PROFESSIONAL DOCTORATES

Unheard Voices: Children and Parents' Experiences of Respiratory Assistance

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Unheard Voices: Children and Parents' Experiences of Respiratory Assistance

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North Wales Clinical Psychology Programme

Thesis submitted in partial fulfilment of the degree of Doctor of Clinical Psychology

June 2017

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Acknowledgments

I would firstly like to thank the participants for their willingness to share their highly emotive stories with me - I have been truly inspired by their resilience. I would like to thank the team at Great Ormond Street Hospital and in particular Jo Cooke, for their support in recruitment and to Dr Jo Wray and Dr Liz Whitehead for their knowledge and guidance throughout. Mo- you know who you are, thank you so much, I would never have been able to do this without you. Finally, I would like to say a massive thank you to my family who have supported me unconditionally throughout my training. Words can't express how grateful I am to you for keeping me smiling, motivated and always putting me first.

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Thesis Abstract

This thesis explored children and parents' experiences of respiratory assistance. A systematic literature review synthesised qualitative studies exploring children and adolescents' experiences and perceptions of living with respiratory assistance. Most children recognised the important function of respiratory assistance on their physical health. They spoke of positive social experiences and some challenges they had experienced. Children discussed their experiences of healthcare providers and offered suggestions, based on their experiences, for future service provision. The review concludes that children's perspectives provide a valuable contribution to the growing evidence base, however more in-depth explorations are needed.

A second paper presents findings from an empirical study, qualitatively exploring parents' experiences of caring for a child with a tracheostomy. This study was guided by the principles of interpretative phenomenological analysis (IPA), with semi-structured interviews conducted with seven participants. Three super-ordinate themes emerged from the data; all interlinked and signify the complex and emotional trajectory of caring for a child with a tracheostomy. The findings raised questions as to whether parents' emotional needs are being met and suggest parents could benefit from additional support from healthcare providers. Implications for clinical practice and recommendations for future research, particularly, longitudinal studies exploring parents' adjustment to tracheostomy care are discussed. The third paper discusses implications for clinical practice that arose from the literature review and empirical paper and emphasises how the thesis explored an understudied area. This thesis concludes with personal reflections on conducting this valuable research.

Chapter 1 – Literature Review

Children's and Adolescents' Experiences of Living with Respiratory Assistance: A Systematic Review of Qualitative Studies

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Abstract

Objectives To date, no review has focused exclusively on the child's reported experience of living with respiratory assistance. The objective of this study was to review empirical studies exploring children's experiences and perceptions of living with respiratory assistance.

Methods Literature searches (1980-2017) of databases (PubMed, Web of Science, PsycINFO and CINAHL) resulted in 1,750 references. Studies were included if they used qualitative methods to explore children's (under 18 years) experiences of living with respiratory assistance, such as tracheostomies and/ or those who were ventilator dependent. Studies that focused only on parents, carers or other family member's perspectives, included only adults, used only quantitative methods or were not published in the English language were excluded. Reference lists of relevant studies were reviewed. Each study meeting criteria was reviewed and assessed and key themes were extracted and grouped.

Results Seven studies were included in this review. Synthesis of the data identified four main themes: children's understanding of respiratory assistance, identity, social experiences and service delivery. Most children recognised the important function of respiratory assistance on their physical health. They spoke of positive social experiences and some of the challenges they had experienced. Children discussed their experiences of healthcare providers in terms of what was helpful to them and provided suggestions, based on their experience, for future service provision.

Conclusion This review identified the valuable contribution children's perspectives make to the growing evidence-base in this area. Further in-depth explorations are needed to provide greater understanding about children's experiences of living with respiratory assistance. Research exploring the journey of a young person with respiratory assistance is important in developing knowledge and service provision in this field.

