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RESEARCH ARTICLE

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Parent and staff experiences of a feasibility trial evaluating neurally adjusted ventilatory assist in infants with acute viral bronchiolitis: A qualitative study

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Abstract

Background: There is limited literature regarding family and staff experiences of participating in clinical trials. A qualitative study was embedded in the NAVABronch feasibility trial evaluating the effectiveness of a novel mode of ventilation, neurally adjusted ventilatory assist (NAVA), in infants with acute viral bronchiolitis.

Aims and Objectives: The aim of this qualitative study was to explore the experiences of parents and health care practitioners (HCPs) involved in the NAVABronch Trial.

Study Design: Semi-structured interviews were conducted with two parents and two focus groups were held with six HCPs.

Findings: Four themes were identified from the focus groups: (1) Creating staff engagement, (2) Education to deliver NAVA, (3) Normalizing NAVA in clinical practice (4) Creating meaningful study outcomes and (5) support of parents during the trial, this theme was generated from the parent interviews. The findings indicated the need for education regarding NAVA for HCPs which would lead to increased confidence, better guidance around the use of NAVA and the need for NAVA to be normalized and embedded into the unit culture. Parents identified the need for further support around preparation for what may happen as a result of the interventions, particularly the weaning of sedation.

Conclusion: Our study indicates that staff and parents had no concerns regarding the trial methods and procedures.

Relevance to Clinical Practice: Conducting clinical trials in Paediatric Intensive Care Units (PICUs) is challenging and complex. There is limited literature regarding family and staff experiences of participating in clinical trials. Understanding their experiences is crucial in ensuring trial success.

KEYWORDS

acute viral bronchiolitis, clinical trials, NAVA, neurally adjusted ventilatory assist, parent and staff experience

1 | INTRODUCTION

Conducting clinical trials in Paediatric Intensive Care Units (PICUs) is challenging and complex.[1] Children are often acutely unwell and the PICU environment can cause anxiety and stress for families.[2] Additionally, it is important to involve staff that may be recording data or delivering care in a different way.

Feasibility studies are often conducted prior to large RCT's of complex interventions to evaluate the study design and help refine the protocol.[3] An element of this is stakeholder involvement in the research process.[3] This qualitative study evaluating parent and staff experiences was embedded in an RCT, the NAVABronch trial (protocol Number: 217195). The aim of the NAVABronch trial was to evaluate the effectiveness of a new mode of ventilation, neurally adjusted ventilatory assist (NAVA) in infants with acute viral bronchiolitis. This study recruited 13 participants during the winter of 2019/20. Participants were randomly allocated to standard dose or low dose morphine. Titration of ventilation was applied over two consecutive days with physiological data being collected during this time. The participants required a change of nasogastric tube as the NAVA ventilator requires a probe that includes a nasogastric tube to function.

1.1 | Background

There is limited literature regarding family and staff experiences of participating in clinical trials. What is available concentrates specifically on the consenting process and what motivates families to take part rather than the practicalities of trial conduct.[4–10] There is a small number of studies that have engaged families in the planning process of an RCT in PICU.[11] Whilst these questions are important in informing a trial, there appears to be only one study that examined experience of study procedures post RCT in the paediatric intensive care population.[12] None of the studies involve titration of ventilation. It is therefore important to seek this information as part of the feasibility assessment of the NAVABronch trial.

Woolfall's study[4] exploring parents' agendas in trial participation highlighted that safety, purpose and practicalities were important considerations for the decision-making process. It also highlighted that there can be misunderstanding or misconceptions regarding trials either at the consent stage or during the study procedures itself. Therefore, the aim of this study is to explore the experiences of parents and health care practitioners (HCPs) involved in the NAVABronch Trial. Specifically, the objectives were to gain an understanding of how parents made their decision to take part in the study, to explore parents' experiences of the consent process, to explore parents' understanding and experience of the study procedures and to gain parents' perspective of the interaction with the research team. With regard to the health care professionals, the objectives were to explore the bedside team's experience of the bedside trial conduct and the experience of using NAVA at the bedside.

