecting wearables can provide data on seizure frequency, used to tailor medical treatments and identify treatment failures. In addition, when seizure detection is paired with an alarm feature, wearables may facilitate interventions during and after seizures, potentially reducing the risks of injury or death.¹¹ In clinical trials of new therapies, wearable DHT could be used to objectively evaluate seizure data.¹² Beyond seizure detection, DHT may collect objective data to monitor treatment-related

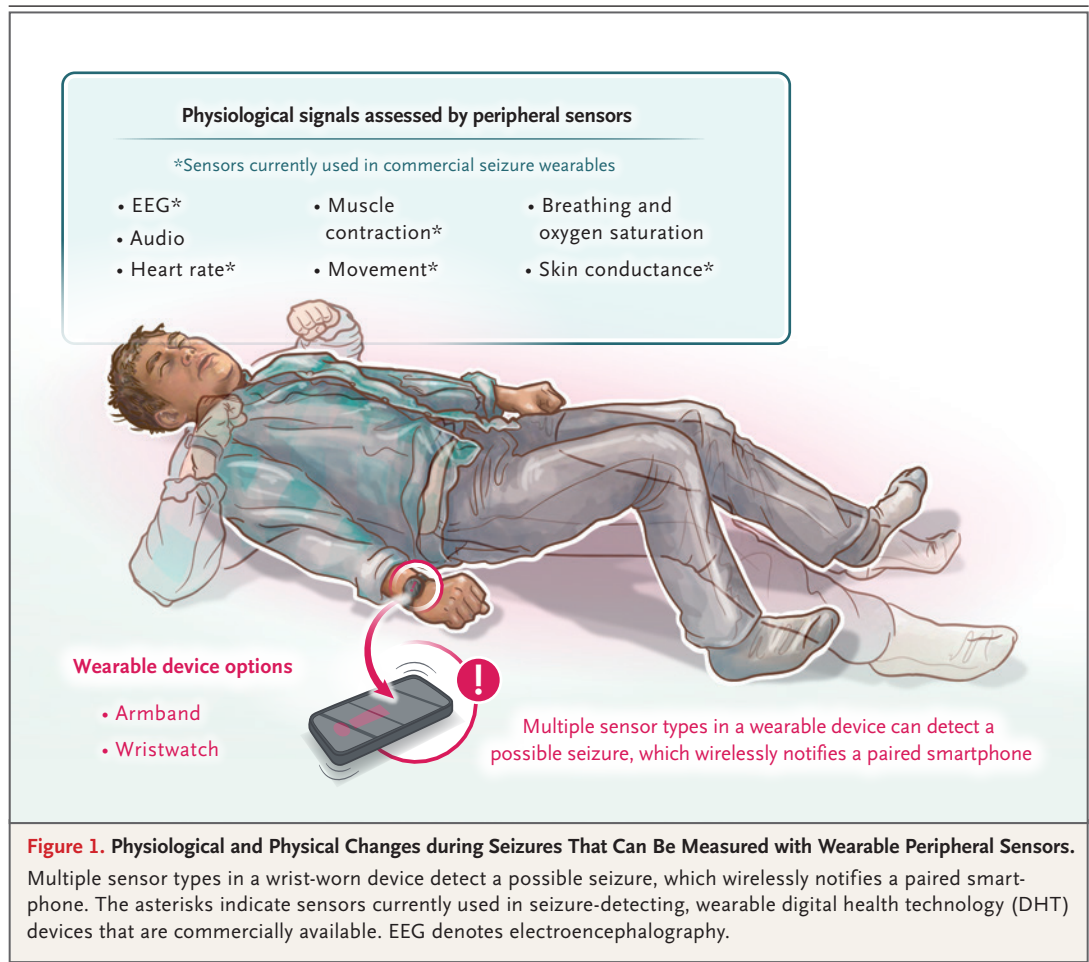
side effects, as well as neurobehavioral and medical disorders coexisting with epilepsy. To date, the development of wearables for epilepsy has focused on the detection of convulsive seizures, since these seizures are most likely to result in injury or death, and robust physiological markers can reliably detect motor and autonomic activity during convulsive seizures.