Keywords: Respiratory assistance, Ventilator-dependent, Children, Adolescents, Perspectives, Experiences

1. Introduction

Increasing numbers of children with chronic medical conditions are now surviving, largely because of medical advances and improvements in medical technology. Previous records have estimated that around 100,000 children in the USA [1] and approximately 6,000 children in the UK are dependent on medical technology [2]. These figures, however, are outdated and most likely underestimate the number of children who, in 2017, are dependent on medical technology.

Children requiring respiratory assistance comprise a sub-group of this population and include children who require ventilator support, tracheostomies, and mechanical ventilation to either assist with or replace spontaneous breathing. The number of children requiring respiratory assistance is less clear. Data from 1997 estimated that 17,000 children in the USA required a tracheostomy [3]. In the UK it was estimated in 2009 that approximately 1000 children were respiratory dependent [4]. For the purposes of this review the term "respiratory assistance" will be used to encompass all terminologies used to describe types of ventilation including, "artificial respiration", "tracheostomy", "tracheotomy", "respiratory dependent", "ventilator dependent" and "non-invasive ventilation".

The needs of a child requiring respiratory assistance vary depending on a number of different factors [5]. Medical diagnoses, age at onset and frequency of need for respiratory assistance all vary; for some children, respiratory assistance may be required intermittently throughout the day whereas others require continuous respiratory assistance throughout the day [6]. Children require a large amount of support from trained caregivers in the management and maintenance of the medical technology used to support their breathing. Improvements in medical technology mean that these children, who previously would have received most of their care in hospital, can live at home with their families with support from

trained caregivers, usually either family members or a nurse. In most cases it is the parent who is the trained and primary caregiver for the child, and research has focused on the parents' or carers' perspective of caring for a child with respiratory assistance [7] or used parent or carer reports to describe the child's experience of living with respiratory assistance [8]. The importance of including the child's perspective in health-related research is well recognised [9]. Eliciting the child's perspective of living with respiratory assistance is important to develop understanding and improve service delivery for this group of children.

The few quantitative studies that have been undertaken with this population have found that ventilator-dependent children reported significantly lower overall health quality of life compared with children of the same age and that children over 12 years of age were significantly less satisfied with their daily lives than younger children [10][11]. These studies have highlighted the need for more research capturing the experiences and perspectives of children.

The focus of this review is on published qualitative studies addressing the experiences of the child with respiratory assistance from the perspective of the child themselves. To date, no review has focused exclusively on the child's experiences and views of living with respiratory assistance. A previous review [12] explored the views and experiences of ventilator dependent children and their parents. It was not carried out systematically and focused primarily on reports of parents' experiences rather than on those exclusively addressing the perspective of the child. The focus of the systematic review reported here is on qualitative research exploring children's experiences of living with respiratory assistance. For the purposes of this review the terms "child", "children" and "young person" will be used to encompass any child, adolescent, and young person aged under 18 years.

2. Methods

2.1 Search Methods

The search which informed the review of the literature was undertaken in April 2017 and the strategy is shown in Table 1. This was applied to key electronic databases to identify papers published between 1980 and 2017. In addition, the reference lists of the published papers were searched. The inclusion and exclusion criteria are shown in Table 2.

Table 1 *Literature Search Strategy*

Databases searched	PubMed Web of Science PsycInfo CINAHL
Limits	1980- (April) 2017 Published in English
Search terms	(child* OR adolescen* OR school-age* OR teenage*) AND (tracheostom* OR tracheotom* OR "artificial respiration" OR "ventilator dependent" "respiratory assistance" OR "non-invasive ventilation") AND (experience* OR view* OR perspective* OR "quality of life" OR impact*)
Additional Sources	Citation lists

Table 2 *Inclusion and Exclusion Criteria*

Inclusion	**Exclusion**
Studies published in English	Books/book chapter
Between 1980-April 2017	Focused exclusively on parents', carers or other family members' perspective of the child's experience
Participants under 18 years	Not based on empirical work
Based on self-report of living with respiratory assistance	Participants aged over 18 years
Qualitative methodology	Quantitative methodology exclusively