What is known about the topic

- Conducting clinical trials in PICU is challenging and complex.
- There is literature discussing parent and family motivation for taking part in research but very little that discusses parents' experiences of taking part in a study on PICU.
- There are no studies exploring the experiences of parents and staff involved in a trial evaluating ventilation.

What this paper adds

- Parents need further explanation around how their child may respond to study procedures/ normal clinical care as part of the trial.
- Planning a trial needs to involve collaboration with all HCPs where appropriate, and education regarding the study procedures and equipment.
- A discussion of meaningful outcomes for both HCPs and families is required when developing the study.

2 | MATERIALS AND METHODS

This study utilized a qualitative design with semi-structured focus group interviews with HCP's and individual interviews with parents in one tertiary PICU in England. The COnsolidated criteria for REporting Qualitative (COREQ) research checklist was utilized to report the findings of this study.[13] The study was approved by the Institutional Review Board of London – Surrey Research ethics Committee. Protocol number: 272724 approved on: 21 April 2020.

A randomized crossover study (NAVABronch) was designed to explore how to optimize NAVA settings in acute viral bronchiolitis. The study also explored effect of different morphine doses on NAVA/PEEP titration, as well as the short-term clinical impact on the patients' physiological responses and tolerability. The trial took place in a tertiary PICU in England and started recruitment in November 2019. The study involved recruiting infants of >36 weeks' gestation and <1 year of age up to 48h after admission to the PICU. Study procedures required titration of the infant's mechanical ventilation for on average 11h, across two consecutive days (5.5h per day) with data being collected throughout this period. Parents were approached for consent within at least 48h of their child's admission to capture these infants during the acute period of illness. This trial is registered with clinicaltrials.gov (Identifier NCT05899894).

Prior to the start of the RCT, no additional training was provided regarding NAVA ventilation as this was used on the PICU already. The study team titrated the ventilation and bedside staff were asked to complete the COMFORT B scale which was in addition to their normal daily tasks, and they received training regarding this at the bedside.

2.1 | Participants and procedures

Thirteen participants were recruited into the NAVABronch trial. Parents of 10 of the participants who had provided their contact details for a summary of the results were approached to take part in the qualitative study in June 2021, purposive sampling therefore was utilized. Parents were contacted via e-mail, text message or post depending on their preferred contact method, inviting them to take part in the study. Both parents were invited to take part if they wished either together or separately. If they indicated that they were interested, a Patient Information Sheet (PIS) and consent form were posted to them. If they wished to take part, they signed and returned a consent form via post in a prepaid envelope. The researcher would than agree with them a convenient time to conduct a telephone interview.

Bedside staff, nurses, physiotherapists, doctors and consultants, who were involved in the NAVABronch trial were approached via e-mail sent by the lead research nurse on the authors behalf in June 2021. When the health care professional expressed an interest, they were sent the PIS and an online consent form which required an e-signature. E-signature was necessary because of COVID-19 restrictions during this time.

2.1.1 | Inclusion criteria for parent interviews

- The parents or carers had a child recruited into the NAVABronch feasibility study.
- The parent/carer spoke English.

2.1.2 | Exclusion criteria for parent interviews

- Non-English speaking.
- Parents/carers whose child had died.

2.1.3 | Inclusion criteria for staff focus groups

- The member of staff was involved in the bedside care of the child during the NAVABronch feasibility trial procedures.
- The member of staff was able to attend the online meeting and available for the duration of the focus group.

2.1.4 | Exclusion criteria for staff focus groups

- Temporary members of staff (locum or bank staff).