Wearable sensors built into smartwatches and other types of DHT are commonly used by consumers to track physiological functions, including activity, sleep, and heart and pulse rates, for fitness and general health goals. There has been tremendous interest in using similar sensors for seizure detection. Some wearable devices are marketed directly to consumers. Other wearables, such as traditional electroencephalography-based DHT devices, are more often used for research and may offer additional features but can be cumbersome, uncomfortable, and unattractive.^{13,14}

Here, we review wearable DHT devices for seizure detection that are intended for long-term use to monitor a chronic condition and are acceptable to users and caregivers, while considering the current limitations of such devices and unanswered questions.

TYPES OF WEARABLES FOR SEIZURE DETECTION

Figure 1 shows physiological signals that are assessed by peripheral, worn sensors. Motion can be measured with accelerometry and electromyography. Heart rate and pulse rate can be measured by means of electrocardiography and photoplethysmography, respectively. Electrodermal activity provides a measure of sympathetic nervous system activity. An audio recording device can detect and record seizure-associated sounds. These measures can be used alone or



combined into a wearable device to improve sensitivity and specificity.¹² Wrist-worn and surface electromyographic devices that use accelerometry have been reported to have high sensitivity but also high false alarm rates.¹⁵ Furthermore, the sensitivity and specificity of physiological measures vary according to the seizure type, patient size, skin color, and whether the patient is at rest or active when the seizure occurs.¹⁶

Wrist-worn DHT devices typically use accelerometry, sometimes combined with electrodermal or pulse rate sensors. The devices can be paired to a smartphone. When movements are detected, the paired smartphone sends a call or alarm to preidentified contacts in order to alert caregivers that a possible seizure is occurring. Some devices include the global positioning system (GPS) location of the wearer. A wrist-worn, accelerometer-only device is approved in Europe (CE-marked) for convulsive seizure detection, and another wrist-worn device that uses accelerometry and electrodermal activity for detecting possible generalized tonic-clonic seizures lasting longer than 20 seconds is approved in the United States and Europe.^{17,18}

Seizures associated with arm-muscle movement can be detected with the use of an electromyographic patch covered by a wireless monitoring device on an armband placed over the biceps muscle. When muscle activity is detected, the device signals a laptop base station, which alerts caregivers by means of a telephone call, email message, or text message.^{19,20} Armband DHT devices may also include three-dimensional accelerometry and photoplethysmography to detect motion and pulse rate changes. These devices are most valuable during rest periods, since they are prone to false seizure detections during daytime activities. In a study involving 28 adults with intellectual disabilities in a long-term care facility, an armband DHT device was not associated with discomfort overnight.²¹

Several mobile device applications, which have not been approved by the Food and Drug Administration (FDA), are marketed for seizure detection. These applications do not have dedicated wearable hardware but are paired with smartphones and smartwatches. The user downloads and subscribes to the application on a smartwatch and pairs it with a mobile phone or tablet. Rather than a specific piece of hardware,