2.2 Search outcome

Details of the search are provided in Figure 1. Following the removal of duplicates, initial database searches resulted in the identification of 1,288 papers. Initially titles were screened to determine their relevance and then abstracts were screened to determine whether they met the inclusion criteria. Full texts were obtained for those papers meeting the inclusion criteria and any cases when it was not clear from the abstract whether the article should be included. In cases where full texts were unobtainable authors were contacted. Papers meeting the criteria were read in full and their reference lists reviewed for further studies fitting the inclusion criteria. This resulted in 7 studies for review.

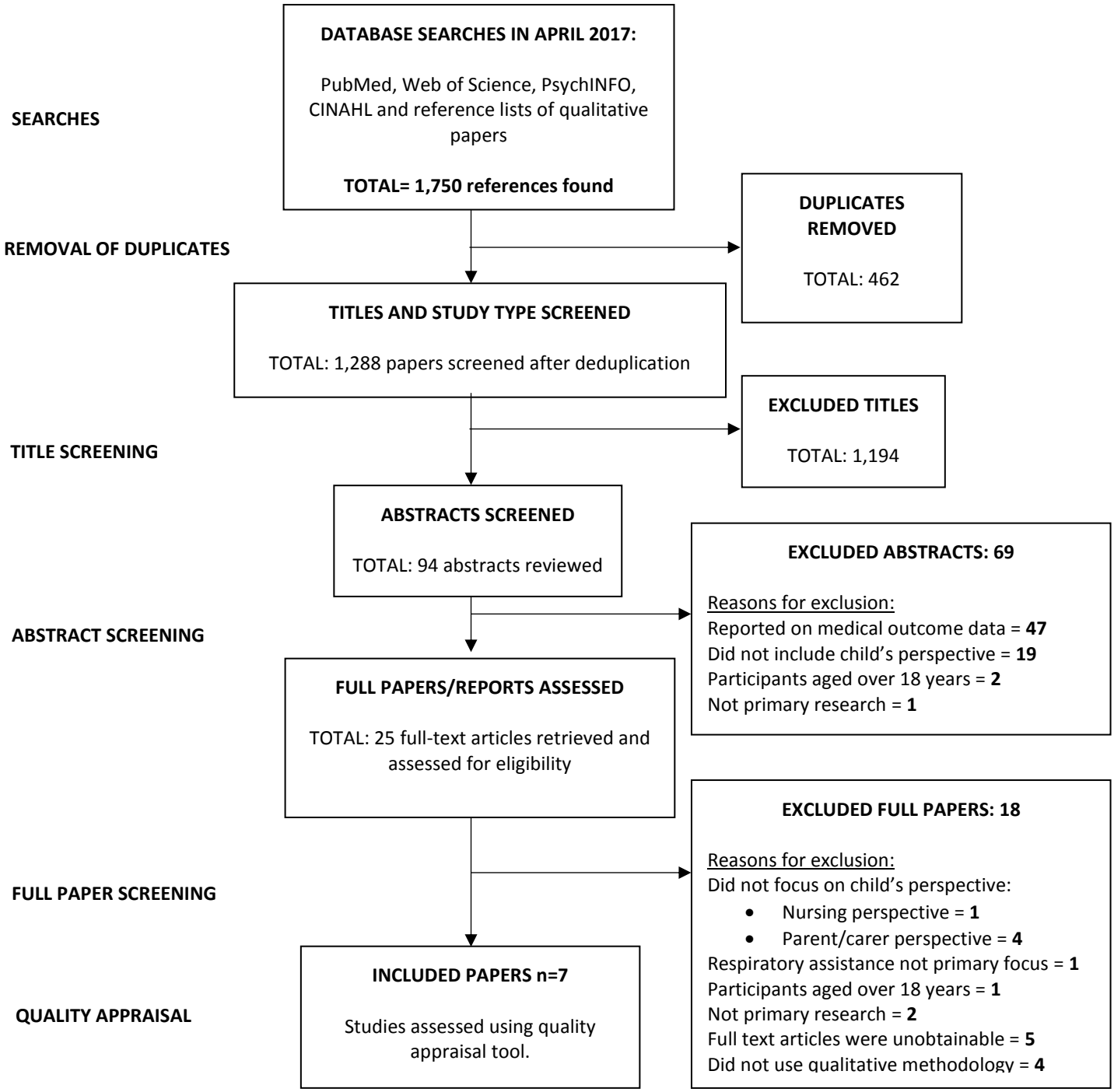

Figure 1. Flow diagram of studies retrieved through database searches.

2.3 Quality appraisal

The critical appraisal of the studies was guided by the Critical Appraisal Skills Programme tool for qualitative research [13] and the methodological rigour of each paper was assessed using a quality assessment form (see Table 3) used by experienced reviewers of qualitative research [14]. The guiding criteria for qualitative studies aim to ensure rigour, credibility and relevance of the findings. An overview of the studies included and the quality appraisal rating can be seen in Table 4.

Table 3. *Quality Assessment Criteria (adapted from* [14]*).*

Quality assessment criteria	Fully met	Partially met	Not met	Not applicable
1. Clear aims/research question				
2. Design appropriate for research question				
3. Recruitment process given				
4. Participants appropriate to research question				
5. Ethical approval/informed consent given				
6. More than one perspective on research question				
7. Data collection method adequately described				
8. Data sufficiently detailed for research question				
9. Researcher bias has been addressed				
10. Clear description of analytical method				
11. Clear description of how results derived from analysis				
12. Analysis not biased by researcher (more than one analyst)				
13. Contradictory data considered				
14. Findings presented in sufficient detail				
15. Findings discussed in context				
16. Implications discussed				
17. Limitations of study discussed				

To assess the methodological quality of each study, items on the quality assessment tool were scored as follows:
Items identified as “fully met” were given a score of +1, items identified as “partially met” were given a score of +0.5, items identified as “not met” were given a score of -1 and items identified as “not applicable” were scored as zero.
The scores were then totalled and percentages were calculated by dividing the total by the number of applicable items.
Percentages were rounded up to nearest whole number.

Author (Year) Location, Quality appraisal (%)	Participant, Sample Size	Research question/aim	Methods	Limitations
Earle, Rennick, Carnevale, & Davis (2006) Canada [6] 53%	5 children aged 4.5-17 years (3 females, 2 males) who had been home ventilated for at least 2 years. Purposive sampling.	Explore children's subjective responses to home ventilation and their perceptions of its impact on their daily lives.	*Multiple case-study approach.* Participant observations during clinic visits, hospital admission, at home and at school and audio recorded semi-structured interviews with the children. Open coding technique followed by the development of themes which were validated during subsequent interviews.	Small sample size across a large age range. Lack of detail about topic guide/questions asked during semi-structured interview, the length of time of the interview and who was present. Unsure if researcher bias has been accounted for by involving multiple analysts. Implications of findings not discussed.
Kirk (2010) UK [9] 53%	28 young people (8-19 years, 17 males, 11 females) requiring continuous support of one or more medical technologies. 14 of these 28 participants used either tracheostomy, mechanical ventilation, or oxygen therapy and only these were included in the review.	Explore how medical technology was experienced and constructed by children and how it influenced their identity and social relationships.	*Grounded Theory Approach.* Interviews were conducted, and some participants' drawings were used to facilitate discussion. Data and field notes were transcribed then analysed, codes developed and the relationship between different themes were explored.	Limited information regarding medical technology e.g. length of time participated support by medical technology. Parents were used as key informants for children with communication difficulties therefore it was unclear if the findings from these children reflected their views and experiences. Unclear if data was analysed by more than one researcher. Limitations not discussed.

