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Seizure detection devices: Exploring caregivers' needs and wishes

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ABSTRACT

Introduction: User preferences for seizure detection devices (SDDs) have been previously assessed using surveys and interviews, but these have not addressed the latent needs and wishes. Context mapping is an approach in which designers explore users' dreams and fears to anticipate potential future experiences and optimize the product design.
Methods: A generative group session was held using the context mapping approach. Two types of nocturnal SDD users were included: three professional caregivers at a residential care facility and two informal caregivers of children with refractory epilepsy and learning disabilities. Participants were invited to share their personal SDD experiences and briefed to make their needs and wishes explicit. The audiotaped session was transcribed and analyzed together with the collected material using inductive content analysis. The qualitative data was classified by coding the content, grouping codes into categories and themes, and combining those into general statements (abstraction).
Results: "Trust" emerged as the most important theme, entangling various emotional and practical factors that influence caregiver's trust in a device. Caregivers expressed several factors that could help to gain their trust in an SDD, including integration of different modalities, insight on all parameters overnight, personal adjustment of the algorithm, recommendation by a neurologist, and a set-up period. Needs regarding alerting seemed to differ between the two types of caregivers in our study: professional caregivers preferred to be alerted only for potentially dangerous seizures, whereas informal caregivers emphasized the urge to be alerted for every event, thus indicating the need for personal adjustment of SDD settings.
Conclusion: In this explorative study, we identified several key elements for nocturnal SDD implementation including the importance of gaining trust and the possibility to adjust SDD settings for different types of caregivers.

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1. Introduction

Epilepsy has a major impact on the lives of people and the risks involved pose a heavy burden on people with epilepsy and their caregivers [1]. Epileptic seizures are unpredictable, cause loss of control, and may lead to serious complications, including sudden unexpected death in epilepsy (SUDEP). The most important risk factor for SUDEP is the presence and frequency of convulsive seizures [2]. Sudden unexpected death in epilepsy is predominantly a sleep-related and unwitnessed event [3–5]. Nocturnal supervision may lower the risk of SUDEP [5,6]. Timely alerts by nocturnal seizure detection devices (SDDs) can prevent such complications and, if accurate, may improve a night's rest. Seizure detection devices develop at a fast pace, and designing novel medical products demands critical choices that are partly shaped by personal values [7,8]. Values from designers and physicians may, however, differ from user's preferences. It is therefore important to avoid fixation on pre-set assumptions about the user or the product.

Previous assessments on users' preferences for SDDs indicated preferences for high accuracy, comfortable, wearable, and non-stigmatizing devices [9–16]. These assessments were

predominantly based on surveys and interviews, yet these methods often do not allow for a deeper understanding of user values [8]. Context mapping is a qualitative research method, frequently applied in industrial design, to explore the end user's needs and wishes for a product [8,17]. User's experiences and examples of interactions with the product are shared in a creative group session to clarify the context of the product. These generative sessions can expose latent wishes and enable designers to fit their product into the lives of the users (Fig. 1) [8]. Context mapping has not yet been applied in the development of SDDs, but may help to optimize implementability. This study focused on nocturnal SDDs and defined the end -user as the person who receives the device's alarms and responds to them: caregivers of people with epilepsy. We explored their latent needs and wishes using a context mapping approach.

2. Methods

To better understand the reasoning behind caregivers' preferences for certain nocturnal SDD features, we used a qualitative research method. A context mapping session creates the ideal setting to elicit emotional responses from the participants. Users' memories, experiences, concerns, and feelings surrounding the use of a nocturnal SDD were explored with the aim to create context awareness. The study was reviewed by the Medical Research Ethics Committee Utrecht with a waiver of informed consent.

2.1. Preliminary mapping

To make pre-set assumptions of the authors explicit, three authors (AW, MB, and RT) were invited to make an individual "mind-map" based on the following themes: "nocturnal seizures,""seizure detection," and "trust." They were asked to list all associations with these three words which came to their mind, based on their experiences as a neurologist (RT), researcher (AW), and mother of a child with epilepsy (MB). These words and connections of words from different perspectives were used to create a framework for result analysis.

