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CRITICAL REVIEW – INVITED COMMENTARY

Wearable devices for seizure detection: Practical experiences and recommendations from the Wearables for Epilepsy And Research (WEAR) International Study Group

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Abstract

The Wearables for Epilepsy And Research (WEAR) International Study Group identified a set of methodology standards to guide research on wearable devices for seizure detection. We formed an international consortium of experts from clinical research, engineering, computer science, and data analytics at the beginning of 2020. The study protocols and practical experience acquired during the development of wearable research studies were discussed and analyzed during bi-weekly virtual meetings to highlight commonalities, strengths, and weaknesses, and to formulate recommendations. Seven major essential components of the experimental design were identified, and recommendations were formulated about: (1) description of study aims, (2) policies and agreements, (3) study population, (4) data collection and technical infrastructure, (5) devices, (6) reporting results, and (7) data sharing. Introducing a framework of methodology standards promotes optimal, accurate, and consistent data collection. It also guarantees that studies are generalizable and comparable, and that results can be replicated, validated, and shared.

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KEYWORDS
devices, epilepsy, mHealth, standards, technology

1 | INTRODUCTION

Research using wearable devices for seizure detection has flourished in the last decade.[1] Despite the rapid advancement of technology and the availability of new devices, the use of wearables in daily clinical epilepsy care remains rare and its benefit is not adequately supported by evidence.[2] The lack of studies demonstrating the validity of data collected in real-world conditions and the lack of collaboration between regulators, health tech companies, and medical professionals have impeded clinical adoption. Another reason for the gap between research findings and the clinical use of wearables may be a lack of standards in data acquisition and analysis in this relatively new area of research. Data appraisal across studies is hampered by variability in data acquisition and inconsistent reporting of essential contextual information in practical settings. The advantages of common data elements in mobile health epilepsy applications were highlighted previously.[3]

Although specific standards for testing and clinical validation of seizure detection devices have been introduced,[4] there remains room for improvement across device development and testing processes. This work builds upon these standards and incorporates practical guidance on study design based on our collective experience. The proof-of-concept that a commercial or noncommercial device is suitable for seizure monitoring is first obtained from validation studies performed in epilepsy monitoring units (EMUs). Outpatient setting studies are crucial for testing and validation.[5–7] Currently, different research groups adopt various methods and report heterogeneous or incomplete information, leading to inconsistency between studies and hindering study comparison and replication. It is important to note that these studies often face technical and usability challenges frequently not reported, resulting in the acquisition of sub-optimal data sets.

Encouraging data and source code sharing across research groups would enable the development of a common methodology and would allow the replication and aggregation of results across studies. The Wearables for Epilepsy And Research (WEAR) International Study Group has joined forces from four international study groups and has agreed, as a first objective, to identify a set of methodology standards encompassing study design, data acquisition, and reporting to guide research on wearable devices for seizure detection. In this rapidly evolving field, we believe that a framework of methodology standards could guarantee that optimal, accurate, and consistent data are collected, that studies are generalizable, and that results could be compared, replicated, and validated.

Key points

- The Wearables for Epilepsy And Research (WEAR) International Study Group identified a set of methodology standards to guide research on wearable devices for seizure detection.
- Seven major essential components of the experimental design were identified and discussed.
- A framework of methodology standards could promote generalizability and replication of studies and data sharing.

2 | METHODS

An international consortium of experts from diverse fields including clinical research, engineering, computer science, and data analytics was formed at the beginning of 2020. The consortium brought together four major research centers (Mayo Clinic Rochester (MCR), Boston Children's Hospital (BCH), King's College London (KCL), and Medical Center – University of Freiburg (UKF)) that have conducted dedicated studies assessing the usefulness of wearable devices for seizure detection.

The study protocols and practical experience acquired during the development of these studies were discussed and analyzed during bi-weekly virtual meetings to identify commonalities (Figure 1), strengths, and weaknesses. Seven major essential components of the experimental design were identified: (1) description of study aims, (2) policies and agreements, (3) study population, (4) data collection and technical infrastructure, (5) devices, (6) reporting results, and (7) data sharing.

Each of the seven components was selected in turn as the major topic of a virtual meeting. During the meeting, the first authors of this work assumed the role of facilitators and stimulated an open discussion based on the experience from each research center. The major points were then summarized and shared for approval with all the coauthors and finally elaborated into a document including consensus recommendations.

