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SPECIAL REPORT

Report of the ILAE SUDEP Task Force on national recommendations and practices around the world regarding the use of wearable seizure detection devices: A global survey

Johan Zelano[1,2,3] | **Sandor Beniczky**[4,5,6] | **Philippe Ryvlin**[7] | **Rainer Surges**[8] | **Torbjörn Tomson**[9] | **the ILAE SUDEP Task Force**

[1]Institute of Neuroscience and Physiology, Department of Clinical Neuroscience, Sahlgrenska Academy, University of Gothenburg, Gothenburg, Sweden

[2]Department of Neurology, Sahlgrenska University Hospital, Gothenburg, Sweden

[3]Wallenberg Center of Molecular and Translational Medicine, University of Gothenburg, Gothenburg, Sweden

[4]Department of Clinical Neurophysiology, Danish Epilepsy Center, Dianalund, Denmark

[5]Department of Clinical Neurophysiology, Aarhus University Hospital, Aarhus, Denmark

[6]Department of Clinical Medicine, Aarhus University, Aarhusm, Denmark

[7]Department of Clinical Neurosciences, Lausanne University Hospital (CHUV), Lausanne, Switzerland

[8]Department of Epileptology, University Hospital Bonn, Bonn, Germany

[9]Department of Clinical Neuroscience, Karolinska Institutet, Stockholm, Sweden

Correspondence
Rainer Surges, Department of Epileptology, University Hospital Bonn, Venusberg-Campus 1, 53127 Bonn, Germany.
Email: rainer.surges@ukbonn.de

Abstract

Wearable seizure detection devices have the potential to address unmet needs of people with epilepsy. A recently published evidence-based international guideline recommends using such devices for safety indications in patients with tonic–clonic seizures (TCS). Our objective was to map existing guidelines and clinical practices at national level. We conducted a survey of the International League Against Epilepsy (ILAE) chapters regarding national recommendations and practical circumstances for prescribing seizure detection devices, and another survey of physicians in the ILAE constituency anywhere in the world, concerning their views and practices regarding recommendations for and prescription of such devices. Fifty-eight ILAE chapters (response rate 48%) and 157 physicians completed the surveys. More than two-thirds of responding countries do not have standards on wearables for seizure detection, although they indicated availability of such devices. The most often recognized indications were safety and objective seizure quantification. In nearly half of countries, devices are purchased by patients or caregivers, and either lack a uniform reimbursement scheme (41%) or patients pay the full cost for the device (48%). Tonic–clonic seizure frequency, nocturnal seizures, and previous injuries were the main factors that influenced the surveyed physicians to recommend wearable seizure detection devices. Our results document the need to implement international clinical practice guidelines at national level and to consider these when deciding upon reimbursement of seizure detection devices.

KEYWORDS

epilepsy, injuries, monitoring, patients' safety

Study group members are presented in Appendix.

1 | INTRODUCTION

Epilepsy is a serious condition associated with significant risks. Seizures may cause physical injuries[1] and in the worst case be fatal such as in refractory status epilepticus or sudden unexpected death in epilepsy (SUDEP).[2] Common sense and current data suggest that the risk of such serious outcomes is increased if seizures are unnoticed and the seizing patient unattended, thus preventing timely interventions aimed at mitigating or reverting the chain of seizure-induced events.[2,3] The fact that many seizures are unnoticed, often occurring during nighttime or in other situations when patients are without supervision, is a major safety concern. In addition, the fact that our conventional methods of monitoring the effectiveness of the prescribed treatment, such as seizure diaries, are unreliable, is a major challenge in efforts to optimize the treatment.

In recent years, there has been a rapid development of different wearable seizure detection devices. The devices are designed to detect biological signals indicating a seizure. Existing devices are based on the use of different biosignals such as electroencephalography (EEG), electrocardiogram (EKG), electromyography (EMG), accelerometry, electrodermal activity, and more.[4] Specific patterns in such signals can be used to detect and record seizures but also to activate a response such as an intervention from a caregiver.