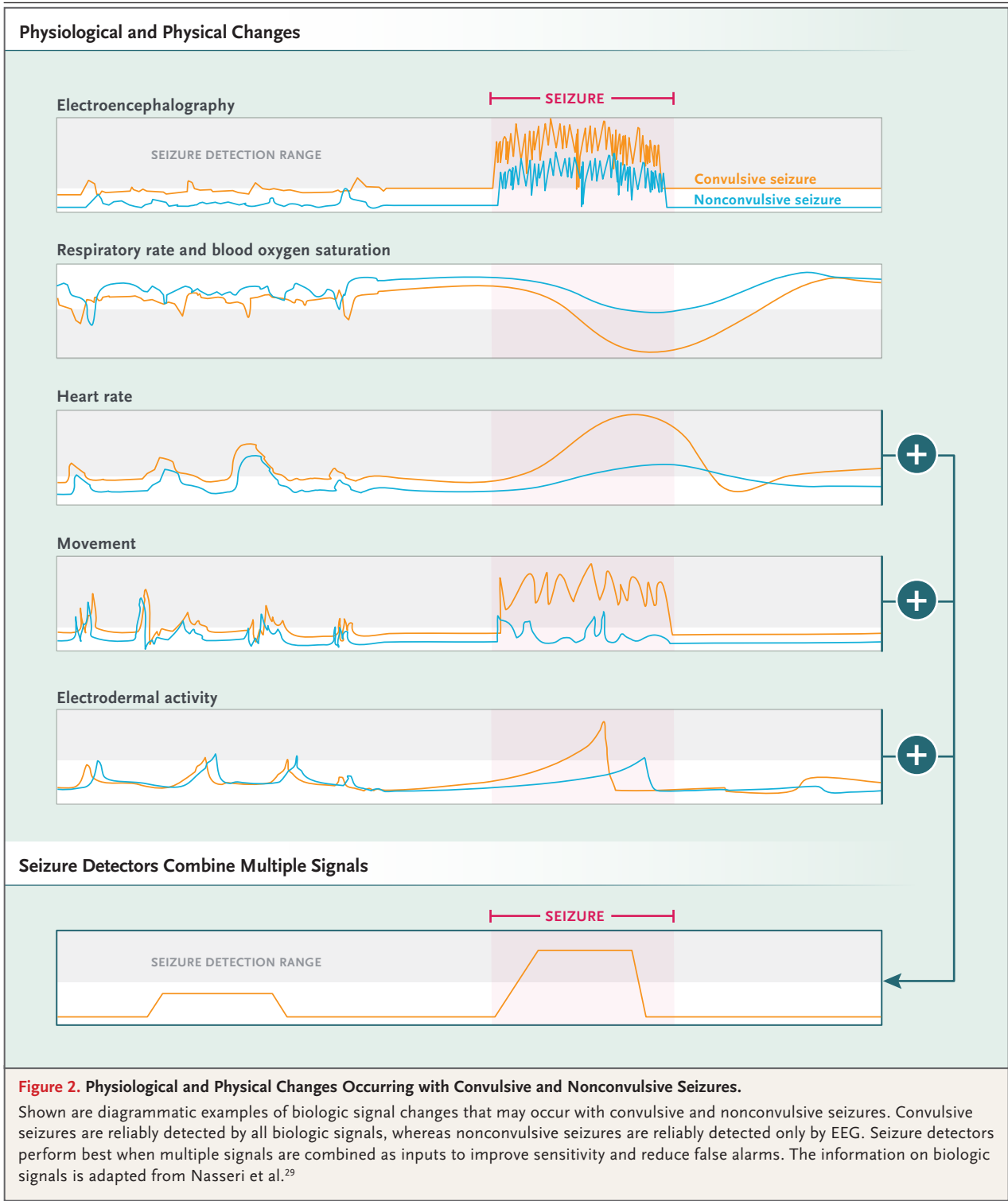
this type of application is classified as software as a medical device and can be approved by the FDA for such use. For people with epilepsy, the application uses the movement and pulse rate sensors of the smartwatch to identify potential convulsive seizures and the linked mobile device to alert preidentified caregivers. Some applications use GPS tracking to show the wearer's location and have a "help" button the user can activate to request assistance from caregivers.¹²

Although most wearable DHT devices are focused on detecting convulsive seizures, detecting other seizure types is also an important goal. Figure 2 shows the biologic signal changes that occur with convulsive and nonconvulsive seizures. The orange lines depicting convulsive seizures exemplify the seizures of our first patient, Sam, and the blue lines represent the nonconvulsive seizures of our second patient, Julie. Biologic signal changes with nonconvulsive seizures typically occur below the threshold for seizure detection by a wearable DHT device. Brief tonic and atonic seizures are more difficult to detect than tonic-clonic seizures because of their shorter duration and lack of clonic activity.²¹ Absence seizures can be very subtle and are often missed by the person with seizures, teachers, caregivers, and family members. A wearable DHT designed to detect absence seizures, comprising a two-electrode electroencephalographic headband wirelessly connected to a smartphone, showed promise in a phase 3 trial.²²

Wearable DHT can be used to collect granular data for clinical discovery. Although some consumer-marketed devices do not collect high-quality clinical data, wearables that do may offer the opportunity to advance epilepsy research while providing a potential benefit to patients and their caregivers. Wearables can detect autonomic changes associated with near death, as well as other physiological changes associated with seizures, and can be used to collect physiological data for studies other than those focused on epilepsy.²³⁻²⁵

The marketplace for wearables is rapidly evolving. In addition to seizure-specific FDA-cleared devices, FDA-cleared or CE-marked devices for physiological monitoring but not seizure detection are used in research and occasionally in clinical settings. Applications running on commercially

available smartwatches and fitness trackers are approved for cardiovascular monitoring but not seizure detection. Data from well-designed studies evaluating the efficacy of seizure detection by devices not specifically designed for this use are lacking.



