Article

Patient Engagement in Medical Device Design: Refining the Essential Attributes of a Wearable, Pre-Void, Ultrasound Alarm for Nocturnal Enuresis

Caswell, Noreen, Kuru, Kaya, Ansell, Darren, Jones, Martin, Jon Watkinson, Benjamin, Leather, Peter, Lancaster, Andrew, Sugden, Paula, Briggs, Eleanor, Davies, Carl, Oh, Chooi, Bennett, Kina and DeGoede, Christian

Caswell, Noreen ORCID: 0000-0001-6832-6822, Kuru, Kaya ORCID: 0000-0002-4279-4166, Ansell, Darren ORCID: 0000-0003-2818-3315, Jones, Martin, Jon Watkinson, Benjamin, Leather, Peter, Lancaster, Andrew, Sugden, Paula, Briggs, Eleanor et al (2020) Patient Engagement in Medical Device Design: Refining the Essential Attributes of a Wearable, Pre-Void, Ultrasound Alarm for Nocturnal Enuresis. Pharmaceutical Medicine, 34 (2). pp. 1-19. ISSN 1178-2595

Patient Engagement in Medical Device Design: Refining the Essential Attributes of a Wearable, Pre-Void, Ultrasound Alarm for Nocturnal Enuresis

Noreen Caswell, [1]✉

Email ncaswell1@uclan.ac.uk

Kaya Kuru, [2]

Darren Ansell, [2]

Martin J. Jones, [2]

Benjamin Jon Watkinson, [2]

Peter Leather, [4]

Andrew Lancaster, [3]

Paula Sugden, [3]

Eleanor Briggs, [1]

Carl Davies, [2]

Chooi Oh, [5]

Kina Bennett, [6]

Christian DeGoede, [3]

[1] School of Psychology, University of Central Lancashire, 118 Darwin Building, Preston, Lancashire, PR1 2HE UK

[2] School of Engineering, University of Central Lancashire, Preston, UK

[3] Department of Paediatric, Lancashire Teaching Hospitals NHS Foundation Trust, Preston, UK

[4] Department of IP and Commercialization Innovation and Enterprise, University of Central Lancashire, Preston, UK

[5] Department of Radiology, Lancashire Teaching Hospitals NHS Foundation Trust, Preston, UK

[6] Centre for Health Research and Innovation, Lancashire Teaching Hospitals NHS Foundation Trust, Preston, UK

Abstract

Background

To date, no pre-void wearable alarm exists to treat nocturnal enuresis (NE)—night-time bedwetting, and children with NE and their families are disappointed in relation to the post-void moisture alarms and medicine currently available. Development of a safe, comfortable and non-invasive wearable pre-void alarm and associated technology, using advanced mechatronics, is underway (the MyPAD device). Each stage of development includes patient and public involvement (PPI), particularly with respect to human factors, in collaboration with physicians, radiologists, psychologists, nurses, engineers and designers.

Objectives

The aim of this study was to help us understand the families' experience of the condition of enuresis, and to provide opinion relating to existing NE alarms, designed to detect moisture, and most importantly, the initial design of the MyPAD wearable technology.

Methods

A PPI workshop in the form of a focus group, made up of children with enuresis and their parents, was conducted during the early stage of the MyPAD product development. The key research questions (RQs) were: (RQ1) What were the families' experiences of using existing post-void enuresis alarms? (RQ2) What do families like about the MyPAD prototype? and (RQ3) What do families not like about the MyPAD prototype? A nurse specialised in terms of NE treatment, including post-void alarms, from the Lancashire Teaching Hospitals NHS Foundation Trust, and two MyPAD design engineers were also present, to explain the MyPAD design concept. Braun and Clarke's

six-phase approach to thematic analysis was implemented, which included familiarisation with the data, initial descriptive coding, identifying themes, reviewing themes, defining and labelling themes and producing a report.

Results

Four common themes were identified from the focus group discussions: the importance of sleep; children do not want to feel different; parents feel frustrated and concerned; resilience and perseverance. These themes applied across the research questions; for example, sleep disruption was highlighted as an issue with existing post-void alarms and as an important requirement for the design of MyPAD. The evaluation of the early version of the MyPAD device has prompted the consideration of changes to some existing facets of the device, including providing multiple alarm types, more options for the design of the garment that houses the device, and the need for clear, age-appropriate and informative instructions relating to how the device should be used, in order to maximise its performance/efficiency and acceptance.

Conclusions

The qualitative data derived from the focus group discussion was incredibly valuable as it enabled the research and design team to experience the perspectives of the families in terms of the challenges and conflicts of managing the condition and the limited utility of existing post-void alarms. This has improved our understanding of the social and environmental challenges that will need to be considered during the design process.

Key Points

This study focuses on qualitative data derived from a Patient Public Involvement workshop conducted as a part of the early development of a wearable medical device to treat nocturnal enuresis.
The opinions and perceptions of children with enuresis and their families were incorporated into the development of the device to ensure its maximum efficiency and acceptance.

1. Introduction

A robust working device can be developed, but it may not be used if it is not sufficiently ergonomic and embraced by its users. Human factors are of prime importance in relation to developing a successful medical device, particularly products designed for self-use. Therefore, patient and public involvement (PPI) and engagement is of prime importance during the medical product design and development stage. The development of a device—MyPAD for children with nocturnal enuresis (NE)—is underway through the collaborative efforts of a wide range of disciplines involving the authors of this paper.