Standards have been developed for the testing and clinical validation of seizure detection devices.[5] These have been used by the "Wearables for Epilepsy and Research International Study group" in their proposal for methodology standards to guide research on wearable devices for seizure detection.[5,6] The International League Against Epilepsy (ILAE) and the International Federation of Clinical Neurophysiology jointly published a clinical practice guideline on the use of such devices.[7] It was concluded that wearable devices can be effective in detecting generalized tonic–clonic and focal to bilateral tonic–clonic seizures and can be recommended for such use for safety indications, although with "weak or conditional" level of evidence.[7] However, the extent to which detection alarms result in meaningful clinical outcomes was deemed uncertain.[7] Nevertheless, two devices have been approved by the Federal Drug Administration for detection of generalized tonic–clonic seizures (GTCS) during the resting state (Table 1).[4] Four additional devices have been approved in the European Union for tonic–clonic seizures or for absences (Table 1).[8]

Given the lack of conclusive data regarding the impact of seizure detection devices on important clinical outcomes and general shortage of data to build on for evidence-based guidelines, we were interested to find out current national recommendations and practices regarding the use of such devices globally. Thus we conducted surveys to explore national recommendations and availability for prescribing seizure detection devices. In addition to ILAE chapters, we surveyed practices and opinions of individual physicians engaged in the care of persons with epilepsy regarding the use of seizure detection devices.

Key Points

- Survey of ILAE chapters and physicians in the ILAE on national recommendations and practices regarding seizure detection devices.
- More than two-thirds of responding countries do not have national standards on seizure detection devices.
- The most important indications were safety and objective seizure quantification.
- Tonic–clonic seizures, nocturnal seizures, and previous injuries were the important factors for physicians to recommend wearable devices.

2 | METHODS

2.1 | Survey

This study used two different questionnaires designed by the authors of this report and distributed through the Webropol tool (licence University of Gothenburg, Webropol Sverige AB, Linköping). The survey was developed by TT, and tested by JZ, SB, and PR in multiple iterations. The first survey, targeting ILAE Chapters, enquired about the existence of national guidelines, availability, reimbursement, and principles for prescribing or recommending seizure detection devices in different countries (see Appendix S1 for full questionnaire).

A second questionnaire was directed to physicians in the ILAE constituency anywhere in the world with the aim to survey their views and practices regarding recommendations for and prescription of seizure detection devices. This second survey consisted first of some basic questions regarding the respondents' country, workplace, and main area of work (pediatric or adult care, epileptology or general neurology) followed by a few general questions regarding guidelines and the respondents' views on main indications for seizure detection devices. A second part of this questionnaire consisted of representative series of case vignettes, covering the most typical use case

TABLE 1 Seizure detection devices approved by the US Food and Drug Administration (FDA) and by the European Union (EU).

Device	Modality	Seizure type	Approval as medical device/region
Empatica Embrace	Multimodal (accelerometry, EDA)	GTCS[a]	FDA Class II/USA CE Class IIa/EU
Brain Sentinel SPEAC	Surface EMG	GTCS[a]	FDA Class II/USA
EDDI SeizureLink	Surface EMG	GTCS[a]	CE Class I/EU
Danish Care EpiCare	Accelerometry	GTCS[a]	CE Class I/EU
NightWatch	Multimodal (accelerometry, HR)	GTCS[a]	CE Class I/EU
Epihunter	Surface EEG with dry electrodes; AI algorithm	Absence	CE class I/EU

Abbreviations: EDA, electrodermal activity; EMG, electromyography; HR, heart rate.

[a]Including Generalized Tonic–Clonic Seizures as well as Focal To Bilateral Tonic–Clonic Seizures.

scenarios, to which the respondent was asked whether the use of a seizure detection device was justified. Separate sets of case vignettes were used for physicians in adult and pediatric care, respectively (see Appendix S2 for full questionnaire).