Author (Year) Location, Quality appraisal (%)	Participant, Sample Size	Research question/aim	Methods	Limitations
Noyes (2000) UK [5] 65%	18 VD young people (6-18 years, 8 females, 10 males). Purposive sampling	Explore the views and experiences of VD young people, and to ascertain their health, social, environmental and educational needs.	*Phenomenological approach.* Face-to-face interviews, photographs were taken of their environments and participants supplied photographs and school work. Talk and draw/play techniques used by some participants. Data analysed using thematic analysis and an adapted framework for assessing patient-centre needs.	Exclusion/inclusion criteria for participants unclear., e.g. length of time the young person had been VD. Researcher bias not addressed. Unclear if more than one researcher analysed the data. Few quotations from participants included in results –lack of clarity around how the results derived from the data.
Noyes (2006) UK [15] 71%	35 VD young people (6-18 years) Purposive sampling.	To describe VD children's (and their parents') experiences and meanings of the child's health and quality of life.	*Heideggerian phenomenology approach* across two phases: initial exploratory work and then in-depth case studies. Transcripts, interview notes, observations and drawings were analysed using a "framework" approach and principles from Heidegger's hermeneutic circle.	Participant demographics unclear (e.g. gender). Limited information about topic guide for interview. Participants' difficulty in articulating their experiences. Parents being present in some of the interviews- possibility of their presence influencing the child's response.

Author (Year) Location, Quality appraisal (%)	Participant, Sample Size	Research question/aim	Methods	Limitations
Sarvey (2008) USA [16] 88%	9 VD children aged 7-12 (4 male, 5 female) who were VD for a minimum of eight hours each day. Purposive sampling.	To obtain the first-person perspective, from individuals who are VD in order to understand what life is like living with a ventilator.	*Phenomenological approach:* Audio-taped interviews (lasting 30-75 minutes), later transcribed and analysed-meaning units clustered using hermeneutic analysis, following this a thematic structure was developed.	Lack of detail around location of interviews and detailed exclusion and inclusion criteria of participants. Potential influence of researcher bias not discussed.
Spratling (2012) USA [17] 91%	11 adolescents (5 males, 6 females) aged between 13-18 years who required respiratory assistance Purposive sampling.	Explore the experiences of medically fragile adolescents who require respiratory assistance.	*Interpretative phenomenology.* Audio recorded semi-structured interviews. Interviews and field notes transcribed, coded, categorised, and evaluated for emergent themes and then emerging patterns. Findings were validated with the research team and participants.	Lack of detail about what was asked and length of time of interview. Participants ability to articulate their experiences as result of communication difficulties/development delays.
Spratling, Minick, & Carmon (2012) USA [18] 85%	5 school-aged children (1 female, 4 males) aged between 6-11 years who had a tracheostomy for at least 1 year. Purposive sampling.	Explore school-aged children's perspective about living with a tracheostomy.	*Interpretative Phenomenology.* Audio recorded semi-structured interviews (20 minutes). Data were transcribed, reviewed for accuracy and coded with evaluation for emerging themes by research team. Field notes and a reflective journal were included.	Parents present in some of the interviews One participant had been de-cannulated prior to interview. Researcher's knew some of the children/families (provided direct care)-potential for contamination.

Table 4. Details of studies included in the review.
Abbreviations used: VD, ventilator-dependent

2.4 Included studies

Seven studies were included in the review, see Table 4. When combined the studies represented the views of 97 children. Across all studies the ages of the children ranged from 4 to 18 years of age. The studies mainly used a type of phenomenological approach (5 out of 7 seven studies) with interpretative phenomenological analysis (IPA) and Heideggerian phenomenology being reported. Grounded theory and a multiple-case study approach were used in the two other studies and no specific methodology was reported as being applied to the analysis in the multiple case study. The methods used in gathering the data included interviews (semi-structured), field notes, drawings, photographs, observations, and questionnaires.