NE is the involuntary voiding of urine during the night. The fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5) suggests that this should occur on two or more nights a week, for at least 3 months, in children aged 5 years and above, without a developmental disorder, for diagnosis to occur [1]. A large British cohort study found the prevalence of nocturnal enuresis to be 8.5% at age 5 (1 in 6 children), reducing to 1.5% at 9.5 years [2]. Nocturnal enuresis is subcategorised as mono-symptomatic (MNE) or non-mono-symptomatic (NMNE), the latter is defined by the occurrence of symptoms of malfunction in the lower urinary tract [3]. Currently, first-line treatments include alarm therapy, using alarms that detect moisture (post-void), or desmopressin drug therapy, and less commonly, tricyclic drugs such as imipramine, amitriptyline, and nortriptyline [3, 4].

Living with enuresis can be distressing for children and their families. Consequently, problems may occur in relation to the child's self-esteem [5], social functioning [6], and mental health [7]. Families may also face difficulties, such as parents feeling helpless [8] and siblings being tired or late for school [9]. Parental disapproval and teasing by siblings have also been documented [4]. It is expected that some families do not seek help as they may believe that the child will 'grow out of it' [10]. However, treatment is recommended, especially for more severe NE [11]. Alarm therapy, using currently available post-void alarms, has shown a 65–75% success rate with 35–55% remaining dry at follow-up [12, 13, 14, 15]. Furthermore, recent trials have demonstrated that a delayed second course of treatment proved successful for 44% of individuals, who did not respond to initial alarm intervention [16]. The definition of a successful intervention is commonly 14 consecutive nights without bedwetting [4].

The exact mechanisms underpinning alarm therapy success are not well understood, although various theories are proposed [17, 18]. All current alarms work with a moisture sensor attached to the user's sheet or bed clothes, which creates an alert to wake the child (and their parent/carer) so that they can complete the void in the bathroom. It is suggested that the alarm is most effective if the user is woken promptly by the alarm and assisted to the bathroom by a parent/carer, especially very young children [11]. A problem with alarm use is adherence to treatment, and research suggests that dropout due to non-acceptance ranges from 4–32% across studies [16, 18]. Therefore, use of an alarm requires support from medical professionals throughout the treatment stage and motivation from the family [3]. It is essential to obtain input from the children and their families who live with the condition of NE, when developing a new (pre-void) wearable alarm system. An optimal way to do that is through the use of qualitative analyses performed on data derived from a focus group.

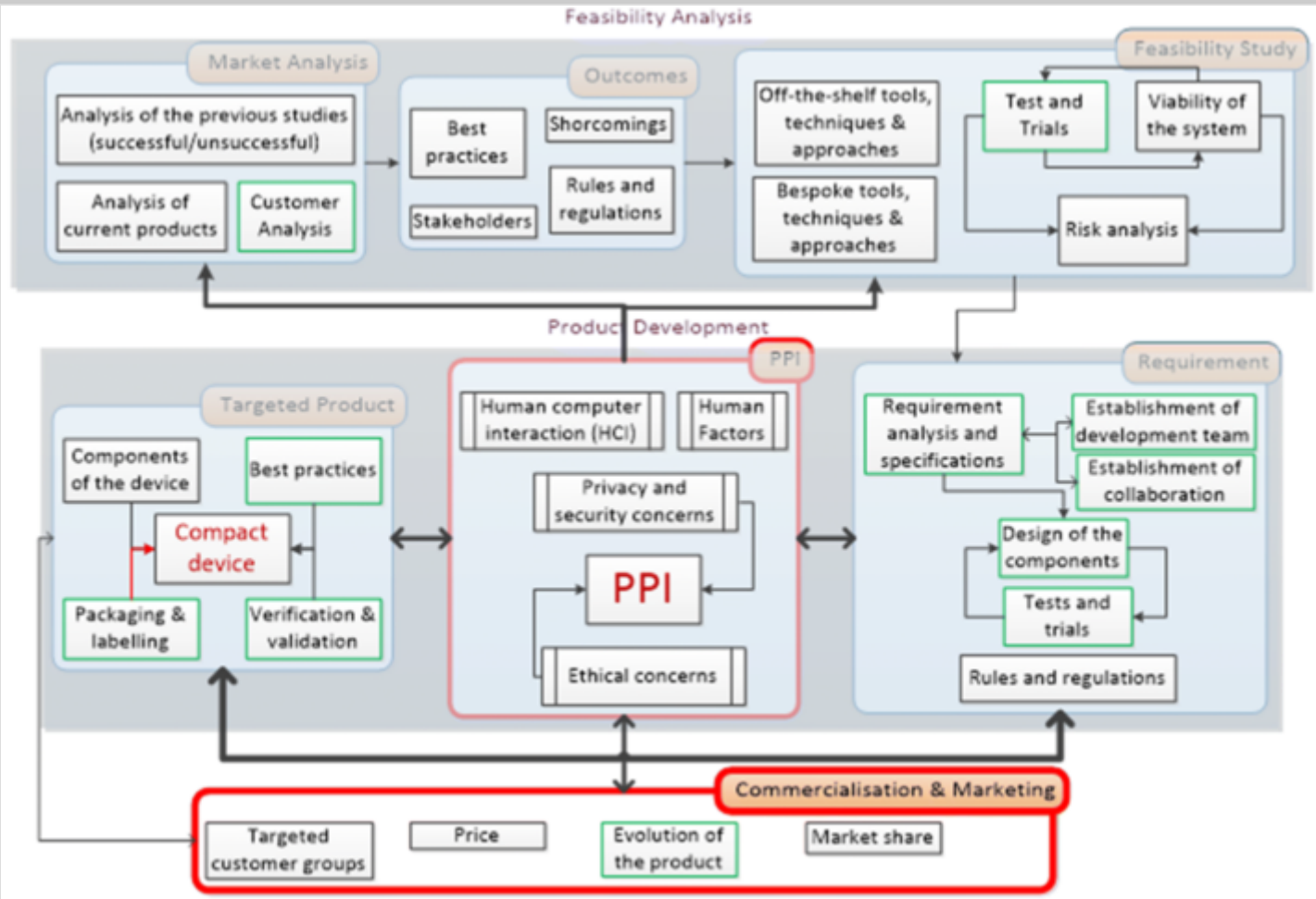
The aim of the MyPAD project is to design a new wearable alarm system, using ultrasound technology, which will detect bladder volume, that is customisable to the user, to prevent inappropriate voiding, which should assist children with NE and their parents/carers in terms of managing the condition. A period of 'learning' will occur with its first use, using artificial intelligence (AI) techniques (for a full description of the device and garment see [19, 20]). This will create an individualised alarm triggering point, which aligns with the