2.2 | Interviews and focus groups

The individual interviews with parents were conducted by the first author (JH) via the phone facility of MS Teams. They lasted approximately 30 min and followed a semi-structured interview guide (Electronic Supplement 1) with prompts. The focus groups were conducted by the first author (JH) via MS Teams, because of the restrictions posed by COVID-19. The two focus groups conducted with the health care professionals were expected to take approximately 1h and utilized a semi-structured interview guide (Electronic Supplement 2). The interviews and focus groups were recorded utilizing the record facility on MS Teams. Field notes were completed immediately after along with a reflective diary of how the interviewer (JH) felt whilst conducting them.

Interview guides were developed using the concepts identified in an extensive literature review, guidance by O'Cathian et al.[14] regarding maximizing the impact of qualitative research in feasibility studies and the NAVABronch trial design.

2.3 | Data analysis

Braun and Clark's six steps of thematic analysis[15] were used to analyse the data from both the focus groups and individual parental interviews. The author (JH) transcribed the interviews verbatim and used NVIVO to code the data and produce subsequent themes. Familiarization (step 1) with the data was achieved through transcribing, reading the transcripts and listening to the interviews several times. Initial codes were generated by JH (step 2) by identifying key words that appeared in the interviews and were written as a list of singular words. Following this, two researchers (JH and JML) collated codes into sub-themes (step 3) (Supplementary Material 3). The themes were then reviewed (step 4) and refined (step 5). These final stages involved discussion and debate between the two researchers (JH and JML) to reach the final themes and sub-themes. The final step is production of the report which is presented in the findings in this paper.

2.4 | Findings

Forty HCPs were approached for participation in the focus groups eight agreed to take part, while two HCPs were not able to attend the MS Teams meeting resulting in two focus groups with six HCP's (Focus group 1 had four participants; focus group 2 had three participants – one staff member attended both focus groups as they had to step out of the first halfway through). Staff had a mean age of 43 years, with a mean length of service in PICU of 16 years. Five of the six were actively involved in current research projects. The focus groups consisted of two PICU consultants, two senior physiotherapists, one senior staff nurse and one clinical research nurse. Five parents expressed an interest in taking part in the interviews, only two parents of one child agreed to participate. Both parents were interviewed together upon request.

Four main themes were identified with sub-themes from the staff focus groups. These were: (1) Creating staff engagement; (2) Education to deliver NAVA; (3) Normalizing NAVA in clinical practice; and (4) Creating meaningful study outcomes. The data collected from the parent

interviews has been described in a separate theme (5) Support of parents during the trial. Themes are described below with illustrative quotes presented.

2.5 | Creating staff engagement

The health care professionals felt that engaging all staff in the research study development, set up and data collection was key to successfully implementing and running the study. There are three sub-themes included in this theme: (1) Benefit of knowing the study details, (2) Inclusivity through multidisciplinary engagement and (3) Prioritization of study support.

2.5.1 | Benefit of knowing the study details

HCP's felt that the wider team were not as aware as they could have been about the study and that staff were perhaps not aware of the study details. This was related to bedside staff involvement and education related to the use of NAVA.

> Not that they were doing the study for the whole time, but it's just that the wider awareness and I think you know, if it was a really big study, you know there would be a lot of posters coming up, a lot of education sessions for the wider team. And I just think that point about. You know the the wider education, I think we missed an opportunity to, you know, educate the entire workforce or try to disseminate the. You know, this research study is coming for the next few weeks or few months because because we you may automatically just get more and more enthusiasm and you know, get more people involved. FG2 P1

Cost of NAVA was seen as an important factor to communicate and help engage practitioners in the study and in the use of NAVA. It was felt that bedside staff seem to view NAVA is an expensive mode of ventilation with unknown benefit in paediatric patients.

2.5.2 | Inclusivity through multidisciplinary engagement

Amongst the focus group participants there was discussion around the inclusion of all disciplines within research in the PICU but also within the NAVABronch study. As this is a respiratory study, it was felt that it affected the wider team. Participants felt HCPs should be involved in the decisions as to what studies should take place, be involved in developing the study protocol, study education and data collection processes. They felt that their expertise should be acknowledged within the area in which they work regarding research in PICU. Currently it is felt that this is primarily led by the medical team.