2.2. Recruitment

We selected two types of caregivers as end users of nocturnal SDDs: (1) professional caregivers, working with people with epilepsy in a residential care facility, institution, or hospital, and (2) informal caregivers, taking care of a person with epilepsy at home. Participants were selected from a residential care facility (professional caregivers) and through patient groups (informal caregivers). We aimed to select four to six participants, with a balanced number of professional and informal caregivers, to create a group large enough to have a broad discussion and small enough to maintain a secured atmosphere for participants to share their thoughts and emotions [8].

2.3. Sensitization

A week prior to the generative session participants received a briefing package, aimed to let their minds wonder on the theme "nocturnal seizure detection." Six different tasks were bundled in a booklet (estimated completion time: two hours) to relive experiences and emotions relating to the monitoring of nocturnal seizures (any type). The following exercises were included:

1) *Describe a typical night when using your SDD on the depicted timeline below. What are you doing and what is happening to your child or client? Express positive and negative feelings you experience during these events.*
2) *Please finish the following sentences: "This is how I feel when... (1). ...I missed a seizure;(2). ...I am awakened by a seizure;(3). ...I am awakened by a false alarm;(4). ...there is no seizure overnight."*
3) *"I am alerted for a nocturnal seizure by means of: ..." Please place a picture or drawing of the devices or methods you use to detect a seizure during the night.*
4) *How do these devices or methods help you during the night? Please describe positive and negative aspects.*
5) *Please finish the following sentences: "I trust a detection method if..." and "I don't trust a method if..."*
6) *"My dream device in 2030 will look like this:..." Please describe different aspects of your ideal device and feel free to draw the device.*

2.4. Session with caregivers

The participants were invited for a group session to share their experiences and to map their insights and feelings. The session consisted of three parts and was guided by one designer (TS) with considerable experience in context mapping sessions, who stimulated

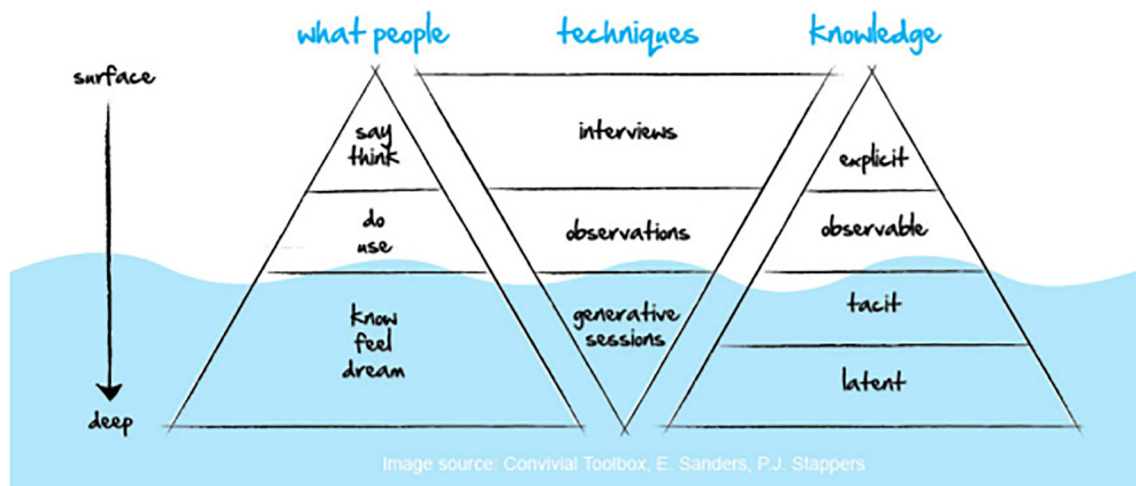**Fig. 1. Latent needs model.** The latent needs model represents a schematic overview of different layers of user's experiences and emotions, and research methods to gain information from these layers. *Image source: Sleeswijk Visser F, Stappers PJ, van der Lugt R, Sanders EBN. Context mapping: Experiences from practice. CoDesign: International Journal of CoCreation in Design and Arts. 2005;1(2):119–149. Reprinted with permission.*

expression of feelings and group discussion, while another author (AW) took notes for the analysis. The total session was also audiotaped.