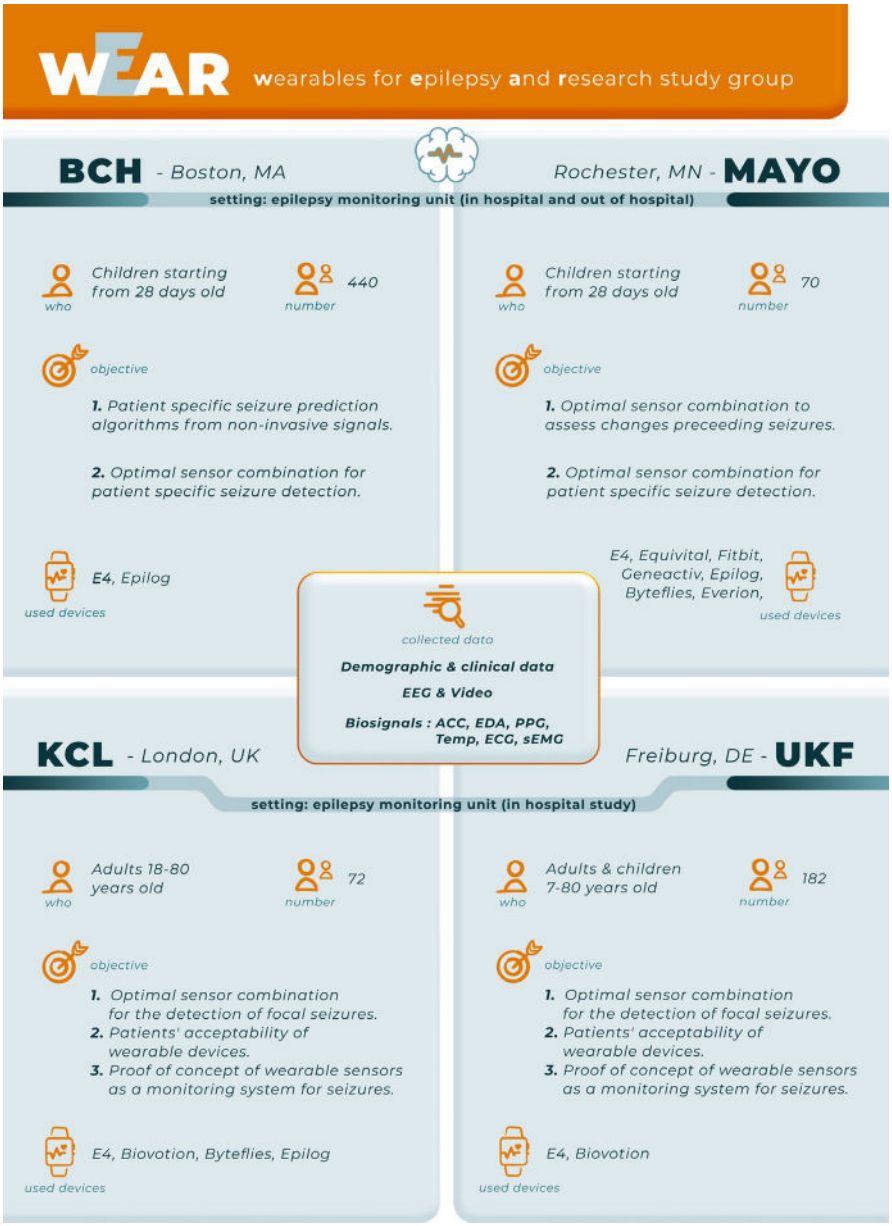

FIGURE 1 Characteristics of the studies across the different centers

3 | RESULTS

3.1 | Identification of study aims

The definition of study aims and related methods determine the patient selection, device choice, data annotations, curation, and data analysis, and should be clearly stated early in the study development process. Seizure detection may serve many different purposes, from closed-loop treatment of acute seizures and impending status epilepticus,[8,9] to retrospective assessment of clinical seizure burden and assessment of the risk of sudden unexpected death in epilepsy (SUDEP), as well as the clinical device or medication trial evaluation. Given the unreliability of self-reported seizure diaries,[10–12] an accurate seizure detection device could be used to optimize medical treatment, avoiding undertreatment due to unreported seizures, and minimizing unnecessary side-effects due to seizure over-reporting. An accurate seizure detection device could also provide objective seizure statistics in clinical trials of new antiepileptic drugs and other epilepsy treatments, which currently depend entirely on patient self-reported seizure diaries.[13] Offline detection could contribute to the diagnosis of nonepileptic paroxysmal events, from psychogenic seizures[14–17] to cardiogenic events. Device performance needs to be proven more accurate than self-reported seizure diaries to potentially improve clinical practice. Seizure detection devices may also be studied for their potential to measure disease severity, for example, associated with SUDEP risk. Ictal autonomic changes,[18] ictal surface electromyography patterns,[19] post-ictal immobility,[20] and post-ictal central apnea[21] are

all potentially measurable by wearable devices and are associated with post-ictal generalized electroencephalography (EEG) suppression (PGES), a risk factor for SUDEP.

The particular seizure semiology types targeted in a study may affect the study design, device choice, and data annotation protocols. Generalized tonic-clonic seizures and focal motor seizures with limb involvement may require movement or electromyography (EMG) sensor devices and may prompt placement of devices on the body segment with greatest ictal movements, whereas nonmotor seizure types like focal impaired awareness seizures may require devices that sense autonomic biomarkers such as electrodermal activity (EDA) or heart rate (HR)/photoplethysmography (PPG), or a combination of all these. Detection of daytime seizures requires wearable devices to be mobile and to be robust to patient movement, whereas devices for detection of nocturnal seizures may be stationary and attached to the patient[22,23] or the bed,[24,25] or a camera may be pointed at the patient from a fixed location.[26] EEG is often the most versatile signal in seizure detection, and mobile EEG-based systems (scalp, ear, or sub-scalp) may be able to detect a wide array of seizure types.[6,27–29] Device acceptability and adherence by patients are essential in seizure detection, and device studies should include assessment of acceptability in the overall study aims.[1]

3.2 | Policies and agreements

The process to obtain ethical approval from the institutional review board (IRB) may be time-consuming and requires careful planning. Essential steps include delineating a clear research plan, and developing the study protocol, but also seeking agreements with device manufacturers, interacting with hospital authorities, and arranging monitoring plans.