child's pattern of voiding and bladder capacity. At night-time, this should wake the child at the pre-void stage. Additionally, the alarm trigger point can be gradually lengthened over time in the hope that, through learning, the patient will reach the point where the device is no longer needed. Currently, there is quantitative evidence of the challenges associated with post-void alarm use [21, 22] and it is hoped that the new pre-void MyPAD alarm will be well received.

In line with National Institute of Health Research (NIHR) recommendations relating to the use of PPI in health and social care research [23], PPI, in collaboration with physicians, radiologists, psychologists, nurses, engineers and designers, has been performed and will be performed in every phase of the MyPAD project as illustrated in Fig. 1
AQ1
. In this study, we focus on one of the PPI workshops conducted during the product development phase and we undertook qualitative research to help us understand the families' experience of the condition of enuresis, and to provide opinion relating to existing alarms, designed to detect moisture, and most importantly, the initial design of the MyPAD wearable technology [19, 20]. A focus group comprising of children with enuresis and their parents was utilised. The main research questions (RQs) were as follows: RQ1: What are the families' experiences of using existing post-void enuresis alarms? RQ2: What do the families like about the MyPAD prototype? RQ3: What do the families not like about the MyPAD prototype? The objectives relating to the research questions are (1) to elicit the perceptions and opinions of those individuals living with and managing NE, and (2) to obtain information relating to the pros and cons of existing devices, and the proposed MyPAD device specifically, with the aim of using the information to improve its efficiency and acceptance by the children with NE and their families.

Fig. 1

Framework of medical product development. *PPI* patient and public involvement



PPI [Patient, Public Involvement]

2. Methods

2.1. Participants

Three children with NE and their parent(s), and one parent whose child did not wish to attend, were recruited to attend a focus group/workshop. A nurse specialised in terms of NE treatment, including post-void alarms, from the Lancashire Teaching Hospitals NHS Foundation Trust, and two MyPAD design engineers were also present to explain the MyPAD design concept. The focus group session was advertised through ERIC (The Children's Bowel and Bladder Society). With consideration of recommendations for an optimal size for a focus group of six to eight participants, excluding researchers [30], and with the knowledge that focus groups can work successfully with as few as three and as many as fourteen participants [30], the original invitation was sent out to seven children and their parent(s). For those who did participate, their expenses were reimbursed and the children each received a £20 voucher for their participation. See Table 1 for participant details.

Table 1

Child participants' age and family information

Child	Age	Gender	Parent in attendance
1	11	F	Mum 1

Child	Age	Gender	Parent in attendance
2	7	F	Mum 2 and Dad 2
3	8	F	Mum 3
4 (not present)	11	F	Mum 4

2.2. Procedure

Participants were provided with age-appropriate written and verbal information relating to the MyPAD device by the design engineers, and were afforded the opportunity to interact with and ask questions about the MyPAD prototype. Participants were informed that the aim of the focus group was to discuss previous alarm use, things that were important to them with regard to alarm design/use, and to provide feedback specifically on the new MyPAD alarm system, which was in the early stage of development. Recruitment took place via the Charity and the focus group session took place at the Charity Headquarters. All participants gave verbal consent for the recording. The session lasted around 3 h with around 120 min of recording in total.

2.3. Analytic Strategy

Braun and Clarke's [24] six-phase approach to thematic analysis was implemented, which included familiarisation with the data, initial descriptive coding, identifying themes, reviewing themes, defining and labelling themes and producing a report. The recording was conducted and transcribed by a trained research assistant; line-by-line coding, theme identification and review was initially undertaken separately by the research assistant and a Health Psychologist (CPsychol), who came together thereafter to discuss the themes extracted and their interpretation. Coding was broad and included all possible patterns and themes. The four themes that were used to understand the research questions accounted for the majority of the data. Researcher comments were not analysed and coded but were used to understand the context of participant comments.