> .... there seems to be a lack of drive for the MDT [multidisciplinary team] to be involved in research. FG1 P3

2.5.3 | Prioritization of study support

Participants highlighted that logistics and support for the study set-up was sometimes challenging. This was regarding availability and access to equipment and staff availability when eligible participants were admitted. It was also felt that research was not seen as an essential part of service delivery.

> I think one of the sort of challenges that we have is its it's not seen as sort of essential part of the service so its always erm there's a little bit of a well how do you actually introduce it, prioritise which study is gonna be started and you know certain things. FG1 P2

2.6 | Education to deliver NAVA

Participants felt that education during the study and after would empower practitioners to utilize NAVA alongside clear guidelines. They expressed that education in relation to NAVA would ensure that HCPs understood how it worked, what the benefits are and how to apply it in specific patient groups. The three sub-themes identified were: (1) Informative guidance, (2) NAVA Education as a study intervention, (3) NAVA Education for clinical practice.

2.6.1 | Informative guidance

The feeling was that current guidance was lacking and needed detail as to the set-up of NAVA in specific patient groups to guide bedside staff. Specific patient groups for example may require different parameters, so making that clear to staff would be important instead of it perhaps being a one size fits all guideline.

> And I think that that the unit has come a really long way with regards to the fact that we now have guidelines that are accessible for people to look at but those guidelines are very dry, very operational and are not actually on the educational side of things. FG1 P3

2.6.2 | NAVA education as a trial intervention

Participants highlighted that a larger scale study would require extensive education of the wider team. They felt this could be achieved by

having bedside staff 'champions', specific staff that were very knowledgeable about NAVA and the trial. This was felt to be important in enabling bedside staff to ask questions and troubleshoot when their patients were receiving this mode of ventilation.

> … and I think that also as well as an education package probably your going to have to have someone on the individual units very highly trained that can go and be a person that can be like ask me any questions. FG1 P3

It was felt that new members of the HCP team as well as existing members would benefit through the study education on NAVA as either a new concept or as refresher training. In turn they felt this would reinvigorate interest in the use of NAVA at the bedside.

2.6.3 | NAVA education for clinical practice

Participants felt that even if a larger trial did not find anything significant, a need for education regarding the use of NAVA at the bedside for all staff was still a necessity because of current lack of knowledge and confidence. Education was a key issue that all staff discussed and felt was crucial in the success of any intervention. Establishing standards of care in different patient groups would be helpful in ensuring staff became familiar with its use.

> so you know it would be really nice if if you would take this study and say even if it doesn't really demonstrate a strong signal is that you'll be able to say actually if we put a standard of care for certain types of patients from the get go and that then drives that education er drives that familiarity everyone then really gets and its only when we really become used to it that the therapy is almost like routine do we completely fine tune it erm. FG1 P1

2.7 | Normalizing NAVA in clinical practice

Participants felt that the normalization of the use of NAVA and embedding it in the unit culture would increase exposure and confidence in its use by bedside staff. The sub-themes included: (1) A cultural shift, (2) Building confidence with (3) NAVA use and Maximizing clinical utility.

2.7.1 | A cultural shift

As NAVA works in a different way to conventional mechanical ventilation, it was recognized by the participants that a change in culture and how ventilation was thought about needed to occur to embrace it as a mode. The lack of understanding of how it worked amongst all HCP's they felt appeared to be a key barrier in its current use and understanding NAVA as a ventilation mode was crucial in its effective utilization. For example, they expressed that it is seen by some as a weaning tool rather than a primary mode of ventilation.