3.2.1 | Informed consent

The process of obtaining informed consent is regulated by principles embodied in the current biomedical research on human subjects,[30] which also considers the needs of vulnerable populations (eg, children, cognitively impaired individuals, and unconscious patients).[31] Comprehensive information must be provided to enable people to voluntarily decide whether or not to participate in a research study and is essential for valid informed consent as defined by the Guidelines for Good Clinical Practice.[30] Despite the low invasiveness of wearable devices, studies involving wearable devices are subject to these regulations, and in particular the transfer and sharing of anonymized data with other groups requires approval. It is important to include an "opt-out" strategy to guarantee the right to autonomy to those participants who prefer to not share data. In particular, sharing anonymized data internationally can be heavily regulated and may require specific consent by the research subject. Moreover, from the point of view of researchers, offering study participants the option to actively disagree with data sharing is preferred over offering an "opt-in," as the intent is to share as much data with other researchers as possible. Opt-in and opt-out policies, also called nudges, have the tendency to promote one choice in favor of the other, while still keeping this intervention easy to avoid.[32] Of course, this will also need to conform to local data protection regulations.

3.2.2 | Interaction with regulatory authorities and adherence to hospital policies

Each center must be guided by its country's local policies and regulations, and additional approvals may be needed when testing devices without existing Conformité Européenne (CE) or US Food and Drug Administration (FDA) approvals. Such studies may be considered clinical trials or performance evaluation studies, requiring additional documentation and in some cases authorization by government regulatory bodies. The rules vary in different countries, and this generates disparities in how devices can be tested and scientific data acquired.

Another important consideration is the security rules governing the computer network infrastructure in the hospital environment. Hospitals regulate and limit access to internal networks to protect sensitive data, and specific approvals are often required to use existing wireless connections or create new networks.

Data safety and protection are important considerations, especially with the European Union's (EU's) General Data Protection Regulation (GDPR) governing data collection and transfer inside the EU and with international collaborators. All clinical institutions based within the EU must follow these rules, whether collecting data or receiving data from partners outside the EU.

3.3 | Study population

Selecting the study population to appropriately address the research question is crucial in study design. In particular, it is important to match the subject characteristics, epilepsy type, or seizure semiology in the study cohort to the goals of the study. We developed prospective cohort studies in which patients with a diagnosis of epilepsy were asked to wear one or more wearable devices. Study

participants were recruited when they presented for epilepsy care or in specific follow-up settings, such as the EMU.

3.3.1 | Inclusion and exclusion criteria

As physiological responses and signal alterations during epileptic seizures may vary across age groups, the inclusion of participants of different ages needs to be taken into account. For example, in our studies, the age of study participants ranged between 28 days (BCH) and 80 years (KCL). Moreover, at the stage of protocol development, it is important to identify those comorbidities that may interfere with study adherence or with data collection and quality. Patients with conditions impeding the ability to participate (cognitive, psychiatric, acutely ill), to wear the device (skin conditions), or with frequent vigorous involuntary movements (eg, chorea, athetosis) were excluded from our studies.

3.3.2 | Data collected

Baseline characteristics of the included participants allow the population under study to be better characterized, the results obtained to be understood and contextualized, and for generalizability of the data to be discussed. For all our study participants, data collected during the study period included basic demographic characteristics including age and gender; clinical information; and seizure characteristics including etiology, localization, type, onset, and frequency of seizures and medications.

While in the EMU, patients were monitored for seizures, which were recorded along with the sensor data from the wearables.

3.4 | Data collection and technical infrastructure

3.4.1 | Video EEG recordings and seizure annotation

Recording data continuously over days with the support of video-EEG is essential to capture an adequate number of events and to reliably identify and characterize seizures through a gold standard.

In our studies, as part of the clinical workup, patients were admitted to the EMU and connected via scalp electrodes to an EEG monitoring system within view of a video camera. The length of stay in the EMU varied based on the patient's clinical care. The majority of adult patients were admitted for a 5- to 10-day stay, with overall shorter durations for children. Some centers (MCR) also included ambulatory patients undergoing home video telemetry (HVT) or patients undergoing intracranial EEG monitoring.

Trained personnel are needed to perform standard video-EEG monitoring, including electrode placement according to the 10–20 international system, and to maintain high-quality recordings. EEG recordings were fully reviewed, and seizure onset and offset were annotated, in addition to supporting information including seizure semiology and ictal focus (as reported in Appendix S1). Centers collaborating in a multi-center clinical study (UKF, KCL) jointly developed and adhered to a review and annotation protocol specifying reviewing terminology and methodology to guarantee consistency in reporting clinical phenomena across patients. This included, for example, definitions of autonomic features such as tachycardia, which is ambiguously defined in epilepsy-related literature; determination of duration of impaired awareness, which is not always actively tested for; and an agreement on how to consistently store this information in a shared database for collaboration. The labeled video-EEG recordings were then transferred to a secure server for storage and analysis, and seizure onset and offset times were applied to the simultaneously collected wearable recordings.

3.4.2 | Wearable data collection and device integration

Data collection with wearables is generally done in one of two approaches: offline collection, where the data are stored locally on the device and then downloaded at a later time, or online collection, where the data are streamed continually via a wireless connection to an external device.

During the online collection, the wearable device usually has a much shorter battery life, since wireless data transmission adds significantly to the overall energy consumption. However, the maximum recording time in the offline collection is constrained by the internal storage capacity of the device. Furthermore, the data must be manually downloaded from the device, potentially requiring regular patient participation.

During online collection, this process can be automated, at the expense of potential for data loss due to connection problems. An added benefit to data streaming is the possibility of live data processing and visualization, allowing caretakers and study personnel to evaluate data as it comes in. Live data streaming is also a key requirement for any intervention or alarm system not directly built into the wearable device.

For our studies, we used both methods in our data collection efforts. MCR and BCH used the offline method with their devices, recording to the local device storage for up to 2 days at a time and then exchanging devices to ensure uninterrupted recording. Devices with stored data were connected to a clinic computer via USB cable, and through an application provided by the device manufacturer, the data were then downloaded off the device and uploaded to third-party cloud storage. The raw data were then downloaded via a website listing all uploaded recordings.