Participants were first asked to present one exercise from the sensitizing package to the whole group. The second part consisted of context mapping. Participants received a large paper with four timelines of different nights: (1) with a seizure; (2) without a seizure; (3) with a false alarm; and (4) with a missed seizure. Different colorful tools were available, together with stimulating words and pictures associated with nocturnal seizures and seizure detection in its broadest sense, to express experiences and emotions. In the last exercise, participants were asked to express their needs and dreams by crafting their ideal SDD from creative tools for future use in 2030 (Fig. 2).

2.5. Analysis

The full audiotaped session was transcribed and analyzed using inductive content analysis [8,18]. Two authors (AW and TS) reviewed the whole content for interesting quotes and insights. These annotations (highlighted quotes and insights) were openly coded to describe all aspects of the content. The generated codes were clustered using constant comparison and organized to find specific patterns [18]. Lastly, clustered codes were grouped into different themes to create a structured overview of the content. Themes and related quotations described in Results section were selected by the first author (AW), verified by the second author (TS), and checked for relevance by all authors. Each quotation was coded referring to the different caregivers: P1-3 for the professional caregivers and I1-2 for the informal caregivers. The final thematic overview was compared to the thematic structure assembled from the author's preliminary mapping to see if both structures overlapped. In case of great differences, the authors would go back to the raw material to see if important insights had been overlooked.

3. Results

3.1. Participants

We selected five participants for the generative session, including three professional caregivers and two informal caregivers. Professional caregivers worked at "Stichting Epilepsie Instellingen Nederland," a large residential care facility for people (children and adults) with epilepsy and learning disabilities. They had five to 37 years of work experience in night shifts and all of them had broad experience with different types of nocturnal SDDs. One informal caregiver was mother of a five-year-old child with refractory epilepsy and learning disabilities living at home and had experience with a multimodal nocturnal SDD and a baby monitor with audio and camera facilities. The other informal caregiver was mother of a seven-year-old child with refractory epilepsy and learning disabilities. She had no experience with nocturnal SDDs, her child slept in a bed next to hers, and she used a listening device with camera before she went to bed herself.

3.2. Generative session

The generative session lasted 3h and 45m, and the transcript included 73 pages with 35.055 words. After data analysis, different major themes emerged, based on the number of actual quotations of the theme and associated quotes. Table 1 represents an overview of the most quoted themes in the database.

The most quoted major themes and related quotations are described in more detail below. The major themes could be grouped into different needs for design and usage of an SDD and wishes related to emotions and purpose of a device. Table 2

Table 1
Overview of most quoted needs and wishes.

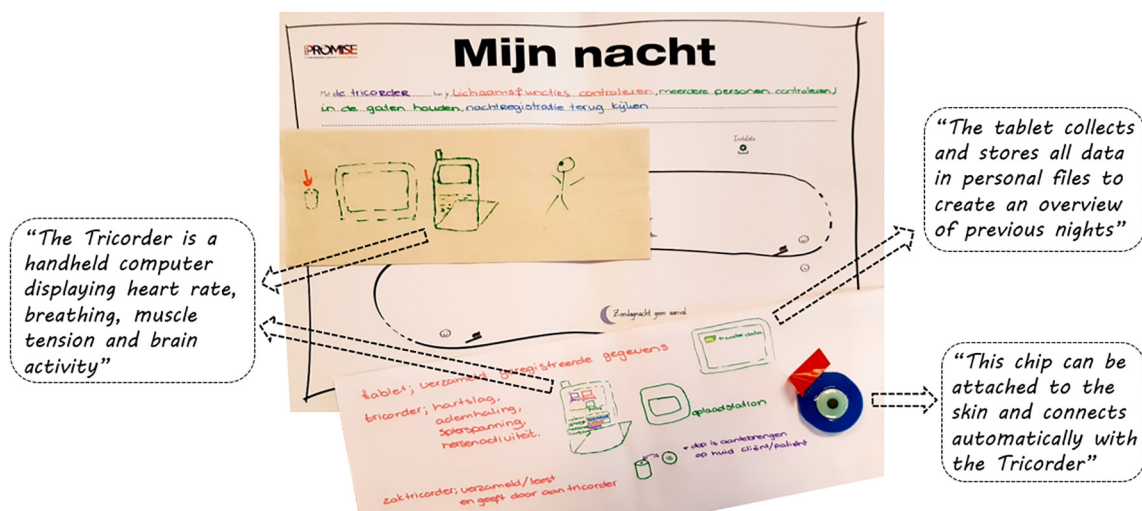| Needs and wishes		No. of quotes
Needs	Alarm	68
	- including false alarm	*20*
	Camera/video/screen	49
Wishes		
Emotions	Trust	51
	Fear	15
	Worry	9
	Sense of control	6
Purpose of device	Night's rest	15
	Safety	9