2.2 | Data collection

Invitations to participate in the chapter survey were sent to contact persons of each ILAE Chapter in May 2022 with a reminder in June and a deadline for responding on July 15, 2022. Invitation to participate in this second survey was announced in the ILAE Newsletters of September, October, and November 2022, and on the ILAE website. The deadline for completing this survey was December 31, 2022. The survey to the ILAE chapter survey received 63 responses from 58 chapters. Duplicates were merged with preference for the most complete response.

2.3 | Statistical analysis

The responses were analyzed with descriptive statistics using SPSS for Mac 29 (IBM Corp).

3 | RESULTS

3.1 | Survey to ILAE chapters

Out of 123 contacted ILAE chapters, 58 (48%) responded to the survey. The response was provided by one person, presumably the person designated to respond to the invitation sent to the chapter ILAE contact person. The corresponding countries are indicated in Figure 1, which also marks the chapters reporting having national guidelines for recommendation of seizure detection devices. Out of all responding chapters, 40 (69%) reported not having guidelines or recommendations on the use and indications for seizure detection devices, 15 (24%) reported using guidelines that have been developed internationally, and 4 (7%) reported having guidelines developed specifically for their country.

Chapters were also asked about available types of seizure detection devices and indications (Table 2). Most chapter respondents reported having devices targeting motor symptoms, followed by EEG, autonomic symptoms/skin conduction, and a combination of motor activity and autonomic symptoms. Regarding possible indications for seizure detection devices, similar proportions of chapter respondents answered safety for patients with tonic–clonic seizures, safety for any patient with epilepsy, objective seizure quantification, differential diagnosis, and family request. Half of the chapter respondents noted that there was no consensus on indications for seizure detection devices.

In many countries (49%), devices are purchased by patients or caregivers independently of healthcare personnel, in 31% they are prescribed, and in 20% of the responding chapters by a combination of the two. Most countries either lack uniform reimbursement scheme (41%) or patients pay the full cost for the device (48%). Some reimbursement is provided in 11% of the responding countries of which two countries (4%) report full reimbursement provided that the device is prescribed by a healthcare professional.

3.2 | Survey to individual physicians

In total 157 physicians responded to the survey (Table 3). The majority of responders were from a European country and hospital-based epileptologists. Only 63 (40%) of the respondents claimed that they