 PERFORMANCE OF SEIZURE-
DETECTING WEARABLES

Most data on wearable DHT for seizure detection come from studies of inpatient epilepsy-monitoring units where the DHT detection can be compared with simultaneous audiovisual monitoring and electroencephalography. Thus, the clinical standard for assessment is an artificial environment where normal activity is constrained, and real-world accuracy may be overestimated or underestimated. In a move toward more pragmatic assessment, some devices have been studied in residential or group home settings, where detections were compared with expert reviews of nighttime video recordings.²¹ Performance data for six wearable DHT devices marketed in the United States or Europe were compared with this standard.¹² The devices included wrist-worn accelerometers or multimodal sensors, armbands that register motion and pulse rate, and surface electromyography-based sensors. Sensitivity for detecting convulsive seizures ranged from 76 to 95%, and most of the devices, when properly placed, detected more than 90% of generalized convulsive seizures. A meta-analysis of all tested wearable sensors showed a mean sensitivity of 91% (95% confidence interval, 85 to 96) for detecting tonic-clonic seizures, which suggests that most wearable DHT devices can detect these seizures.¹⁵

The false alarm rate is a critical measure for differentiating devices. For marketed DHT devices with published data, the rates range from 0.1 to 2.5 false alarms per day. False alarm rates are higher for children than for adults, and most false detections occur during wakefulness.²⁶ The marked heterogeneity in false alarm rates suggests that the sensor type and detection algorithm, as well as when, how, and by whom the device is used, are critical factors in minimizing false detections.¹⁵ It is important to consider the ability of the wearer to rapidly cancel a false alarm, since rapid cancellation can minimize the challenge of false detections. Table 2 summarizes seizure detection effectiveness and regulatory clearance status according to the type of wearable device.

Some wearable DHT devices can detect nonconvulsive seizures.^{28,29} Seizures with prominent movement such as tonic, hypermotor, or myoclonic seizures could be more challenging to

detect, since they are usually shorter in duration than generalized convulsive seizures.¹² However, accelerometry and pulse rate armband sensors detect these seizure types with a median sensitivity of 73 to 89%.²¹ No marketed wearable DHT device can reliably detect nonconvulsive seizures such as focal impaired awareness seizures, though devices that use electroencephalographic sensors or peripheral signals such as pulse rate are in development.³⁰

 HOW SEIZURE-DETECTING
WEARABLES ARE USED

The most important indication for a seizure-detecting wearable is improving safety during and after a seizure. People with epilepsy have a high rate of premature death, and death is often the direct result of seizures, especially tonic-clonic seizures, which can cause fatal accidents, drownings, aspiration, and sudden, unexpected death.³¹ Sharing a bedroom can reduce the risk of sudden, unexpected death among people with epilepsy.⁷ Basic aid, such as repositioning the person during or immediately after a seizure, may prevent death in some cases. Seizure-detection devices that alert nearby caregivers may extend that protective effect beyond immediate proximity to the person during or shortly after a seizure. However, a DHT device helps only if it is consistently worn. Some users may believe that they need to wear the device only while sleeping, yet 30% of sudden, unexpected deaths among persons with epilepsy occur while they are awake.³² Given the currently unpredictable nature of seizures, occasional failure to use a wearable DHT device while awake during the day or asleep at night could negate the potential benefit of the device.

A study involving 30 people with uncontrolled epilepsy assessed mastery of a wrist-worn device during a hospital stay for seizure monitoring.³³ After one training session, 50% percent of the participants required no further assistance in wearing and charging the device and pairing it with a smartphone and tablet. However, 37% of the participants required additional support or training, and 13% needed constant supervision in performing some or all of the tasks. The most challenging tasks were charging the device and pairing it, as well as remembering to use a replacement device when the primary device was

Table 2. Seizure Detection Effectiveness and Regulatory Clearance According to the Type of Wearable Digital Health Technology (DHT).[‡]*

Type of Wearable DHT	Sensor and Biologic Signal Detected	Seizure Types Detected	Sensitivity	False Alarm Rate	Regulatory Clearance [†]
Seizure-detecting, wrist-worn DHT	Accelerometer: electrodermal activity, skin temperature	Tonic-clonic	High; range: 31–100%; meta-analysis: 0.93 (95% CI, 0.85–0.99)	Lowest when used at rest; range: 0.1–0.6/day; meta-analysis: 2.5/24 hr (95% CI, 1.95–3.1)	Yes
Armband	Electromyography, with or without accelerometer and photoplethysmography	Tonic-clonic	High; range: 76–94%; meta-analysis: 0.90 (95% CI, 0.71–1.00)	Lowest when used at rest; range: 0.1–2.5/day; meta-analysis: 0.96/24 hr (95% CI, 0.25–1.66)	Yes
Mobile DHT application, including SaMD	Smartwatch application and accelerometer, with or without photoplethysmography	Tonic-clonic	Unknown	Unknown	No
EEG-based DHT	EEG	Most seizure types	Absence seizures: 99.6%	Absence seizures: 5/day	No approval for home or community use