The quality of the studies varied and limitations included difficulties with the participants' ability to articulate their experiences, the inclusion of parents in interviews and the potential this had to contaminate the results. In addition, several studies did not report on the length of time the participants had had respiratory assistance, making it difficult to establish differences across the trajectory of time living with respiratory assistance.

3. Synthesis

Thematic synthesis was used to synthesise the findings [19]. Quotations for participants and authors' comments under the headings "findings" or "results" from each paper were copied in to a separate word document for coding. The thematic synthesis involved three stages as outlined by Thomas and Harden [19]. Firstly, quotations and authors comments were read several times by the reviewers and coded line by line for each study. This line by line coding allowed the translation of concepts from one study to the next. After this was completed, all the codes from each study were compiled together. The reviewers looked for

similarities and differences between the codes and they were grouped together accordingly. The second stage of the thematic synthesis involved developing descriptive themes which captured the meaning of groups of initial codes. This was completed by one of the reviewers and then discussed with the other two reviewers.

For the final stage of the synthesis, the descriptive themes that emerged were considered in the context of the aim of this review, seeking to explore the experiences of children living with respiratory assistance. The reviewers inferred barriers and facilitators to living with respiratory assistance from the views the children were expressing and considered these in the context of service delivery. Each reviewer first did this independently then as a group. This discussion allowed more analytical themes to emerge. This resulted in the development of the four main themes with associated sub themes.

Data from each study were used to construct a list of key themes. Themes were generated through the authors' comments about the data and quotations from participants. The themes from each study were organised into main themes and sub-themes. These themes evolved and changed throughout the process. This resulted in the following four main themes with associated subthemes:

1. Understanding respiratory assistance (Sub-themes: Function and Acceptance; Children as Experts);
2. Identity and respiratory-assistance (Sub-themes: Perceptions of Self; Self-Esteem; Future Ambitions);
3. Social Experiences and Living with respiratory assistance (Sub-themes: Support; Social Isolation; Never Alone);
4. Service Delivery (Sub-themes: Relationships with Healthcare Providers; Awareness; Education).

3.1 Understanding of Respiratory Assistance

Most children demonstrated a sophisticated level of understanding of the function of the respiratory assistance supporting them. Some children expressed an acceptance of the respiratory assistance, whereas other children described the negative impact.

3.1.1 Function and Acceptance

Respiratory assistance provides support with breathing. Difficulties breathing are described as an, "exhausting and debilitating experience" (p.396, [15]). In a number of the studies children's reports of the impact the respiratory assistance had on their physical health was described [6,9,15–17]. Authors found that, irrespective of age or reasons for ventilation, children reported that respiratory assistance helped them to breathe [6], helped with making them feel better [15] and helped them stay alive [9]. In each of these studies the children were able to recognise that the medical technology served an important function for their health and survival and also contributed to their overall quality of life, enabling them to do the things that would not be possible without respiratory assistance.

In the study of Earle and colleagues [6] some children reported a sense of acceptance towards their respiratory assistance. Similar findings were also reported with adolescents who said that they found their respiratory assistance to be helpful in making the most of their daily lives [17]. Although it was unclear whether this acceptance was related to age or the length of time with respiratory assistance, it was suggested that children appeared to be more accepting of their respiratory assistance when it was not visible, for example when it was only required during sleep [6].

Some children described negative experiences of respiratory assistance. In one study a child described a feeling of being "pulled away from others" when being attached to the

ventilator (p.194, [16]). In another study, a child reported the experience of being ventilated by a machine as a source of physical pain and discomfort [9].

3.1.2 Children as Experts

Children with respiratory assistance require a large amount of medical care. Often their daily lives revolve around medications, self-catheterisation, having their airway suctioned and transporting ventilator equipment. In a number of the studies the children demonstrated a high level of knowledge with regard to the medical technology supporting them [6,9,16]. In the study of Sarvey [16] all of the participants were able to describe what machine they used, how it worked and what was required to keep it functioning. The children demonstrated a level of expertise in their respiratory assistance. In one study all of the children were described as being knowledgeable about their medical care [6] .