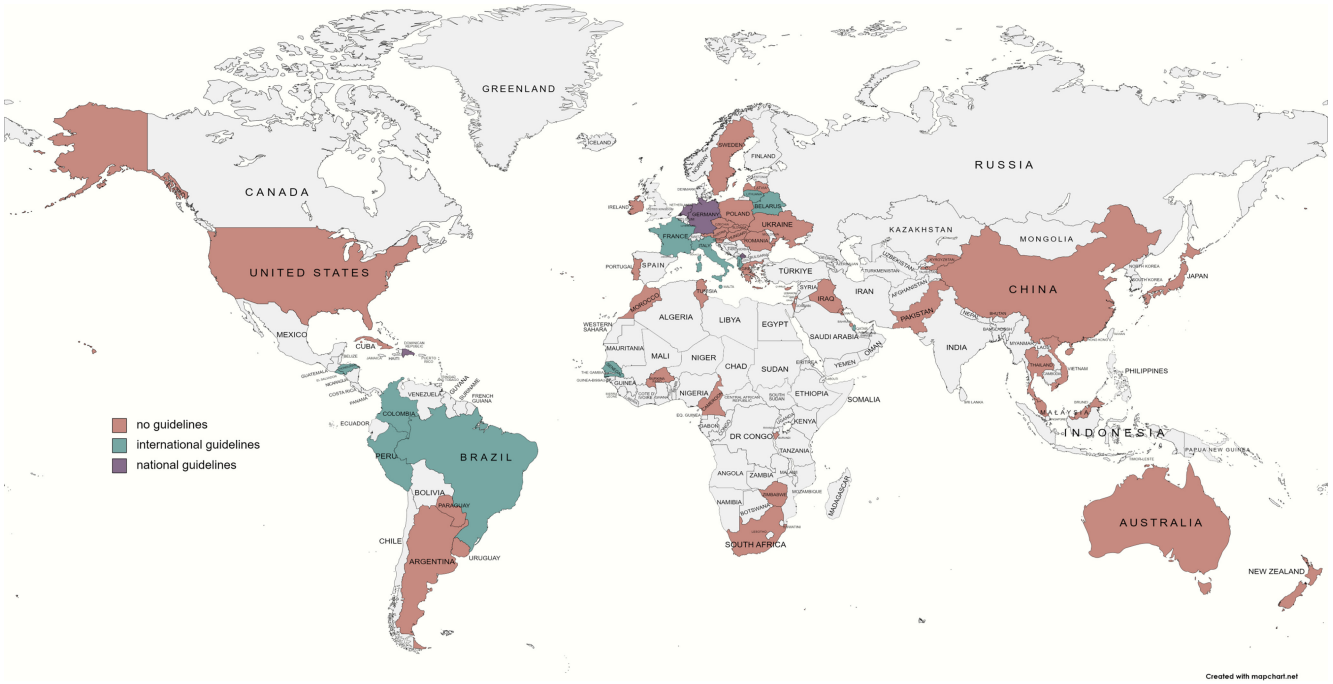

FIGURE 1 Map of guideline availability in countries whose chapters responded to the survey.

TABLE 2 Summary of chapter responses to questions about biosignals targeted by available devices, and the main indications.

Chapter answers on available devices and main indications			
	Available	***n* (responses)**	**%**
Biosignal targeted			
Motor symptom	19	50	38
EEG	15	50	30
Autonomic symptom/ skin conduction	13	50	26
Combination of motor and autonomic symptoms	14	50	28
Indication			
Safety for patient with TCS	15	56	27
Safety for any patient	15	56	27
Objective seizure quantification	14	56	25
Differential diagnosis	12	56	21
Demand from family	11	56	20
There is no consensus on indication	28	56	50

were aware of any clinical practice guideline on seizure detection devices. When asked about which factors influenced their decision to prescribe seizure detection devices, availability of a caregiver responding to the alarm, frequency of TCS, nocturnal seizures, and previous injury were considered very important by most responders (Figure 2).

3.3 | Case vignettes

We finally explored the importance of different clinical factors in a series of case vignettes, by letting responders indicate at what seizure frequency they would prescribe a seizure detection device (Figure 3). The pediatric cases were shown to responders indicating that they worked with children and the adult cases for those working with adults.

In a child with focal unaware seizures, more responders were inclined to prescribe a seizure detection device in the presence of nocturnal seizures or previous injuries. Without any of these aggravating factors, half of the responders indicated that they would never prescribe a seizure detection device. If the case included TCS, only 20% indicated that they would never prescribe a seizure detection device.

A similar pattern emerged for adult cases. In an adult with focal unaware seizures, 60% indicated that they would never prescribe a seizure detection device, but this was reduced to <30% in the presence of previous injury. If the same circumstances applied to a case of TCS, <15% of responders answered that they would never prescribe a seizure detection device. Interestingly, the responses were not that different if the adult case was altered to

indicate a longer response time; that there would be a latency for a caregiver available to intervene of 30 min instead of 5 min.