Conversely, at KCL and UKF, online data streaming was used. The wearable devices were constantly connected to a companion device via Bluetooth, and a custom-built Android application was used to receive the raw data directly from the wearable device and upload it to a data storage server on the clinic premises (Figure 2). All components of this system like the Android app and the server framework are open-source software available on GitHub.[33] Wearable devices were exchanged twice per day, in the morning and evening, to allow for battery charging given the shorter battery life in streaming mode. We also had frequent problems with the devices' Bluetooth connectivity. The wearables often disconnected from the companion device, either due to the patient walking out of range or due to other, sometimes unexplained reasons. This would lead to frequent and extensive data loss (see Measures of Data Completeness section), especially if the wearable device did not offer an on-device data buffer or automatic reconnect to the companion device.

3.4.3 | Synchronization between wearable and video-EEG data

Time synchronization between an external device and the video-EEG is particularly important in the field of epilepsy research. The clinical seizure onset, used as the ground truth in developing models for seizure detection and prediction, can often be pinpointed with sub-second precision by clinical experts. Thus synchronizing the internal time of the wearable device to the time of the video-EEG system is essential for data analysis. Furthermore, depending on the specific device used, internal inaccuracies can cause small shifts in the timekeeping between individual biosignal data streams.

There are two principal ways of achieving synchronization between a wearable device and a video-EEG system. The most accurate and technically more advanced way is to directly and precisely adjust the on-device timekeeping of the wearables to the time used in the clinical video-EEG system, for example, by some wireless connection. This will give millisecond synchronization between the two time bases, but may require some technical set-up beforehand, and it might not even be available as an option if the wearable device does not support this operation. The second way of achieving synchronization is through the study staff, who can manually induce a visible and recognizable change in the wearable's recorded signals while also showing this actionn on the video or EEG signal. Alternatively, an artifact or label can be placed simultaneously during the device and EEG recording, and then be confirmed by EEG, as some standard video-EEG systems suffer from an occasional minor desynchronization of the EEG and video. The data streams can then be synchronized retrospectively by adjusting the wearable data timestamps to align the events with the video-EEG. Although the data streams can be synchronized to sub-second precision with this method, it requires manual modification of the data.

Both methods are susceptible to the internal drift of timekeeping in the wearable, caused by inaccuracies in the real-time-clock circuits in these devices. This drift can accumulate over time, up to several seconds of inaccuracy over several hours of recording. Therefore, it is advisable to repeat the synchronization process periodically during the recording. The automated method is more suitable

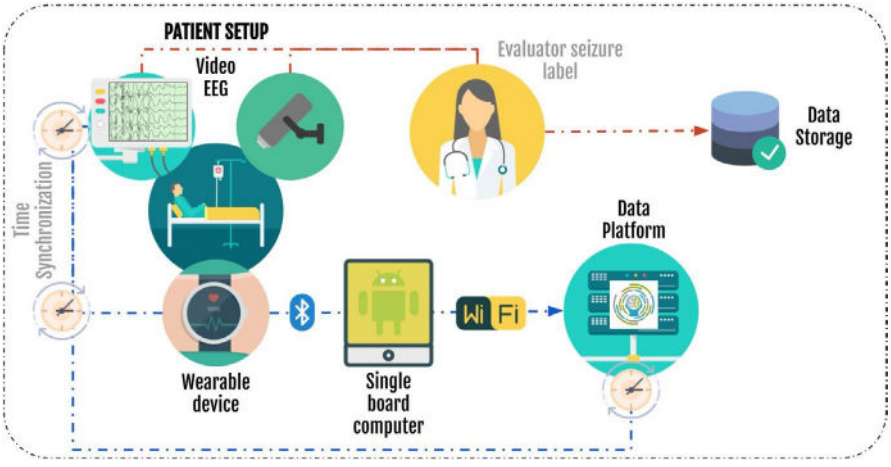

FIGURE 2 Setup of the technical environment for in-hospital studies on wearable devices for seizure detection (setting epilepsy monitoring unit)

for this, as the synchronization could be triggered, for example, every few minutes. Another method to deal with drifting timestamps directly is to measure individual calibration parameters for each device that is used in a study. Thereby, the precise sampling rate for a device is found by a calibration procedure, to a degree of accuracy that allows for a later recalibration of the timestamps in the recorded signals. Synchronizing the wearable data with the video-EEG system can enable integration of both into a common data viewer, which facilitates a better understanding of abstract wearable data in the context of the actual clinical setting.

In our studies, we have used both methods to varying degrees of success. MCR used the manual approach in combination with sample rate calibration, making use of the accelerometer (ACC) signal the device records to register the patient's movements. Whenever the device was exchanged for battery charging and data download, the study personnel shook the device for a few seconds in front of the camera of the video-EEG system, resulting in a series of distinct spikes in the ACC signal. These could then be used to synchronize wearable data signals with the shaking motion in the video signal, and to confirm the accuracy of the recalibrated timestamps. BCH also used a manual approach to synchronize the device and video-EEG recordings. Before putting the device on the patient, the research personnel simultaneously triggered the E4 button to create an event mark in the wearable data signal, and the event marker button of the video-EEG system. This is done because of the video-EEG camera, prompting the EEG technician to also mark on the video-EEG that a wearable device recording has started. Whenever the device is removed from the patient, the same procedure is repeated. Later, the marked events in each of the data streams can be aligned to attain synchronization. At the two other sites, a more automated method was employed. Because the devices are programmed to synchronize themselves to the clock of the companion Android device whenever they are first connected via Bluetooth, it is only necessary to synchronize the Android devices to the video-EEG time base, which can be done easily via a network connection. Consequently, each center synchronized their wearable devices each time they were exchanged for battery charging, with intervals ranging from twice per day to every 2 days.