3. Results

In order to answer the three research questions, four overarching themes were generated from the focus group data collected: the importance of sleep; children do not want to feel different; parents feel frustrated and concerned; resilience and perseverance.

3.1. The Importance of Sleep

Sleep was an important theme throughout the focus group discussion. It was relevant to the experience of past alarm use and was also important in relation to the design of MyPAD.

The first thing to note is that the families had found that the volume of the devices they had used previously was too high with parent Mum 2 likening the sound to an '*air raid*

siren' and parent 4 describing the experience of waking up to the alarm as '*like being in a war zone*'. This was not only difficult for the parent and child who were hoping to respond to the alarm, but also the rest of the family. Discussion with the families gave a sense of the impact of alarm-related sleep disturbances on daily life. The families wanted to be dry but there was a sense of a cost/benefit analysis by the parents; weighing up what was best for the family versus the impact of alarm use.

> "*I think th- I mean we gave up, partly, with it because umm we were just up all night—we just couldn't keep going with it and um, for us, um the lack of sleep and the effect of that got to us before th- the beneficial—umm impact and uh what we were finding, was a lack of cooperation with the things we have to do during the day as well … we just had to stop*…" Parent, Dad 2.

The fact that some children do not awaken to alarm sounds was expressed by Parent and Child 3.

> "*What if the kid stays asleep… then the mum doesn't hear it… if I don't wake up what's the whole point of it? Because, mum, if she knows I won't wake up, she'll come and give me like [a] nudge saying, 'just get up*" Child 3.

Further sleep concerns related to dysfunctional voiding. In relation to MyPAD a particular concern was raised around how this might affect the frequency of alarm sounding if the bladder had not fully emptied after toileting in the night.

> "*I guess the danger would be if they hadn't voided completely, they're gonna get back into bed and its gonna go off again straight away*" Parent, Mum 2.

Although this is a sleep concern for the parent, it may be that the device is not appropriate for the family at this time, as the child displays symptoms of lower urinary tract disease (LUTD). Effective treatment of an overactive bladder (or postponement, dysfunctional voiding) can lead to cessation of NE [26]. As the parent suggests, using MyPAD, or any enuresis alarm when LUTD symptoms are present, may cause unnecessary stress and frustration and is not recommended.

Sleep-related concerns were also raised when the use of a smartphone for the alarm system was suggested, that could then sound in the parent's and child's room. It seemed that parents did not like phones in bedrooms. Parent 1 reported a rule of '*no tech in the bedrooms*' while Parent 4 agreed that '*I don't like my phone in my bedroom either because I would be on it all night*'. Concerns were related to messaging friends, blue light and internet use. Parents in the current sample would prefer an alternative to smartphones for the sounding of alarms, if this is possible.

The final point related to sleep and sleep disturbance was the comfort of device. If past devices were uncomfortable and interrupted sleep, then families were disinclined to use the device. One parent and child in particular found this to be an issue.

> "*…it was hurting there (gestures) and I woke up in the night because of it"* Child 2.

> *"It was uncomfortable, she couldn't lie on her front and sleeping like that…*" Parent, Dad 2.

3.2. Children Do Not Want to Feel Different

Another key theme was a sense of children wanting to 'fit in' with their peers and not do anything to make themselves stand out or feel different. NE caused some feelings of isolation in the children as two out of the three children present reported that that they felt they could not participate in childhood activities such as sleepovers.

> '*…I don't really go to sleepovers so I only—sometimes I sleepover at my nans*' Child 2.

> '*….Just gave up on that*' Child 3.

The older children seemed to have ways to work around this; however, when they were in this environment, they wanted discreet methods of protection and in one case, social events had disrupted alarm use.

> "*well we've seen really really good results with it, it was fantastic… incredibly marked improvement…but where the problems have come in with it: school trips and sleepovers—it's the social side. So [the child] was dry up until [*the school trip*] 2 weeks ago. So, we'd had about… 4, 5 weeks—probably more than 4 or 5 weeks straight completely dry and then school trip, didn't wear the alarm, and two out of three wet nights so, so yeah*" Parent 1.

This shows a difficulty with previous, post-void alarm use in relation to social situations and how alarms, even if successful, may not be used in such instances as children don't want to stand out or have to explain their condition to their peers. This was also relevant when discussing alarms that were used in the day.

> "*It's really, I think one of the things that they resist in school is any possibility that they're gonna be noticed or different or anybody'd say… we did try with a night-time alarm during the day once and erm just with it*

> *buzzing, not with the alarm going off, but even just her knowing that she had it on"*—Parent 4.

One child expressed how even leaving the classroom can be a reason for being noticed as doing something 'different'. One of the parents described how her child felt different and wished there was someone out there to share the experience and help with feelings of isolation created by NE.

> "*I suppose it's, and one of the things that my daughter has said is 'there's no one out there to tell me when this is ever going to work, that I'm ever going to get better' and we couldn't, all the continence nurses, continence people, they're dealing with current problems, and she, she wanted something like, y'know you can find dyslexia, famous people who are dyslexic… and famous people who've got autism, and all of this, and I said well they're probably not gonna talk about…you know, toileting, but she said "I'd just love to hear, that 1, this is ever going to work, and I'm ever going to get better, and 2, that even if I don't, that it's okay*." Parent 4.