TABLE 3 Responder characteristics in the survey to individual physicians.

	n	%
Responders individual phycisians		
Epileptologist—Adult	67	43
Epileptologist—Pediatric	32	20
Neurologist—General	16	10
Neuropediatrician	33	21
Pediatrician	8	5
Missing	1	1
Total	157	100
What is your main workplace?		
Hospital	112	71
Outpatient clinic	30	19
Private practice	9	6
Other	6	4
Total	157	100
ILAE chapter		
Africa	2	1
Asia and Oceania	23	15
Eastern Mediterranean	2	1
Europe	97	62
Latin America	14	9
North America	11	7
Country not in ILAE chapter	1	1
Missing	7	4
Total	157	100

4 | DISCUSSION

The ILAE chapter survey clearly demonstrated that most countries who responded to this survey lack guidelines and consensus regarding indications for wearable seizure detection devices and that devices are purchased by the patients who also carry the costs without reimbursement in most countries. For individual physicians, nocturnal seizures and frequency of TCS were the most important individual clinical factors informing the use of seizure detection devices. History of seizure-related injuries and availability of someone able to intervene were also considered important by most respondents, whereas other seizure types than tonic–clonic and patient age were generally considered not relevant for offering seizure detection solutions. These priorities were also largely reflected in the responses to the case vignettes (Figure 3). For patients with more than 1 GTCS/month, most physicians would consider prescribing devices regardless of patient age, history of nocturnal seizures, or injuries. In contrast, for patients with other seizures (focal unaware), nocturnal pattern and in particular history of seizure-related injuries impacted on physicians' willingness to consider prescribing devices. Among those with frequent GTCS, the time to a potential intervention (5 or 30 min) from a caregiver did not seem to make a difference. Although this may seem surprising, it does not say that responders think that a device would be equally useful in both instances—with a longer latency until the arrival of assistance, the expectations regarding the potential gain with the devices could be the management of injuries rather than prevention of SUDEP.

To our knowledge, this is the first global survey of recommendations and practices regarding wearable seizure

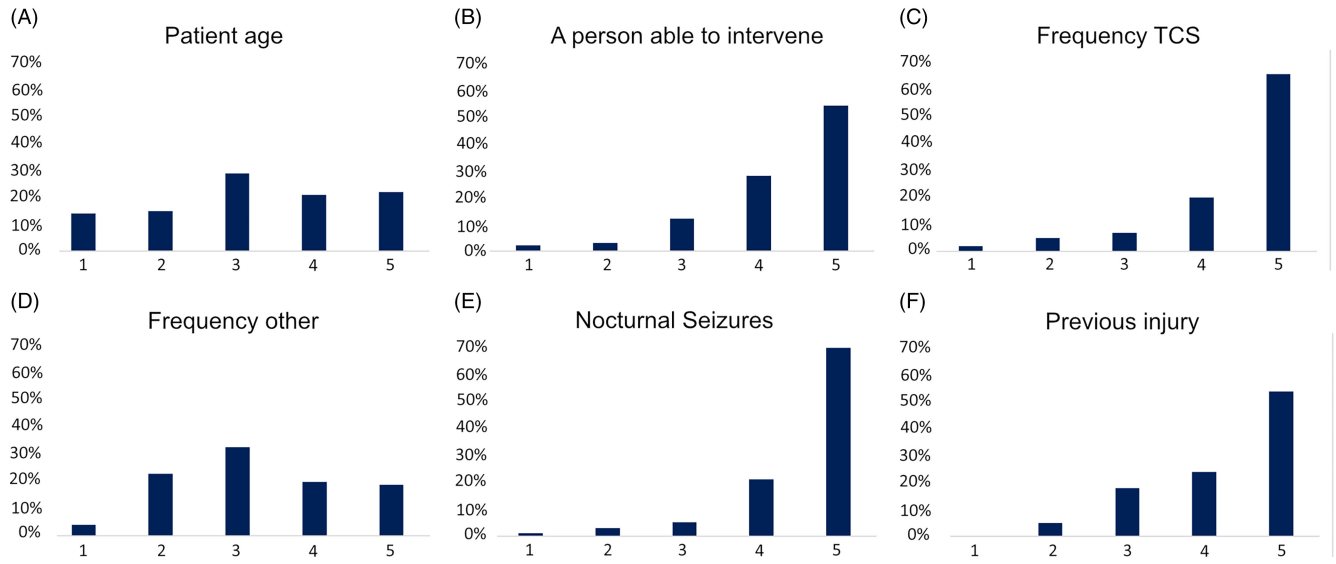

FIGURE 2 Importance of clinical factors in the individual physicians' survey when considering a seizure detection device (scale 1–5, 1 = least important.)