* The data on sensitivity and false alarm rates are from Shum and Friedman,¹² Naganur et al.,¹⁵ and Bruno et al.²⁷ The meta-analysis data are for wrist-worn and ankle-worn devices (ankle-worn devices are not clinically available but were used by clinical studies).¹⁵ EEG denotes electroencephalography, and SaMD software as a medical device.

† In the United States, the Food and Drug Administration (FDA) evaluates DHT on the basis of the risk category. Class II devices (intermediate risk) require FDA clearance, and class III devices (high risk) require FDA approval.

unavailable. Data from a survey of people with epilepsy and caregivers suggest that use of a seizure-detection device can result in fewer seizure-related injuries.³⁴ However, no studies have prospectively examined the effects of wearable devices in providing protection against seizure-related injuries and sudden, unexpected death or other seizure-related deaths.

Wearable DHT devices improve the accuracy of seizure reporting, since as many as 60% of seizures are unrecognized by people with epilepsy and their caregivers.³⁵ Accurate reporting of changes in seizure frequency allow health care providers to assess disease activity and treatment efficacy. The lack of objective measures of seizure frequency affects clinical care — for example, assessment of whether a new treatment is beneficial or whether a patient is truly seizure-free and can safely drive a vehicle. An inability to accurately quantify seizure frequency can adversely affect clinical trials, adding statistical noise, increasing the cost and complexity of the studies,³⁶ and possibly leading to an erroneous conclusion that an effective therapy is ineffective. Studies are assessing whether wearable sensors can help people with epilepsy, health care providers, and trialists reliably quantify seizures. However, the available devices detect only tonic-clonic seizures; they cannot accurately detect nonconvulsive seizures, which account for most epileptic seizures.

LIMITATIONS AND PRACTICAL CONSIDERATIONS

Wearable DHT devices that detect seizures offer great promise for the management of epilepsy but have limitations. Current devices work only for convulsive seizures and have not been shown to reliably detect other seizure types. In addition, false detections, which occur mostly during periods of activity, limit the use of these devices. Moreover, data showing that wearable DHT devices reduce the risk of injury are limited, and there is no evidence that they reduce the risk of sudden unexpected death in epilepsy. The use of devices to quantify seizures and improve treatment is also not yet evidence based. Patient preference, stigma, and cost are critical considerations for ensuring that wearable devices are easily adopted and consistently used by people with epilepsy who would benefit from them.³⁷

People living with epilepsy express a strong interest in using seizure-detecting DHT to improve safety, epilepsy self-management, and independence, despite concerns about data privacy and technological usability.^{27,38} Seizure-detection devices that are worn on the wrist or have designs that draw minimal attention to them have been shown to be acceptable to most people with epilepsy.²⁷ Users prefer devices that fit securely but are easily removed, wireless, and comfortable.^{27,39} However, patient characteristics such as age and income may influence preferences and could be potential barriers to use.⁴⁰

Device performance is important (Box 1). Battery life — that is, the interval between required battery charges — is an important consideration. For example, to charge currently available devices requires that the device be taken off the body, and once it is off the body, there is a risk of lower use. A survey of people with epilepsy who used seizure-detection devices showed that although there was general agreement that a sensitivity of more than 90% for detecting seizures was critical, a false alarm rate that was acceptable varied according to seizure frequency.⁴⁰ For people with frequent seizures, a rate of 0.1 to 0.3 false alarms per day was acceptable, whereas for those with infrequent seizures, a rate of less than 2 false alarms per month was acceptable. In another survey of users' experience with seizure-detection devices, the respondents were more likely to be satisfied with and continue using a clinically validated DHT device, regardless of the type, as compared with an unvalidated device.⁴¹ False alarms and missed seizures were the most common reasons for deciding to stop using a DHT device.