Understanding these feelings and experiences is important in the design of the device and garment of MyPAD as these children have challenges to face. When discussing the design of MyPAD the idea of not wanting to feel different also came across and the children described that feeling comfortable in the garment and have something discreet.

> "*Well yeah, I want them to be hidden, 'cause I don't want to be marching round in something that's massive*" Child 1.

The importance of the device being 'acceptable' to the child was reinforced by one parent.

> "*The other thing I think is erm that the children need to be compliant, as well, cause you're sat there now just like 'oh I wouldn't do it, I wouldn't do it' and I think, 'well I've lost already' y'know with like so it is a way of making it really child friendly, cause, if the kids don't wanna do it, it's just losing battle…*" Parent 3.

Another source of debate amongst the children, which also may relate to compliance and wear-ability, comes from the garment's colour/style. The age of the child was an important factor and their preference aligned with what allowed them to 'fit in' with their age group. One parent made this point explicitly.

> "*…I mean obviously as children get older; they've got different preferences*."

Younger children wanted pink while older children wanted black. However, all agreed that 'boxer shorts' or 'shorties' were the preferred cut as this was apparently 'in fashion' for all children. This shows that the design of the garment and acceptability by children will be important for compliance and thus important for success of the device.

3.3. Parents Feel Frustrated and Concerned

There was a sense of frustration and concern from the parents with the condition itself and also with attempts to manage it. This was demonstrated by Parent 4 when she described waking up to change the sheets with her child.

> "*I mean she'd wake up and change, but it meant we weren't crawling around changing the bed… which is just… soul destroying isn't it? When you can't think straight and it's the middle of the night and it's all… so–so yeah, for us it was similar… this is just making sure that we don't have to wash all the sheets every night…*" Parent 4.

Here when the experience is described as 'soul-destroying' one can get a sense of the exhausting challenge of getting up throughout the night to change the bed. This highlights the emotional effect and stress associated for the parent and child. In the last sentence the parent uses 'all' and 'every' which again gives a sense of feeling overwhelmed by the routine of changing clothes and changing sheets. This was something that all the families agreed was one of the things they most liked about MyPAD and that is the pre-void alarm system.

> "*I think preventing wetting in the first place is ju- is brilliant—such a good idea*" Parent 3.

For some parents, the pre-void system also addressed another source of frustration by "catching it before it happens" as they felt that a moisture alarm was not addressing the problem.

> "*We just didn't find the point of a moisture detector because by which point it's too late…the only good it made, did for us, was okay… we need to change the bed and that was, that was it*" Parent 3.

Although the parents in this sample were particularly knowledgeable about NE and different treatments, there still appeared to be a lack of information provided about how a post-void alarm should work, i.e., it should awaken the child as they begin to void, and the child should awaken and finish voiding in the lavatory. This led to feelings of doubt. However, in designing MyPAD, it might be useful to include a leaflet with clear information about how the alarm should be fitted, and how it should work, which could help to increase parent and child knowledge, and therefore motivation to use the device.

Perhaps also include an initial teaching/training paradigm at the beginning, involving a demonstration and practice session, linked to fitting and using the device correctly, and using the data derived from it. For example, another source of frustration for parents seemed to be not having a full understanding of the specifics of the condition of NE itself, and the mention of how the use of fluid balance charts were "*difficult to manage*" (Parent 4).

> "*...over years of consultant visits it's all 'Oh we'll just have to see' and 'This is probably what's going on' and 'This might be' and to have that definitive data* [referring to data that the MyPAD device will provide] *I feel —would have felt really reassuring that we were moving in the right direction*" Parent 4.

> "*The forms are really hard to do so you have to write down every time, however many MLs you consume and then you have to write down how many MLs you wee out—you have to do that every time you go to the consultant for 4 days and nights, it sounds like it's not a lot but—if this* [referring to the MyPAD device] *was able to provide that information that would be fantastic*" Parent 1.

The parents felt that the MyPAD device would provide useful information; having measurements of bladder fullness pre- and post-void would provide information on urine output without having to struggle with fluid balance sheets.

3.4. Perseverance and Resilience

The sense of frustration demonstrated in the previous theme is certainly understandable. However, it was offset throughout by a strong sense of perseverance, resilience and of parents spreading encouragement to others. Referring to a post-void alarm:

> "*… it worked, you just have to keep going at it…*" Parent 4.

This family remained positive despite the fact that they had to use an alarm for far longer than the 'few weeks' they were told it would take.

> "*No, but… she wore an alarm for… possibly 2 years*" Parent 4.

This shows incredible resilience; however, it is not often reported that a moisture sensor alarm will take this amount of time to be effective. One other family in the focus group reported that they had started to see improvement within 2 weeks. However, there was still a sense of perseverance throughout the families and many had been involved in multiple trials and used different apps. All families mentioned trying at least two devices in the past, and two families mentioned that had participated in previous research trials.

> "*… possibly some years ago now she took part in a trial with a phone…*" Parent 4.