detection devices, but it has some important limitations. First, the response rate was moderate for the chapter survey and low for the survey targeting individual physicians. Second, there was a European dominance in particular in the physician survey. The low number of responses from Africa and Asia may reflect that these devices are not available or approved in these regions but also highlight the need for educational efforts targeting these regions. Another possible explanation for the few responses from these regions is that SUDEP is not considered a major cause of death in low-income countries where other causes such as injuries and drowning may dominate, and the most burning issue is access to medication. Hospital-based epilepsy specialists also dominated among responders, which is expected given that the survey targeted members of the ILAE. Hence, physicians in private practice and outpatient care were not well represented in the survey. It is also very likely that those opting to respond have a special interest in seizure detection devices. Hence, the results may not be representative of opinions of all physicians involved in the management of people with epilepsy, such as general neurologists or pediatricians, but more reflecting the views of physicians with a special interest in epilepsy, which is not necessarily a drawback.

It should also be acknowledged that, while seizure detection devices can be used to obtain an improved basis

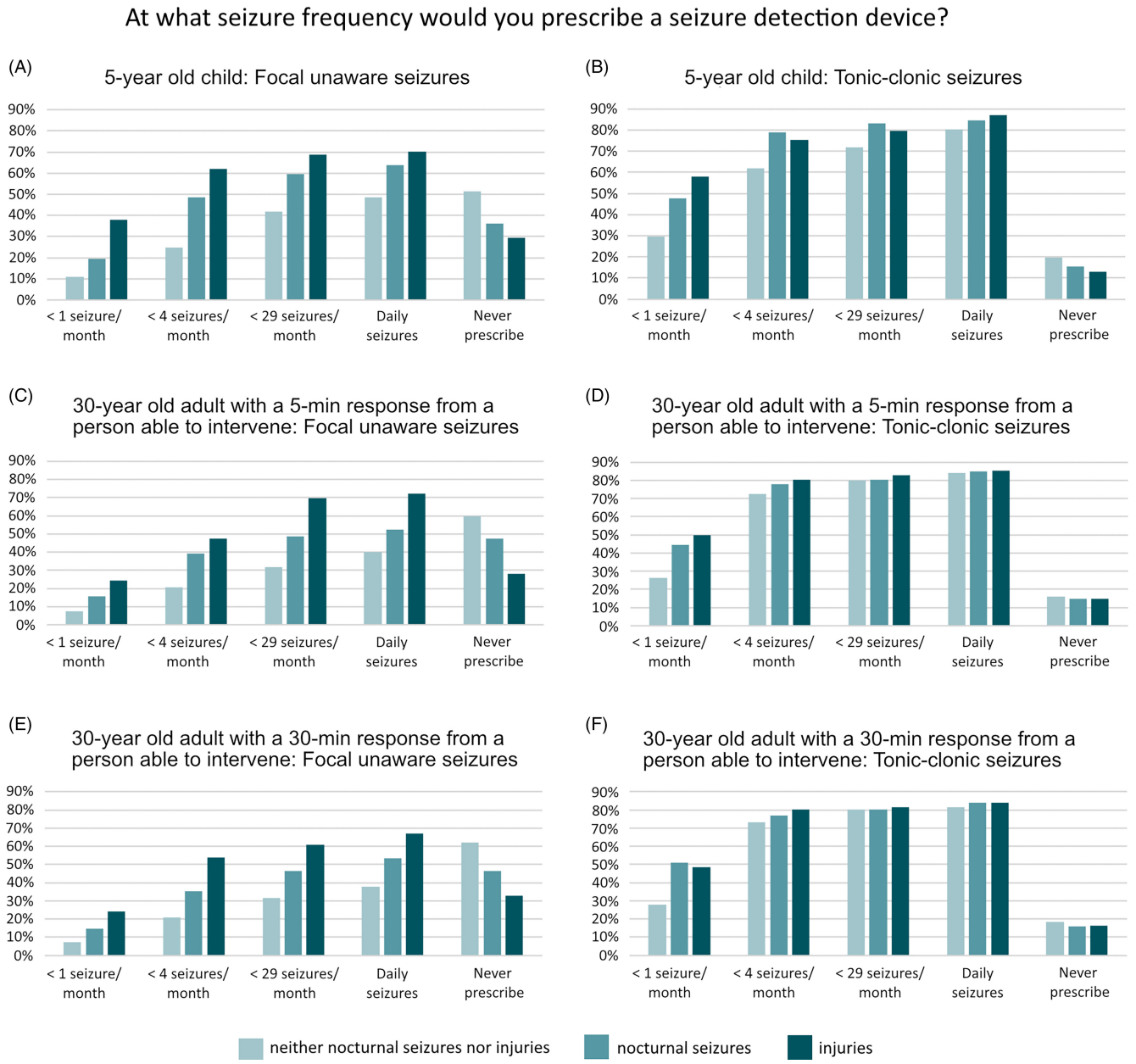

FIGURE 3 Case vignettes and proportion of responders that would prescribe a seizure detection device at different seizure frequencies.

for treatment decisions and not only to facilitate immediate interventions when seizures occur, our survey was designed primarily to assess opinions related to the latter indication. Further, the survey did not include any question about why physicians would opt not to prescribe devices and to what extent this decision related to the performance of the available devices.

For the chapter survey, it should also be acknowledged that we do not know to what extent the response given by the chapter represents an individual's opinion or the impression that the individual has about the prevalent opinion in the chapter.