The cost of a DHT device is a concern among people with epilepsy and their caregivers. Most seizure-detection devices are paid for primarily by the patient, through up-front device costs and subscription fees, and even devices with regulatory agency approval may not be covered by health insurance. In the United States, a prescription is required for the FDA-cleared wrist-worn device, and some insurance companies provide reimbursement for the cost of the device. Out-of-pocket costs remain a barrier to widespread use. In one U.S.-based survey of people with epilepsy, two thirds of the respondents stated that they would not use a device unless the cost was covered by insurance.⁴²

Box 1. Considerations for Selecting a Wearable Device.

Ability of device to detect seizure type of concern Availability of caregiver to respond to alarm Comfort Time of day seizures typically occur Stigma and willingness to wear Ease of use Battery life (interval between charges) Cost Data privacy Burden of false alarms

Other concerns include ease of use, data privacy, and confidentiality.⁴³

FUTURE NEEDS FOR WEARABLES IN EPILEPSY

The initial success of wearables in detecting convulsive seizures must be extended to include detection of focal and other subtle seizures with adequate sensitivity and specificity. This may require alternative physiological seizure markers, more data, and artificial intelligence to combine markers.^{29,30} Clinical trials for new epilepsy therapeutics that target drug-resistant focal seizures will benefit from wearables that can detect the most common nonconvulsive seizures.

Seizure detection remains the focus of commercial wearables for epilepsy. However, seizure prediction and seizure forecasting are areas of great interest and ongoing development.⁴⁴ People with epilepsy acknowledge that the unpredictability of seizures is extremely challenging. The ability to predict, for a given patient, that a seizure is imminent or is likely to occur within a number of hours could allow for safety planning and even intervention with rescue medications. Patient- and caregiver-maintained seizure diaries may play a part in the development of prediction algorithms by identifying environmental and health factors associated with seizures that can be combined with biologic signal data from seizure-detection devices. In this way, data derived from clinical observation and wearables may be combined in the future to identify patient-specific risk factors and seizure-prediction models.¹⁴

Sudden, unexpected death is the most tragic outcome of epilepsy and remains a focus of seizure detection, yet no device has been proved to reduce this risk. Although wearables can alert caregivers, who may be able to rapidly intervene

during or after a seizure, the question of what interventions, if any, will reduce deaths due to seizures remains unanswered. For patients who live alone, detecting a convulsive seizure may not help in securing potentially lifesaving first aid during or immediately after the seizure. Closed-loop systems that detect a seizure and react with a treatment or even forecast and prevent seizures are being developed, and these systems could change epilepsy therapies.¹⁴ Wearable DHT devices may also help estimate the risk of sudden, unexpected death. Data recorded by such wearables could contribute to individualized risk calculation, increase our understanding of the mechanism of sudden, unexpected death in persons with epilepsy, and inform interventions to prevent it.⁴⁵

CONCLUSIONS

Wearable DHT is poised to change seizure detection and, potentially, the approach to treating epilepsy. More accurate seizure counts will help determine the efficacy of treatments. Wearables promise greater independence for many people with epilepsy. In 2021, the International League Against Epilepsy and the International Federation of Clinical Neurophysiology published a clinical practice guideline recommending seizure-detecting wearable DHT to reduce seizure-related morbidity and mortality and improve documentation of seizure frequency.³⁷ The guideline recommended using clinically validated wearable DHT for automated detection of convulsive seizures when there are safety concerns, espe-

cially in the case of unsupervised people with epilepsy who do not share a bedroom but live in housing where alarms can result in intervention within 5 minutes. This recommendation makes it clear that seizure-detecting DHT must be clinically validated and used appropriately. For Sam, who has juvenile myoclonic epilepsy and convulsive seizures, a wrist-worn DHT device may enhance his safety and independence, but only if he wears it reliably and has caregivers nearby to attend to him during and after a seizure. For Julie, who struggles to quantify her subtle focal seizures, which she is unaware of, a DHT device that would meet her needs is not available.

Rapid progress in the development of wearable DHT offers the promise of improved outcomes for health and quality of life and an opportunity to advance our understanding of seizures and epilepsy. As DHT evolves to reliably detect nonconvulsive and subtle motor seizures, the technology will be more widely accepted. Pragmatic and in-field studies documenting sensitivity and false alarm rates, as well as studies that assess critical outcomes such as the morbidity and mortality associated with seizures, are required to drive widespread adoption of DHT by practitioners, people living with epilepsy, and their caregivers.

Some DHT devices are referenced in this review; however, this review is not an endorsement by the authors, the *Journal*, or the Massachusetts Medical Society; the devices mentioned in this article are not comprehensive of all DHT on the market or in development.

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

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