Fig. 2. Example 'dream device in 2030' as drafted by one of the informal caregivers. Explanation during the interview: "The 'Tricorder' is inspired by the movie Star Trek, where the characters walk around with handheld computers. They are able to scan and read your whole body. In future, it would be ideal if you can walk around with one small computer in your hand, your pocket or attached to your trousers. You stick a chip like this (blue patch in the picture) on the person with epilepsy and the Tricorder automatically connects. The Tricorder shows heart rate, breathing, muscle tension, and brain activity, for multiple people at the same time. The data is clustered per person and you can easily switch between different people. All data is collected and stored on one tablet, so you can easily get an overview of the previous nights and weeks per person, to recognize patterns over time. The Tricorder also generates alarms. These can be personalized on the specific features you want to be alerted for. Every person has his/her own alarm melody, so you can recognize who you are alerted for."

represents an overview of these needs and wishes and distinctive examples of caregiver's preferences. The thematic overview generated from the inductive content analysis had great overlap with the structure created from preliminary mapping by the authors, indicating that the most important themes were included.

3.2.1. Trust

"Trust" emerged as the most coded theme and the most quoted wish from the caregivers. There was overall agreement that "technology can fail" and the best monitoring system would be continuous observation by a person. Participants realized that this would not be feasible in practice, as parents need to sleep and professional caregivers have multiple clients to look after. Handing over the care of your child to a device has everything to do with trust. During the session, different factors were mentioned on how to gain trust in an SDD. First, participants stressed the importance of integrating different modalities into one device to increase the trustworthiness. Secondly, the better the insight on all of these parameters overnight, the more they would trust it. Participants expressed their preferences for personal adjustment of the device's algorithm. A recommendation of a professional (e.g., neurologist) would also make it easier to trust a device. Participants preferred a set-up period over "plug-and-play," as feedback of SDD performance following such period in a hospital/institution or at home could increase trust. The informal caregivers agreed that hospitalization of their child, even for a longer period, would outweigh the trust gained by this test period.

"[…] and when I see that he has found his peace again and falls asleep, I sometimes return to my own bed reluctantly, because I just want to stay with him sometimes to give him the feeling that there's someone around for him, but also for my own sense of security. As long as you're with me, I won't miss a thing. But on the other hand, when I lay there, he will have a good night's rest, but I won't." (I1)

"And the next best thing was… I would take a woollen thread, put one end around my pink and the other end around the client's because then you are always there. But that's not reality." (P3)

"For adults I would opt for an automatic system for emergency medication, but when I think about such system for my own child,

I would say: "no, that's too risky." I would prefer to control the situation myself […] especially with children, they are much more vulnerable than adults. I would like to have some human control." (I2)

"[…] Yes, that's how it currently works with EEGs and MRI scans, we now fully trust the information generated from these systems. The same applies for detection devices, we have to learn to trust them. If a device, for example, measures low muscle tension and you see for yourself that the muscle tension is low, you will feel that the device works. This way we learn to trust a device." (I2)