Another limitation of the current work is that it does not capture the patients' perspectives, experiences, or preferences. This has to be done in separate surveys, but it needs to be kept in mind when interpreting our results. Previous studies have indicated that persons with epilepsy in general are willing to use wearable seizure detection devices, but that their performance in terms of false alarm rates is a major concern.[9]

With the rapid technical development, wearable devices are moving targets. It must be understood that the physicians' replies can only be based on the specific devices that were available in their individual setting at the time of the survey. Nevertheless, there was a reasonable consensus among the responders that high frequency of tonic–clonic seizures is the most important clinical factor for considering a device. This is in line with the ILAE recommendations.[7] While standards for assessment of the technical device performance in terms of sensitivity and false alarm rates have been developed,[6] high-quality studies on the impact of seizure detection devices on important clinical outcomes such as injuries, SUDEP, and other mortality are lacking. Similarly, there is a shortage of studies regarding the impact of seizure detection devices on quality of life for patients and carers. These important gaps probably contribute to the shortage of national recommendations and lack of reimbursement schemes. The knowledge of both the availability and potential benefits of such devices may also be scarce in some regions and countries, prompting dedicated educational activities on the topic by ILAE commissions, task forces and national chapters.

The discrepancy between the rapid technical development of devices and the limited understanding of their impact on important clinical outcomes, calls for new initiatives. While the effect of such devices on monitoring and better control of GTCS may be well assessed in future trials, the challenges of investigating the effectiveness of interventions on rare outcomes such as SUDEP are well known.[10] This should, however, not discourage from the development of studies aiming at analyzing possible effects of use of seizure-detecting devices on the risk of SUDEP, other seizure-related mortality and morbidity including injuries and overall treatment success. Where randomized trials are difficult to perform, observational studies can be considered, and for such studies the establishment of patient registers could become very useful. The generated data could also enable studies of the cost-effectiveness of wearable seizure detection devices facilitating decisions on reimbursement.