> Is can everyone just gets a NAVA probe stuck in at the beginning, which we can happen to use as an nasogastric tube? And actually in in part of their daily review you may say, well, actually let's just do an assessment of does NAVA give us any benefit? And I think that's the same thing as when you introduce like nurse monitoring or whatever is only when it becomes almost complete, standard of care can then people start really, really fine tuning it. And that's my feeling because otherwise it becomes its that nutty professor who's walking around. FG2 P1

They felt that ensuring NAVA is seen as a normal part of patient care was important. They expressed that this could be achieved by providing education from day 1, and this would be key to changing the culture. This initial investment in education would then ensure that practitioners could confidently teach NAVA and how it works at the bedside as it would be accepted practice.

2.7.2 | Building confidence with NAVA use

Confidence, or lack of, with NAVA was expressed by all participants as being a key requisite for successfully using NAVA at the bedside and within a research study. It was expressed that confidence was lacking in its use across all HCPs in the PICU with a small proportion of staff confident in its use. When those who were confident with NAVA were working NAVA was utilized; however, they felt that when someone less confident took over the care of that child conventional ventilation was often reapplied.

> sometimes nurses er had patients on NAVA as part of the study but then didn't feel hugely confident in what NAVA was or what they were meant to be doing about it not as part of the study per se but then about stuff the whole patient management so I think I was coming in as a kind of backfill and doing some of that education for those nurses that were bedside not from a research perspective but from the the equipment that was being used so I think there are some people on the unit that are very familiar and confident but actually when you look at the vast population of nurses that are bedside actually are very underconfident in the the overall management of patients on that piece of equipment. FG1 P3

2.7.3 | Maximizing clinical utility

Alongside a culture shift and increasing confidence, it was felt that NAVA technology needed to be a higher priority when ventilating

patients. HCP's have become comfortable with the conventional modes of ventilation that are utilized and also due to lack of education NAVA wasn't always utilized when and where it could have been beneficial, or it was used when nothing else was working.

> I think I don't think it's it's that new though it's it's been lingering around for a while and I think people that have sort of embraced it have embraced it all along even within a unit. So the units that agreed to have it come into their PICU's, there are certain champions within those teams usually that think about NAVA like why don't we try naval, where are the others kind of forget about it let alone units that haven't embraced it because it's too expensive or it's not for us? Or was the priority at all? FG2 P5

2.8 | Creating meaningful trial outcomes

The outcomes of the study need to be meaningful to practitioners, children and their families. The sub-themes here are (1) Clinically relevant outcomes and (2) Generalisability of study findings.

2.8.1 | Clinically relevant outcomes

It was felt important that the study outcomes for a larger study needed to be meaningful to both the clinical team as well as the child and families. It was felt that if this was to become a larger study, then this needed to be explored further to ensure that it had value for all involved in patient care. Participants felt that families and staff may have different views on what would be a meaningful outcome.

> you know this is this isn't just about length of care this isn't just about length of ventilation if we can show patient's on this mode are comfortable and ventilating well and wean quickly on it and actually if you've got a nasal tube and your NAVA probe is stuck down well you can get them out of bed and put them in a bouncer and have mum cuddling them in a sling because also your ventilation is going to upregulate with that increased energy demand that their gonna have from doing those other activities actually is that better for the mum and baby bonding scores is that gonna be better for how quickly our patients get on their developmental milestones is that gonna have you know much wider … FG1 P3

2.8.2 | Generalisability of the trial findings

As this was a feasibility, study staff felt that perhaps some of the study outcomes or measures were specific to the PICU in which it was conducted. Participants expressed that sedation practices were different in other PICU's, and therefore, this would need further thought as to what the measurable outcomes would be and what would be relevant to other PICU's.

> so I think there really important questions and there measures that other units would understand and be able to say is this method applicable to my erm to my unit or somewhere else. FG1 P3

2.9 | Support of parents during the trial

In the parent interviews motivation to take part in the study was discussed along with the unexpected stress and support required for parents during this time. The three sub-themes identified here are (1) Motivation to take part in the trial, (2) Parental stress and (3) Parents understanding of the trial procedures.