3.5 | Devices

Across the four study sites, we used several different wearable devices for data collection from study participants. Among the most prominent devices were *Biovotion's Everion*, *IMEC's sensor bracelet*, *Epitel's Epilog*, *Byteflies' Dots*, and *Empatica's E4*. The data quality and patient acceptance of some of these devices have been reported previously.[34–36] In our studies, only the *Empatica E4* device was used at all of the four sites.

Wearable devices of the types used in clinical epilepsy studies can be categorized in various ways, all of which should factor into the decision when selecting a device for a study:

1. Medical certification: Wearables, in general, are employed in many different fields beyond medicine, so for use in studies as described here, the certification as a medical device can be an important factor. *IMEC's sensor bracelet* for example, as a prototype device, is not certified as a medical device, whereas the *Empatica E4* has a European CE class IIa certification as a medical device.
2. Modalities: Different devices record different biosignals at different sample rates, so an informed decision needs to be made about exactly what is needed to facilitate the outcomes of the given study. Multimodal devices are generally regarded as more effective and versatile,[37–39] whereas a device recording only one modality may be sufficient for a very specific task. *Epitel's Epilog*, for example, provides only a single-channel EEG signal, whereas the *Empatica E4* records three-axis accelerometry (ACC) at a sampling rate of 32 Hz, EDA at 4 Hz, skin temperature at 4 Hz, and PPG at 64 Hz, which is processed on the device to a filtered blood volume pulse signal.
3. Data mode: Generally, there are two modes in data collection, online or offline, as described further in Section 3.4.2. In most cases a given device supports only one mode for recording data, so either the study protocol needs to be adjusted to support the device, or an appropriate device needs to be chosen for an already established study protocol. The online streaming mode is a requirement for systems that should include any kind of alarm or intervention. *Byteflies' Dots*, for example, support only offline recordings, whereas the *Empatica E4* has the option to employ both methods.
4. Battery life: With current battery technology, the battery life of smaller devices or those that employ online raw data streaming is usually measured in hours, whereas somewhat larger devices with offline, on-device data storage can sometimes be active for days without the need to recharge. *IMEC's sensor bracelet*, for example, has a typical battery life of seven days, while the *Empatica E4* has a manufacturer-specified battery life of 24–48 h, although in our studies we often observed empty batteries after half that time. This was in part due to the shorter battery lifespan when the E4 is used in streaming mode.

5. Device placement: Wearables are usually placed at a specific part of the body, which can be influenced by the study protocol and should be considered when choosing a device. In turn, the placement of the device may affect both the sensitivity and specificity of a prospective seizure detector. The *Empatica E4*, for example, is worn around the wrist, while the *Byteflies' Dots* can be attached to any part of the body by use of an adhesive patch.

Furthermore, research-grade devices, such as the *Empatica E4*, often have several advantages and disadvantages over other devices that are marketed directly to consumer end-users. Access to raw data is a necessity for many research studies, but something that consumer-grade devices and services rarely provide. Furthermore, companies offering research-grade devices are sometimes open to collaboration, for example, by supporting researchers with specialized knowledge of device capabilities.

On the other hand, research devices are often more expensive than their consumer counterparts and can be more cumbersome and uncomfortable to wear, since the device's aesthetic design is not a priority for the manufacturer. In our studies, however, we consistently got more positive feedback from patients on the wearability of the *Empatica E4*, as compared to the *Biovotion Everion*, which is a device on the market for regular consumers to buy.[34]

3.6 | Reporting results

3.6.1 | Usability challenges and users' perspectives

Wearable devices are progressively becoming an available and innovative tool for continuous seizure monitoring. People living with epilepsy have expressed interest in using new technologies in their daily life[40] and several unmet needs might be addressed by adopting digital solutions into health care services.[40,41] The research focused on hypothetical scenarios has highlighted that motivation to use wearables is not driven only by the accuracy and reliability of the device performance. A design incorporating comfort and ease of use is also essential for acceptance and long-term adoption.[34] Obtaining feedback from patients after direct experience wearing devices is the only way to fully understand the practical and technical issues faced.[42] However, feedback on device comfort and usability has been collected only sporadically in previous studies, and information reflecting the direct experience of study participants is missing. The limited number of investigations exploring users' direct experience reported improvement of quality of life for both patients and caregivers,[42] a benefit to autonomy and increasing independence in activities,[23,42] as well as a generally good evaluation of technology usability.[7,23] Barriers to use, as reported, include discomfort in wearing the device during sleep, technical difficulties, and the burden of adding another aspect to routine epilepsy care.[42] In addition to the key requirements of a reliable and accurate performance, a successful integration of digital solutions into a patient pathway requires acceptance of the technology. The latter is required for long-term engagement, which is essential to a good detection performance, and to optimize the benefit to the patient. To identify and avoid potential barriers to a long-term engagement with the technology, patients' views and needs need to inform the development of the technology and study design, and users' opinions on usability and acceptability should be collected systematically. Methods to obtain feedback from study participants range from a focus group (useful during the first stages to guide research questions and research development), interviews (at set time points during the study, for example, study end or in case of participants withdrawal), collection of participants' observations (any time in the course of the study), and questionnaires (allowing direct comparisons between subjects and the identification of subject-related factors influencing their experience in the study). At KCL and UKF, participants' experience and the perceived ease of use and comfort of the technology were assessed at the end of the study using a self-administered Technology Acceptance Model Fast Form (TAM-FF).[43] Moreover, in a group of study participants, the experience of wearing multimodal sensor devices was also assessed via semi-structured interviews covering questions on their experiences and concerns using the wearables, their thoughts about ambulatory use of wearables, and their reasons for stopping to wear the device if applicable.[44]