3.2.2. Alerting

The most quoted need by the participants was "alarm." During the session, there was no clear consensus on what the caregivers wanted to be alerted for. From the professional caregivers' perspective, it is crucial to be timely alerted for potentially dangerous seizures. As these caregivers have to care for multiple people with epilepsy at the same time, it is inconvenient to be alerted for every minor seizure. Conversely, one of the professionals gave an example of a client who experienced mainly minor seizures, but could not fall asleep afterward without someone comforting him. One of the informal caregivers indicated that she wanted to be informed about every seizure including the minor ones. She wanted to be alerted even for the minor seizures as she noted that they have a great impact on the child's behavior the next day especially if these events cluster. During the group discussion, it was suggested that different types of alarms for different seizure types could address these different needs for alerting. For example, major seizures could set off loud buzzers, while minor seizures could be alerted by more quiet notifications. Personal adjustment of the alarm settings may provide a solution to meet the differences in caregiver's needs.

All participants preferred having false alarms rather than missing potentially dangerous seizures. At the same time, they also expressed that the number of false alarms should be limited and this limit seemed to vary between caregivers. The tolerability of false alarms in professional caregivers seemed to be higher than the tolerability in parents who are alerted during their sleep. The informal caregivers emphasized the importance of a good night's rest to provide good care the next day, while the professional

Table 2
Overview of major themes in needs and wishes.

	Themes	Examples of caregiver's preferences
Needs		
Design	Materialization	- Portable alarm station, not audible to the child
		- Comfortable device with freedom of movement
	Algorithm	- Automatic categorization of different types of seizures
		- Personalization of device algorithm (by caregiver's feedback or automatically)
	User Interface	- Different types of alarms for minor or major seizures
		- Clear overview of the past nights
Usage	Practice	- - Facilitates to check upon the child/client without disturbing him/her
	Purchase	- Recommended by the attending physician/neurologist
	Settings	- A monitored set-up period supervised by a physician
		- Options for personalization of settings
Wishes		
Emotions	Trust	- Multimodal devices are believed to be more trustworthy
		- Insight on different parameters overnight may increase trust
		- Personalization of the device's algorithm can help to gain trust
		- Recommendation by a neurologist may increase trust
		- Confirmation of accurate alerting during a set-up period may build trust
	Fear	- A reliable SDD may decrease the fear of losing your child
	Worry	- More information may also provoke worrying thoughts
	Control	- Feeling in control by anticipating the possible effects of one or multiple seizures
Purpose of device	Good care	- Providing a restful night for people with epilepsy and their caregivers
	Insight	- Providing an overview of seizure activity, so one can anticipate certain changes in behavior.
	Safety	- Too many false alarms can cause 'alarm fatigue'; one can become less alert
	Independence	- A reliable SDD may facilitate the transition from dependence to independence

caregivers did not mind the false alarms keeping them busy at night, as long as it did not jeopardize the care for the other clients.

> "A quiet notification will provide enough information. [. . .] Because when I receive three messages in one hour about minor seizures, I already know what is going to happen. I know my child. I don't have to call anyone. I immediately rush to the place where my child is, to get her, because this means trouble." (I2)
> "Silent seizures are the most tricky ones, the ones we do not notice and provoke respiratory arrest. Those are the seizures you want to be alerted for at all times. That would make work a little less stressful. [. . .] A silent seizure, and that I will find my client dead in bed, I hope that's something I will never have to experience. [. . .] So, I don't mind running for nothing." (P1)

3.2.3. Video feedback

The third most quoted theme was the need for video feedback; both professional and informal caregivers emphasized the importance of live video tracings. Video footage would allow monitoring from a distance without having to disturb the person with epilepsy at every false alarm. Invasion of privacy was also discussed, but all caregivers agreed that the benefits of video monitoring outweigh these adverse effects. One professional caregiver mentioned the risk of missing a seizure when one has to review multiple video tracings.