2.9.1 | Motivation to take part in the trial

Parents were motivated by doing something for other children and giving something back. Alongside this they felt that there were benefits from their child taking part and that they became involved in their care through participation. They felt that they were part of helping move practice forward. However, they expressed that the decision-making process was not an easy one as up until this point they had not had to make any decisions about their child's treatment.

> Well it was a mixture of things I think for us it was we were very conscious that she was getting good care uh and erm we wanted to be able to give back but also the benefits of the NAVA what alternative ventilation thing erm it seemed to it seemed to be beneficial in her case so. I1 P101

2.9.2 | Parental stress

The key issue that participants highlighted in the interview was the distress of their child when sedation was weaned, and the child becoming more awake. Parents found this very difficult, and they felt unprepared for it. There was a point when parent's questioned whether they had made the right decision.

> Um I got really the thing that really stressed me out I think (dad), (dad) was a bit more engaged in the while study thing I think well I spent a lot of time sitting in the room with a breast pump but erm I think the thing I hadn't anticipated was cos they had to lighten her sedation and so she suddenly seemed very distressed. I1 P102

When their child was asleep the parents felt reassured that the child was pain free and comfortable but when awake they did not feel that this was necessarily the case. This led them to question whether taking part in the study was the right decision. Parents could not remember whether anyone had explained how their child may behave when they woke.

> And I think the most distressing thing at that point was that oh we've chosen something and what if it was the wrong thing and... I1 P102

2.9.3 | Parents' understanding of the trial procedures

The parents had a good basic understanding of how the ventilator worked and what it may mean for their child. They mentioned the probe and replacing the Nasogastric tube and that the sedation would be lightened. They also relayed some of the potential benefits of the mode of ventilation.

They felt that the information they received from the study team was clear and informative and that all aspects had been explained in advance.

> Yeh so from what I from what I remember there was there was gonna be an extra sensor put down erm which would rest on her diaphragm and would be able to erm anticipate when she herself was going to breathe and and reducing the frequency of that so so I think the other type of ventilation that she was on was a sort of a breathing in and out always erm in a particular rhythm. I1 P101

3 | DISCUSSION

The aim of this study was to explore the experiences of parents and HCPs involved in the NAVABronch Trial. The main findings from the study were the need for education regarding NAVA for all HCPs which would lead to increased confidence, better guidance around the use of NAVA and the need for NAVA to be normalized and embedded into the unit culture. Inclusivity of all HCPs in contributing to research and research priorities was also discussed. Parents identified the need for further support around preparation for what may happen because of the interventions, particularly the weaning of sedation. Parents appeared to have a good understanding of the intervention and were motivated by future patient benefit and benefit to their own child.

The data collected from participants of the NAVABronch trial included 13 participants. However, because of the impact of COVID-19, the participants interviewed were few and there was a gap between the start of data collection for the RCT, and the data collection for this study which may have impacted recall. However, there is pertinent and important information discussed that relates to literature that is already available and this will be crucial in informing a larger RCT.

Time and resources are often a reported barrier to involvement in research from an HCP perspective. In turn, a lack of education and support regarding research as demonstrated in Scala and Price's[16] systematic review of nurse's engagement with research also has an impact. The review highlighted that leadership and educational opportunities were key in engaging nursing staff in research activity as was felt by the participants in our study. Research priorities and prioritization of studies were discussed, with a view to it being the choice of a select few rather than the majority and with the medical team being the main driving force. There have been recent national scoping exercises to understand the research priorities in recent years from doctors, nurses, allied health professionals and families within PICU[17,18]; however, whether this happens in individual PICUs is unclear. Priorities are often different for HCP's and families, with HCP reportedly focusing on clinical outcomes and families on the long-term outcomes.