3.6.2 | Data quality and completeness

The value of collected data can be assessed by data completeness and data quality. Data quality measures evaluate properties like the noisiness, accuracy, and potential information gain of the data, whereas data completeness gauges data loss during recording. In the context of exploratory research, both data quality and completeness are of utmost importance, and several steps were taken to reflect that need. Collecting raw, unprocessed data from wearable devices, forgoing any internal processing, can facilitate the assessment of data quality. This will give a complete and clear picture of the suitability of the device for the task at hand. Furthermore, sharing data across different research sites and groups can enhance the value of the data set, advance the understanding of data complexities,

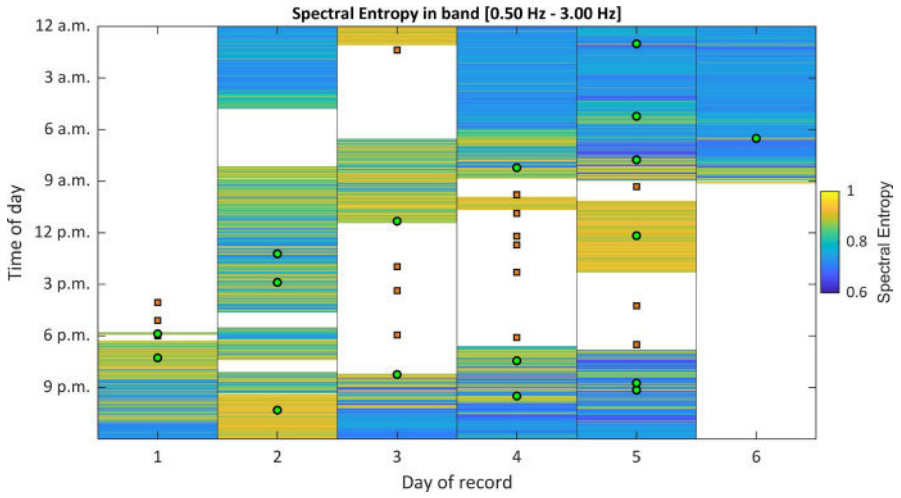

FIGURE 3 Spectral entropy of the blood volume pulse signal of the E4 device during the recording of a single patient recruited at the UKF site. The signal gives an idea of the quality of the BVP data for heart rate calculation; blue means the signal is of higher quality, that is, contains fewer artifacts. The gaps show times when there was a problem with the recording and no BVP signal was present. The green circles mark seizures during which wearable data were recorded; the red squares mark seizures where no data were available

and facilitate scientific exploration of the data. Another important tool to effectively assess data value is the use of data dashboards. These dashboards usually take the form of a website that aggregates data completeness and quality measures as new data come in and displays it with intuitive charts and tables. Especially in the context of live data streaming, they can monitor system function and user adherence.

Measures of data completeness

Gaps in the data can be caused by several issues related to data collection. A common cause of data loss is the limited battery life of the device. Charging the battery takes time (typically hours), and even if a second device is used to replace the one with an empty battery, this creates a small but noticeable gap in the recording.

Another common source of data loss is connection problems with wireless data streaming. With a Bluetooth connection, the maximum range between the wearable and its companion device is usually 10 m within the same room. Whenever a wearable device is disconnected, it needs to automatically reconnect and transfer any buffered data, otherwise, any data collected while the device is disconnected will be lost. The *Empatica E4* device used in our studies does not implement such functionality in Bluetooth streaming mode. When this device loses its Bluetooth connection it powers off completely and must be manually restarted for the connection to be re-established. This led to significant data loss in the two studies that used the device in streaming mode.

Finally, data gaps can be introduced by human interaction. Taking the device off for a short time, for example, during a shower or neuroimaging, causes several minutes of data loss. Incorrect operation of the device can also lead to lost data. Some of these causes for data incompleteness can be avoided, for example, by the careful preparation of a study protocol detailing proper usage of the device. Others are inevitable, and some gaps in the data set are unavoidable.

In the studies presented here, the data loss varied with the different sites and their respective data-collection protocols. The data coverage presented here was determined in two different categories: the overall data coverage and the number of missed seizures during each patient's recording. Data coverage is computed by counting the number of samples per modality collected from the wearable device, per patient, and dividing by the number of expected samples given the recording time. This method potentially undercounts the data loss because it ignores any loss when the device is not worn. The same methodology is applied to counting missed seizures, that is, only seizures that happened within the start and end of the recording are counted toward the expected amount.

Among patients who wore the *Empatica E4* device in the UKF and KCL sites, the data coverage was only 52% and 40%, respectively, with the loss of data attributed in large part to the live data streaming functionality, but it was also affected by device recharging and the patients bathing during their in-hospital stay. Conversely, in the two other sites that used the offline recording mode of the device, the data loss was <10%.

Figure 3 highlights data completeness considerations for a patient in the UKF cohort. Two gaps in the data as well as missing seizures can be seen in this example. The

recording for this patient is missing approximately 30% of its expected data, and 17 of 33 seizures were missed as a result.