> "[. . .] Sense of urgency or I check the camera first and then I run. It is actually so, when I check the video, I immediately see that he has a convulsive seizure and if this is the case, I will start running. Sometimes I think: 'just run'." (I1)
> "For me, the disadvantage of video monitoring (we have 18 videos in building 9) is that you miss events because of the large amount of videos. Because you have to watch the screen with all the videos and the screen with the acoustic detection system at the same time. So that's a lot to focus on at once." (P2)

4. Discussion

Throughout the design process of medical devices, it is important to appreciate the users' perspective. The context mapping approach enabled us to explore caregivers' latent needs and wishes for nocturnal SDD design. In comparison with quantitative research (e.g., questionnaires), this method allows for deeper understanding of values, by providing experiences and examples to clarify the context and expose latent desires. Context mapping thereby complements other qualitative research (e.g., interviews) by truly revealing deeper emotions and believes.

We identified "trust" as a fundamental wish from caregivers and discovered several factors helping to gain their trust in a device, includingintegration of different modalities, insight on all parameters overnight, personal adjustment of the algorithm, recommendation by a neurologist and a set-up period. Needs for alerting seemed to contrast between professional and informal caregivers, thus underscoring the importance of the possibility to adjust device settings.

Our study is limited by the small number of participants. Small sample sizes are inevitable using context mapping methods, as larger groups will prevent to create the secured atmosphere that is needed to explore deeper thoughts and emotions [8]. Our study was particularly targeted to professional and informal caregivers of people with refractory epilepsy and learning disabilities and did not include other professionals (neurologists, epileptologists) or people with epilepsy, thus limiting the generalizability of our results to other user groups. Specific experiences of caregivers

(age of the person with epilepsy, seizure type and frequency, severity of learning disabilities, and SDD usage) may have biased the results.

We identified three other qualitative studies on user preferences for SDDs [9,10,19]. In accordance with our findings, a value-sensitive design study identified trust as one of the most relevant values for caregivers and professionals [9]. Our data complement these results by providing several approaches on how to gain trust in an SDD. A recent qualitative interview study indicated the readiness of people with epilepsy to use wearable SDDs on the assumption that they would provide an existential and comforting experience [19]. This underscores the importance to engage users in the designing process in order to ensure an optimal level of acceptability and usability. Semi-structured interviews of people with epilepsy following a short trial with wearables in the hospital revealed preferences for wireless, small size, comfortable devices that can be used without support [10]. Another quantitative study focusing on self-managing a wrist worn device identified differences in coping with new technologies among participants [20]. These digital inequalities are strongly related to illness-perception-related factors (e.g., perceived disease timeline and personal control) and should be considered during implementation [20].

We identified five large-scale quantitative studies using questionnaires to explore user's preferences [11–15]. In one survey, most people with epilepsy favored non-stigmatizing, multimodal devices but expressed varying needs for SDD usage, varying from "keeping track of seizures" to "alerting relatives" [11]. This is line with our results that needs for alerting contrast between different caregivers. In another survey, most participants expressed their favor for wearable devices and willingness to care for the device (e.g., charging) or attend extra appointments scheduled [12]. It is, however, unclear what the participants expected from these interventions as the performance of these hypothetical devices was not specified in the questionnaire. Two short multiple-choice questionnaires identified 'the ability to detect all seizures', "continuous SDD use" and "alerting within one minute after seizure onset" as important user's preferences [13,14]. A questionnaire that addressed elements of SDD performance (sensitivity or false alarm rate) independently indicated that the majority of participants favored 100% correct detections and no false alarms [15]. In accordance with our findings, the tolerance for false alarms appeared varied between users: Those with higher seizure frequencies are more willing to accept frequent alarms compared to those with lower seizure frequencies [15]. Only two out of five survey studies specified the actual number of SDD users, which was 2–6% [11,14]. Additionally, the questionnaires did not combine different details related to a specific SDD design, to create a realistic device used in daily practice. The closed question format can pose bias and the reported preferences are not complemented by underlying considerations and possible solutions. Our context mapping session provides such complementary data, but is limited by a small sample size. We aim to conduct a large-scale discrete choice experiment that incorporates the values of the current study. This design has the advantage that it may unveil how respondents value selected SDD features by asking them to state their preferences on different hypothetical SDDs.

Declaration of Competing Interest

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