> "*We have just come off a 26-week trial with the little red box…*" Parent 1.

As the parents discussed the different things that they had used it was clear that although a lot of different products and strategies were adopted, all children and families were different and liked/disliked different things. For example, talking about the same device Parent 1 reported "good results", Parent 4 reported that the child had come to 'ignore the signal' and Child 2 reported 'it's in my bag from school' with the parent following up that the child 'doesn't like wearing it'. The important thing seems to be for the families to each find something that is suited to their needs and priorities. One of the parents expressed this as something she liked about the MyPAD.

> "*well I think that's the- where the concept of having it, so it actually has a learning function, to learn the user's specific situation umm sounds very, very sensible, [because] obviously if you've got reduced capacity then, you know, you- you're gonna struggle more than others*" Parent, Mum 2.

4. Discussion

The aim of the research was to gather qualitative (PPI) data (processed using thematic analyses) from children with enuresis and their parent(s) in relation to an early prototype of a medical device; the MyPAD pre-void, wearable, enuresis device, based on ultrasound technology. There were three research questions: RQ1—What were the families' experiences of using existing post-void enuresis alarms? RQ2—what do the families like about the MyPAD prototype? and RQ3—what do families not like about the MyPAD prototype?

RQ1: Previous experiences of post-void alarm use was mixed in terms of the success of the intervention(s). Sleep disturbance/deprivation (and its subsequent effects the following day on activities, particularly schoolwork) was at the forefront of expressed 'worries' for both the children and their parents. There was a paradox involving the wish for the child to get a good night's sleep versus wanting them to be dry. Existing alarms were deemed to be too loud; awakening the entire family. Studies have shown that around a third of families cannot tolerate alarms, for various reasons [16]. Sound volume concerns have been cited elsewhere [22] and in this group it was suggested by two parents and one child that it would be beneficial to have a quieter alarm that could be heard in the child's room and a separate one for the parent. This was seen as useful so as not to disrupt the whole house with a loud alarm, but also because some children do not wake to alarm sounds. This is a common problem with alarms for NE, and as such, guidelines for current alarm use recommend that the parent wakes with the child and helps them to rise [3]. Other research suggests that lower pitch sounds, particularly a recorded maternal voice, are around three

times more effective for waking children of this age group than high pitched alarms [25]. This has been reported previously within the literature, where 50 families were contacted regarding alarm tolerance. Of the 42 who responded, 19 had success with the alarm and 23 did not. Of those who did not find success with the alarm, 17% cited child compliance as the main issue. This shows the importance of considering what the child wants in alarm treatment but also meeting as many of the child's requirements as possible such as comfort of device and alarm sound, so as to ensure compliance with alarm therapy.

Although moisture alarms are a grade A recommended treatment by the International Children's Continence Society and a first-line treatment in national and international guidelines [3, 29], they can only be effective if the family perseveres with them. If the family is facing challenges such as sleep disturbance and they also have a sense of frustration or lack of confidence in the alarm system, or they have a poor understanding of how the alarm works [18], they are less likely to use it. In addition, the optimal time for alarm use has been recommended as 2–3 months [3] with one report revealing that extending over 3 months did not increase the success rate in non-responders [16]. The results from this study suggest that these timescales are somewhat unrealistic and in reality, post-void alarm treatment can take much longer to become effective. This reflects other evidence showing that only 6% of parents surveyed would consider using a post-void alarm [10].

In terms of the development of the MyPAD device, it is suggested that several alarm options be provided, including the option for one or both parents to record an alarm 'message' to awaken their child. The request for more information (than has previously been given) in relation to both the condition and the alarm as an intervention should be provided. In terms of the development of the MyPAD, it is suggested that a clear, concise, information leaflet be provided along with the device, that uses language suitable for this age group. At the start of the intervention, the child and parent(s)/carer(s) undergo a teaching/training protocol in relation to the aims of the device, the correct fitting of the device, and its capabilities. For example, the type of data that can be extracted from the device, and how that might be used to bolster the chance of success in using it. Despite the 'frustrations' experienced previously, there was a continued effort to address the problem of enuresis, and the families had tried several different alarms, aids, trials and apps between them in an attempt to tackle the problem.

RQ2: The second question, relating to what the families liked about the MyPAD device, is best understood through an understanding of their expressed frustrations with previous devices. Many of the sources of frustration, such as the alarm sounding after voiding, the alarm being too loud, and having difficulty understanding the condition itself, and the never-ending task of having to wash the bedding, are in line with previous findings [5, 28]. However, parents felt that these problems could be negated with the MyPAD device. This was due to its ability to 'see inside the bladder' to wake the child at the pre-void stage and the data it could provide on bladder capacity. Information from the children relating to the 'look' of the garment designed to house the MyPAD device was also useful, and opinion seemed to exist as a function of age, with younger children desiring a pink garment, and

older children wanting a black garment; all children liked a 'boxer shorts' cut, and were hugely insistent that the garment should be comfortable to wear and should not disturb the child's sleep as a consequence of its design. The garment and device should be as inconspicuous as possible, so that the child is not made to feel 'different', especially in social situations. This is particularly significant for these children, as previous findings have reported self-esteem difficulties in children with NE [5, 27]. Currently, the MyPAD garment is based on the design of cycling shorts, constructed with black, lycra material, to ensure both comfort and a secure fit. Comfort trials are underway currently with non-enuresis children, and a 14-week trial will also be undertaken among children with NE.