Measures of data quality

Data quality is an important property for any scientific data set. The quality of data collected from wearable devices can be degraded by several issues related to the sensor hardware and application. Any physical sensor has mechanical or electrical imperfections that can produce sensor noise. Imperfections can also be caused by external stimuli introducing an unwanted variation of the data, a so-called artifact. These artifacts can sometimes be corrected after data collection, but other times completely disrupt the underlying data. A relevant example is motion artifacts in the PPG data collected from the *Empatica E4* device. A PPG sensor works by measuring the light reflection of the skin, which changes with blood volume, that is, with each pulse. However, light from an external source, for example, sunlight, can compromise the reflective value measured by the photodiode of the sensor. If the device was not tightly fastened around the wrist, the actual blood volume pulse data for that segment is not recoverable. This can be a significant problem for data collection during physical activity or during convulsive seizures. Another source of poor data quality is inaccuracies introduced by the sensor, for example, caused by faulty or deteriorated hardware.

To measure data quality, numerous methods can be found in existing literature, and are usually specific to a certain sensor modality.[4,15,35,45,46] Discussing the pros and cons of specific data quality indices is out of the scope of this report; instead, we give an example of a data quality measure applied to the wearable device recordings of a single patient from the Freiburg cohort. Figure 3 shows a plot of the spectral entropy calculated from the *Empatica E4's* BVP signal collected from a single patient at the UKF site. Spectral entropy gives an idea of the quality of the BVP data for heart rate calculation. Lower values mean the signal is of higher quality, that is, contains fewer artifacts. The signal quality is generally higher overnight when patients rest. During the daytime, patients tend to be more active, and the signal is prone to movement artifacts, represented by higher values in spectral entropy.

3.6.3 | Seizure detection evaluation

The common goal of most epilepsy-related studies with wearable devices is to achieve robust seizure detection and prediction. Reporting results of evaluations of these methodologies is an important part of any study and should follow a defined protocol and refer to specific standards.[4] Sensitivity and specificity are the two cornerstones of reporting results of binary classification, especially in a medical context. Sensitivity, also often called recall in a machine learning context, measures the proportion of true positives (TPs) to all expected positive instances. It must always be reported as a study outcome, because for seizure detection it directly describes the respective methodology's ability to robustly detect seizures from the wearable data. On the other hand, specificity measures the proportion of true negatives to all expected negative instances. To report measures like specificity based on negative instances in the context of wearable seizure detection, the data stream must be segmented into equal-sized portions of either the seizure or nonseizure class. Due to the large data imbalance of these two classes that is usually observed in epilepsy studies, with sometimes multiple days of nonseizure portions in the data interrupted only by often minute-long seizure portions, the specificity measure is artificially boosted to consistently report values of >98%, even if there are many false positives (FPs). Because of this lack of informative value, specificity is often omitted when reporting on the performance of a seizure detection system. Instead, the false alarm rate (FAR) or positive predictive value (PPV) can be reported as inverse measures of a seizure detection system's ability to correctly identify nonseizure periods. The FAR reports the number of false detections over a certain timespan, often chosen as a day (24 h). For example, a FAR of 0.5/24 h would mean that the system, on average, produces one false alarm every 2 days. FAR can also be separately reported for daytime and night-time periods, as false nocturnal alarms may be much more disrupting and less acceptable to patients and caregivers. The PPV, also often called precision in a machine learning context, is the proportion of TPs to all detected positives. It thus gives a measure of the number of FPs to TPs, for example, a PPV of 50% would describe a result of the same number of FPs as there are TPs. At least one of these measures, FAR and PPV, must always be reported as a study outcome, to properly convey the number of FPs a system is likely to produce. One possible way to counteract false alarms could be to ask patients to perform specific periodic movements like brushing their teeth. These movements, recorded by the wearable, could then be used to adjust a model to be more robust against nonepileptic activities of daily living.

To visualize the results of an evaluation of a seizure detection model, or to compare the performance of multiple models, the receiver-operating characteristic (ROC) curve is a widely used and accepted tool. It plots the probability of detection against the probability of false alarm (FP and TP rates) of a binary classifier at varied discrimination thresholds. Thereby, it visualizes the trade-off a model

makes between detecting true events and producing false alarms.

For all of these measures, there is generally a trade-off between reporting them on a per-patient basis and taking the mean across patients or reporting the overall value over the whole applicable data set. Optimally, both aggregations should be reported in the outcomes of a study, as they often both provide slightly different but equally worthwhile conclusions.

3.7 | Data sharing

Free and open platforms for sharing data and facilitating collaboration are important research resources. Open databases (from which data can be explored and downloaded), and novel algorithms and source code (that can be shared between collaborators) are important tools in neuroscience projects. Different examples can be cited, including openneuro.org, epilepsyecosystem.org, ieeg.org, and physionet.org. Research teams should be encouraged to share raw data and data processing scripts to allow replication and validation of results. Online competitions have also been successful at fostering the development of high-performance seizure detection and forecasting algorithms based on intracranial EEG,[47–49] and similar results with wearable data could be expected. Moreover, sharing data, methodologies, and results with partner organizations, like other clinical centers or even device manufacturers, can be greatly beneficial to the advancement not only of the research field of wearable seizure detection in general but also the usability and development of new devices and technologies. This includes the sharing of raw data collected during studies, as well as any scripts and software used in the processing and scientific analysis of the data, especially concerning seizure detection. To facilitate data sharing, a standardized data format and schema should be adopted to prevent the use of different and potentially not compatible formats. This would promote the replication and validation of results in a collaborative manner and encourage the aggregation of data across research groups. In the long run, giving valuable and constructive feedback on device performance and usability to manufacturers, and sharing these experiences with other organizations, could be a huge boon to possibilities in the treatment of epilepsy, and patients with epilepsy by extension. To accommodate and facilitate the aforementioned sharing of data and experiences, however, a need for open and structured systems and forums exists. Here, clinicians, researchers, developers, manufacturers, as well as patients could collaborate and contribute to the advancement of the treatment of epilepsy with the use of wearable devices. And although strict data protection rules like the EU's GDPR may hinder collaboration, the authors express their hope that these restrictions will not jeopardize the major benefits of sharing pseudonymized or anonymized data for research progress and patient care.