A study conducted by Deja et al.[12] reviewed acceptability of a UK-based trial (FEVER) by surveying parents and staff pre, during (just parents) and post study. Interestingly some staff perspectives changed with regard to the intervention post study. This was in part because of collaboration between all clinical staff during the planning stages and during the trial where they were able to observe the impact on the patients from the intervention. This helped alleviate concerns about the study as it involved a change from usual practice. Interestingly, this collaborative practice is something that was regarded as important in our study findings. The acceptability study[12] also highlighted that the health care team preferred education delivered by the trial team rather than colleagues, and it was found that scientific knowledge regarding the study was improved if it had been provided by the study team as opposed to colleagues. Related to this was the discussion in our study around knowledge and confidence with NAVA which was seen to be lacking across all health care practitioners. It has been demonstrated that implementing evidence-based practice into PICU is challenging. PICU is a complex environment, the need for a change needs to be explicit and practitioners need to be ready for the change.[19]

An objective of the study was to understand parent's motivation for taking part in a research study. One of the most common explanations for parents consenting to their child taking part in a study is to benefit others and to benefit themselves and their child.[11,20–22] This is echoed by the findings in our study where parents expressed a wish to help others and to benefit their child. A study by Helgesson et al.[23] explored what parents in Sweden find important when deciding to take part in clinical trials. The most important information that they based their decision-making on was practical information about what will be involved if their child was to take part. In another study looking at participation of children in randomized controlled trials,[20] decision-making involved the parent's own knowledge and previous experience, their child's current health and staff attitudes and communication about the research itself was identified as important. Many

children admitted to PICU with bronchiolitis have been previously well or have not had a previous intensive care admission; therefore, knowledge of the environment and the equipment used within it may be quite limited.

When parents were interviewed, the main event causing them distress was when sedation was reduced, and their child began to wake. This concern was echoed in the FEVER trial acceptability study[11] where parents became concerned when sedation was weaned that medication was not available for their child's comfort and wished to withdraw their child from the study. This was echoed in a study exploring stressors for parents in PICU where the child looking like they were in pain was ranked as the fourth highest stressor.[24] In Harvey et al.'s study conducted in the USA (2017),[22] parents discussed consenting to the study procedures, but perhaps not being fully prepared for what the procedures would involve. This was often because of lack of understanding and not fully thinking through the emotional impact of the study. These findings suggest that discussion with parents around weaning from sedation and waking patients and how they may present is needed. Dahav and Sjostrom strand's study[25] exploring parent experiences of PICU in Sweden states that parents felt it was important for everything to be explained before a procedure or change took place.

4 | LIMITATIONS

A limitation of the study was the small numbers of participants that took part in the focus groups and that only two parents of one child participated in the interviews and these were interviewed together upon request. The impact of COVID-19 affected the ability to continue any research activity and necessitated amendments in the study protocol that required ethical approval. Staff were also still impacted by COVID-19 with high workloads. Therefore, participation in this study by HCPs may not have been a priority for them during the COVID-19 pandemic. Despite these challenges the data collected is relevant and informative for a larger RCT.

As is often the case with focus groups and interviews, participants are likely to have an interest in the topic under discussion. All staff that participated had an interest in research and a number had held or currently held a post that involved some aspect of research. It would have been interesting to understand the views of those that did not have this experience or interest. During analysis there may have been the opportunity to introduce bias as the researcher had an interest and knowledge base around the intervention however a second researcher analysing the findings helped negate this.

5 | CONCLUSION

Our study indicates that staff and parents have no concerns regarding the study procedures themselves for the proposed RCT. The focus groups with HCPs and interviews with parents have been informative. A number of considerations have been suggested when developing a larger RCT to test the effectiveness of NAVA in infants with acute viral bronchiolitis: (1) Collaboration amongst HCPs and families to ensure meaningful outcomes, (2) A well-developed and informed education package to inform the study and engage HCP with a view to maintaining education post study, (3) The development of informative guidelines and recommendations for which patients would be suitable for NAVA and (4) Further research looking at parent experiences of weaning sedation and child's waking in PICU.

CONFLICT OF INTEREST STATEMENT

There are no conflicts of interest from any of the authors.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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SUPPORTING INFORMATION

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

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