RQ3: In terms of what the families did not like about the early MyPAD prototype, this mainly related to the alarm, and particularly the need for a phone app. Parents in particular did not want a phone in their child's bedroom during the night, as they thought that the child may talk to others (friends) during the night-time. Limitations of this research relate to (a) a lack of knowledge regarding the children's specific condition (i.e. NMNE vs MNE), (b) recruitment of female children only, (c) a small patient and parent sample size. One child reported NMNE symptoms, and it may be that pre-void alarm therapy should be applied only when/if such symptoms are dealt with. The recruitment of male children may have provided more insight, particularly in terms of (a) the experience of enuresis and (b) the look of the garment that houses the MyPad device.

The ultimate aim of 'patient centrality' is to engage the patients, the professionals who provide their care, and in this case their wider support network (family/carers) as partners in the design and development process, in order to bring about a clinically useful and *meaningful* end product [32]. One of the core principles of patient participation relates to ensuring that engagement is made as easy, feasible and as flexible as possible, to accommodate patient requirements without undue or unnecessary burden, as well as being cost effective in relation to scientific and business imperatives [31, 32]. With these goals in mind it was deemed that participant recruitment through a familiar agency (ERIC), coupled with qualitative methodology applied to data obtained from a focus group setting would be optimal. However, although invitations to participate were issued to seven children and their parents, the attendance rate was low in terms of the number who participated in the focus group session. Therefore, the recruitment strategy for later stages of the development process will be even more rigorous and will involve individual interviews with each child and carer, at multiple time points, alongside quantitative measures relating to comfort of fit and efficiency of the device. Moreover, as the focus group method was deemed to yield some very useful data, the opportunity to attend a focus group will also be offered.

5. Conclusions

Overall, the findings from this study confirm the importance of including PPI at the early design stage of medical devices. The focus group data were incredibly valuable as they enabled the research and design teams to experience the perspectives of the families and the challenges and conflicts of managing the condition and their perceived problems with

pre-existing post-void alarms. More importantly, their evaluation of the early prototype version of the MyPAD device has prompted the consideration of changes to some existing facets of the device, including providing multiple alarm types, more options for the design of the garment that houses the device, and the need for clear, age-appropriate and informative instructions relating to way in which the device should be used, in order to maximise its performance/efficiency and acceptance. Limitations associated with participant recruitment will be addressed in subsequent PPI studies relating to the MyPAD device.

Acknowledgements

The views expressed in this publication are those of the authors and not necessarily those of the National Health Service (NHS), or the National Institute for Health Research.

Compliance with Ethical Standards

Funding This report is independent research funded by the National Institute for Health Research (Invention for Innovation) [i4i].

Conflicts of Interest For each Author, Noreen Caswell, Kaya Kuru, Darren Ansell, Christian DeGoede, Martin Jones, Benjamin Jon Watkinson, Peter Leather, Andrew Lancaster, Paula Sugden, Eleanor Briggs, Carl Davies, Chooi Oh, and Kina Bennett, no conflict of interest was declared.

Ethical Approval MyPAD – Intelligent Bladder Pre-void Alerting System; II- LA-1116-20007. The techniques, methods and Patient and Public Involvement and Engagement (PPI) in this study were approved ethically by NHS Health Research Authority: North West–Greater Manchester Central Research Ethics Committee (ID:247101).

Informed Consent Participants were provided with information relating to the study aims (verbally and in age appropriate written format), and their right to withdraw at any point during the focus group discussion and up to 7 days after the meeting.

References

1. American Psychiatric Association. Diagnostic and statistical manual of mental disorders (DSM-5). 5th ed. American Psychiatric Pub; 2013.

2. Butler RJ, Heron J. The prevalence of infrequent bedwetting and nocturnal enuresis in childhood: a large British cohort. Scand J Urol Nephrol. 2008;42(3):257–64.

3. Neveus T, Eggert P, Evans J, Macedo A, Rittig S, Tekgül S, et al. Evaluation of and treatment for monosymptomatic enuresis: a standardization document from the International Children's Continence Society. J Urol. 2010;183(2):441–7.

4. Glazener CMA, Peto RE, Evans JHC. Effects of interventions for the treatment of nocturnal enuresis in children. Qual Saf Health Care. 2003;12:390–4.

5. Ertan P, Yilmaz O, Caglayan M, Sogut A, Aslan S, Yuksel H. Relationship of sleep quality and quality of life in children with monosymptomatic enuresis. Child Care Health Dev. 2009;35(4):469–74.

6. Hinde M, Hjertonsson M, Broberg A. Low self-esteem of children with enuresis. Mental and social health compared in different groups. Lakartidningen. 1995;92(36):3225–9.

7. Equit M, Klein AM, Braun-Bither K, Gräber S, von Gontard A. Elimination disorders and anxious-depressed symptoms in preschool children: a population-based study. Eur Child Adolesc Psychiatry. 2014;23(6):417–23.

8. Morison MJ, Tappin D, Staines H. You feel helpless, that's exactly it: parents' and young people's control beliefs about bedwetting and the implications for practice. J Adv Nurs. 2000;31(5):1216–27.