4 | CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE STUDIES

This manuscript provides a methodological framework that could guide future research on seizure detection devices, as well as practical information from the experience of our groups. We identified seven essential components of the experimental design for which we would like to provide specific recommendations (Table 1).

In 2021, a joint working group between the International League Against Epilepsy and International Federation of Clinical Neurophysiology (ILAE-IFCN) has endorsed a clinical practices guideline, most importantly listing several specific areas, concerning automated seizure detection using wearable devices, that are still in need of further research and development.[50] This article can be seen as a first step toward the practical implementation of studies aimed at addressing this need. Specifically for phase 0–3 studies,[4] the recommendations compiled here can serve as a basis to develop detailed and robust study protocols.

We believe that sharing the experience of multiple international centers could help clarify the often intricate process underlying research in this field. The collection of more homogeneous data has the potential to enable the development of collaborations across research groups and to boost clinical advancement of these devices.

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TABLE 1 Recommendations for studies using wearable devices for seizure detection

1. Study aims
• Main study aims should be identified early as they influence most aspects of study design • Seizure detection purposes include closed-loop treatment of acute seizures and/or status epilepticus, assessment of seizure burden and severity (toward sudden unexpected death in epilepsy [SUDEP] and seizure recurrence risk stratification), and clinical trial outcome evaluation, among others • The type of seizures to be investigated should be defined from the start, as this informs the required biosignals and therefore limits the choice of wearable devices to be used
2. Policies and Agreements
• Early involvement of the key figures is recommended to guarantee study feasibility. This includes device manufacturers, hospital authorities, IT departments, and study participants through informed consent • Participants' approval for future sharing of the anonymized data set should be obtained
3. Study population
• Clinical and demographic information needs to be collected and reported to clearly define the population addressed • General seizure semiology should be specified, for example, motor vs non-motor seizures • Seizure annotation protocols and accurate description of the ictal phenomenology are of paramount importance to allow accurate data analysis and comparisons, especially when video cannot be shared for privacy reasons • Mutual agreements between centers on standardized definitions and methodology should be made in multi-center studies
4. Data collection and technical infrastructure
• A clear description of the data collection procedures is paramount to understand the results obtained, and to uncover and potentially mitigate technical challenges • Considerable thought must be put into the device integration and synchronization effort. Wearable devices have an inherent time drift and need to be regularly synchronized with the video-EEG system. A Bluetooth connection for data collection can have some benefits such as live data availability, but they should be weighed against the greater potential for data loss and reduced battery life • Having a battery recharging plan ahead of the study may prevent the loss of data given wearable devices' short battery life • To accurately collect seizure details under the supervision of an epileptologist is fundamental to subsequently design high-quality studies • Some type of dashboard or other means of viewing collected data should be used to keep an overview of the data set and patient adherence. Furthermore, joint visualization of wearable and video-EEG data can be beneficial for understanding the context of information gained from the wearable device
5. Devices
• Choosing the preferred device for a study can be difficult; If it is possible to practically test multiple devices before the study starts, this will remove a considerable amount of uncertainty during the actual data collection • Both ease of technical integration as well as data quality and quantity measures should be considered and tested thoroughly beforehand • Depending on study aims and research goals, a choice between research devices or even prototypes, and consumer devices must be made. Research devices usually provide easier raw data access while consumer devices usually offer better usability and acceptability among patients • Study aims and research goals should influence the choice of a device; for research exclusively on convulsive seizures a mono-modal device may be sufficient, but research on other seizure types may require multi-modal data
6. Reporting results
• Users' opinions on usability and acceptability should be collected and reported • Data quality and quantity should be evaluated and reported systematically • The treatment of artifacts and poor-quality data should follow an objective protocol, which should be reported in the study
7. Data sharing
• Raw data and data processing scripts should be shared to allow replication, validation, and aggregation of data across research groups

CONFLICTS OF INTEREST

MR is supported by the National Institute for Health Research (NIHR) Biomedical Research Centre at the South London and Maudsley Hospital; and the Medical Research Council (MRC) Centre for Neurodevelopmental Disorders (MR/N026063/1). TL serves on the Council and as Past President of the American Clinical Neurophysiology Society, as founder and consortium principal investigator (PI) of the pediatric status epilepticus research group (pSERG), as an Associate Editor for Wyllie's Treatment of Epilepsy 6th edition and 7th editions, and as a member of the New Onset Refractory Status Epilepticus (NORSE) Institute, and Critical Care EEG Monitoring Research Consortium (CCEMRC). He served as Associate Editor of *Seizure*, and served on the Laboratory Accreditation Board for Long Term (Epilepsy and Intensive Care Unit) Monitoring in the past. He is part of patent applications to detect and predict clinical outcomes, and to detect, manage, diagnose, and treat neurological conditions, epilepsy, and seizures. TL is co-inventor of the TriVox Health technology, and TL and Boston Children's Hospital might receive financial benefits from this technology in the form of compensation in the future. He received research support from the Epilepsy Research Fund, National Institutes of Health (NIH), the Epilepsy Foundation of America, the Epilepsy Therapy Project, and the Pediatric Epilepsy Research Foundation, and

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section.

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