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CONFLICT OF INTEREST STATEMENT

PR reports fees provided to his institution by UCB, Livanova, Arvelle pharmaceutical, Angelini pharma, and UNEEG for speaker or adboard activities. RS has received fees as speaker or for serving on the advisory board from Angelini, Arvelle, Bial, Desitin, Eisai, Janssen-Cilag GmbH, LivaNova, LivAssured B.V., Novartis, Precisis GmbH, Rapport Therapeutics, UCB Pharma, UNEEG and Zogenix. TT reports research support to EURAP from Angelini, Accord, Bial, EcuPharm, Glenmark, GSK, UCB, Sanofi, Teva, Zentiva, Jazz/GW, SFGroup, and speakers' honoraria to his institution from Angelini, Eisai, UCB and GSK. JZ reports speaker honoraria from UCB, Eisai, and as employee of his institution (no personal compensation) being investigator in clinical trials sponsored by UCB, Bial, GW Pharma, and SK Life science.

ETHICS APPROVAL

The Swedish Ethics Review Authority waived the need for an ethical approval, and gave an advisory statement that there were no ethical objections to the study (decision number EPM 2022-00876). We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

DISCLAIMER

This report was written by experts selected by the International League Against Epilepsy (ILAE) and was approved for publication by the ILAE. Opinions expressed by the authors, however, do not necessarily represent the policy or position of the ILAE.

ORCID

Johan Zelano https://orcid.org/0000-0001-9445-4545
Sandor Beniczky https://orcid.org/0000-0002-6035-6581
Philippe Ryvlin https://orcid.org/0000-0001-7775-6576
Rainer Surges https://orcid.org/0000-0002-3177-8582
Torbjörn Tomson https://orcid.org/0000-0003-0554-5352

REFERENCES

1. Asadi-Pooya AA, Tomson T. A reappraisal of injuries and accidents in people with epilepsy. Curr Opin Neurol. 2021;34:182–7.
2. Sveinsson O, Andersson T, Mattsson P, Carlsson S, Tomson T. Clinical risk factors in SUDEP: a nationwide population-based case-control study. Neurology. 2020;94:e419–29.
3. Ryvlin P, Nashef L, Lhatoo SD, Bateman LM, Bird J, Bleasel A, et al. Incidence and mechanisms of cardiorespiratory arrests in epilepsy monitoring units (MORTEMUS): a retrospective study. Lancet Neurol. 2013;12:966–77.
4. Esmaeili B, Vieluf S, Dworetzky BA, Reinsberger C. The potential of wearable devices and mobile health applications in the evaluation and treatment of epilepsy. Neurol Clin. 2022;40:729–39.
5. Beniczky S, Ryvlin P. Standards for testing and clinical validation of seizure detection devices. Epilepsia. 2018;59(Suppl 1):9–13.
6. Bruno E, Bottcher S, Viana PF, Amengual-Gual M, Joseph B, Epitashvili N, et al. Wearable devices for seizure detection: practical experiences and recommendations from the Wearables for Epilepsy And Research (WEAR) International Study Group. Epilepsia. 2021;62:2307–21.
7. Beniczky S, Wiebe S, Jeppesen J, Tatum WO, Brazdil M, Wang Y, et al. Automated seizure detection using wearable devices: a clinical practice guideline of the international League Against Epilepsy and the International Federation of Clinical Neurophysiology. Epilepsia. 2021;62:632–46.
8. Bruno E, Viana PF, Sperling MR, Richardson MP. Seizure detection at home: do devices on the market match the needs of people living with epilepsy and their caregivers? Epilepsia. 2020;61(Suppl 1):S11–S24.
9. Bruno E, Simblett S, Lang A, Biondi A, Odoi C, Schulze-Bonhage A, et al. Wearable technology in epilepsy: the views of patients, caregivers, and healthcare professionals. Epilepsy Behav. 2018;85:141–9.
10. Ryvlin P, Ciumas C, Wisniewski I, Beniczky S. Wearable devices for sudden unexpected death in epilepsy prevention. Epilepsia. 2018;59(Suppl 1):61–6.

SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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