9. Morison MJ. Living with a young person who wets the bed: the families' experience. Br J Nurs. 2000;9(9):572–88.

10. Schlomer B, Rodriguez E, Weiss D, Copp H. Parental beliefs about nocturnal enuresis causes, treatments, and the need to seek professional medical care. J Pediatr Urol. 2013;9(6):1043–8.

11. Walle JV, Rittig S, Bauer S, Eggert P, Marschall-Kehrel D, Tekgul S. Practical consensus guidelines for the management of enuresis. Eur J Paediatr. 2012;171(6):971–83.

12. Houts AC, Berman JS, Abramson H. Effectiveness of psychological and pharmacological treatments for nocturnal enuresis. J Consult Clin Psychol. 1994;62(4):737.

13. Forsythe WI, Butler RJ. Fifty years of enuretic alarms. Arch Dis Child. 1989;64(6):879.

14. Evans J, Malmsten B, Maddocks A, Popli HS, Lottmann H, UK Study Group. Randomized comparison of long-term desmopressin and alarm treatment for bedwetting. J Pediatr Urol. 2011;7(1):21–9.

15. Apos E, Schuster S, Reece J, Whitaker S, Murphy K, Golder J, et al. Enuresis management in children: retrospective clinical audit of 2861 cases treated with practitioner-assisted bell-and-pad alarm. J Paediatr. 2018;193:211–6.

16. Hyuga T, Nakamura S, Kawai S, Nakai H. Evaluation of the effectiveness of a short-term treatment and repeat treatment of nocturnal enuresis using an enuresis alarm. Urology. 2017;105:153–6.

17. Butler RJ, Holland P, Gasson S, Norfolk S, Houghton L, Penney M. Exploring potential mechanisms in alarm treatment for primary nocturnal enuresis. Scand J Urol Nephrol. 2007;41(5):407–13.

18. Schulz-Juergensen S, Langguth A, Eggert P. Effect of alarm therapy on conditioning of central reflex control in nocturnal enuresis: pilot study on changes in prepulse inhibition (PPI). Pediatr Nephrol. 2014;29(7):1209–13.

19. Kuru K, Ansell D, Jones M, De Goede C, Leather P. Feasibility study of intelligent autonomous determination of the bladder voiding need to treat bedwetting using ultrasound and smartphone ML techniques. Med Biol Eng Comput. 2019;57(5):1079–109.

20. Kuru K, Ansell D, De Goede C, Jones M, Caswell N, Leather P, Lancaster A, Sugden P, Briggs E, et al. Intelligent autonomous treatment of bedwetting using non-invasive wearable advanced mechatronics systems and MEMS sensors. Med Biol Eng Comput. 2020; 58(1):(in Editing). Available from: http://clok.uclan.ac.uk/28686/.

21. Wagner WG, Johnson JT. Childhood nocturnal enuresis: the prediction of premature withdrawal from behavioral conditioning. J Abnorm Child Psychol. 1988;16(6):687–92.

22. Oğuz U, Sarıkaya S, Özyuvalı E, Şenocak Ç, Halis F, Çiftci M, et al. Family compliance with the use of alarm devices in the treatment of monosymptomatic nocturnal enuresis. Turk J Urol. 2014;40(1):52.

23. NIHR. Patient and public involvement in health and social care research: A handbook for researchers by research design service London. Available from: https://www.google.com/url?
sa=t&rct=j&q=&esrc=s&source=web&cd=1&ved=2ahUKEwiH8MOC8d3kAhXGIlAKHSV
london.nihr.ac.uk%2Fwpcms%2Fwp-
content%2Fuploads%2F2018%2F10%2FRDS_PPI-
Handbook_2018_WEB_VERSION.pdf&usg = AOvVaw2p6HhyqmaZa4Duk6O8Lwo2. Accessed 18 Sep 2019.

24. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol. 2006;3(2):77–101.

25. Smith GA, Chounthirath T, Splaingard M. Effectiveness of a voice smoke alarm using the child's name for sleeping children: a randomized trial. J Paediatr. 2019;205:250–6.

26. Franco I, Von Gontard A, De Gennaro M, Members of the International Childrens's Continence Society. Evaluation and treatment of nonmonosymptomatic nocturnal enuresis: a standardization document from the International Children's Continence Society. J Pediatr Urol. 2013;9(2):234–43.

27. Longstaffe S, Moffatt ME, Whalen JC. Behavioral and self-concept changes after 6 months of enuresis treatment: a randomized, controlled trial. Pediatrics-Springfield. 2000;105(4):935–40.

28. Pugner K, Holmes J. Nocturnal enuresis: economic impacts and self-esteem preliminary research results. Scand J Urol Nephrol. 1997;183:65–9.

29. O'Flynn N. Nocturnal enuresis in children and young people: NICE clinical guideline. Br J Gen Pract. 2011;61(586):360–2.

30. Gill P, Stewart K, Treasure E, Chadwick B. Methods of qualitative data collection in qualitative research: interviews and focus groups. Br Dent J. 2008;204:291–5.

31. Getz KA. Charting a course for the patient centricity movement. Clin Res. 2015;29(2):36–40.

32. Getz K. Reflections on the evolution of patient engagement in drug development. Pharm Med. 2019;33:179–85.