3.2 Identity and Respiratory Assistance

Children strived to be seen as “normal” and discussed their hopes and aspirations for the future. Mixed findings were reported in relation to children’s self-esteem.

3.2.1 Perceptions of Self

A core finding from this review is that a number of children reported that they wanted to be seen as a person, with interests, abilities and experiences separate to their respiratory assistance [6,9,15–17]. In Sarvey’s study [16], the children reported that they believed others viewed them as “different”. A common finding was that children saw the respiratory assistance as one part of their lives and wanted to emphasize that they lived “normal”, “ordinary” lives [9,16].

Children frequently reported seeing themselves as similar to other children of their age. Children emphasised their "normality" by making comparisons to other children their age and of their experiences of playing with siblings and the activities they took part in [15,16].

Challenges to identity development were reported by a number of the children [9,16,17]. Some of the children reported that the constant presence of nurses made it difficult for them to be themselves [17] and other children viewed not being able to be left alone as intrusive [16] and feeling like they had lost their privacy [9]. In Spratling's study [17] some of the children described the importance of healthcare workers, such as nurses, seeing them as individuals rather than focusing solely on their medical needs.

The visibility of respiratory assistance and identity were points of discussion in two of the studies [6,9]. For some children requiring respiratory assistance at school, whether to reveal or conceal their need for medical technology was not a choice that they had. Children whose respiratory assistance was not always visible described managing their identity by being selective about who to disclose their medical needs to [9]. As discussed previously, in Earle's study children's acceptance of their respiratory assistance appeared to be linked to whether it was visible to others, suggesting that not appearing "different" to others was an important factor in managing their identity [6].

These findings indicate that for children with respiratory assistance, a key part of their identity work focuses around a desire to be seen as "normal" and similar to other children, rather than defined by their physical health difficulties.

3.2.2 Self-esteem

Children with respiratory assistance reported mixed findings in relation to self-esteem

[5,10,15,16]. In one study [16] it was reported that all participants in the study viewed themselves as people of "worth to themselves and others" (p.193) suggesting that the children valued themselves. In contrast, other studies have found that children with respiratory assistance report low self-esteem [5,15]. In Noyes's study [5] the children, who had spent extended periods of times in hospital, spoke about not feeling "valued as part of society" (p. 1211).

3.2.3 Future ambitions

Children's hopes for the future and their aspirations were discussed in a number of the studies ([6,9,17]. In one study [6] some children's hopes focused on aspects separate to their respiratory assistance such as career ambitions, whereas for others it was related to becoming less dependent on respiratory assistance, illustrating that the challenges children face with respiratory assistance did not always appear to impact on their future hopes and aspirations. Achieving independence is a normal developmental milestone that young people work towards, typically during adolescence [20]. Similarly, in Kirk's study [9] children of different ages reported a goal of "living an ordinary life" with some children reporting their aspiration to be able to live independently and to have children. Comparable findings were reported in a study of eleven adolescents with respiratory assistance, and the authors suggested that striving for independence was of even more importance for an adolescent with respiratory assistance than for healthy adolescents [17].

3.3 *Social experiences and living with respiratory assistance*

Friendship groups played an important part in supporting children however restrictions to activities and frequent medical input limited social experiences and impacted

on personal privacy.

3.3.1 Support

A common finding was the high value the children with respiratory assistance placed on their social networks, especially friends at school [6,9,17,18]. Children of different ages valued their friendships, describing them as supportive [17], a source of companionship [18], and as being one of the things that "made them most happy" (p. 277, [6]). In Earle et al.'s study [6] the children described reciprocal relationships; helping each other with class work and spending time together outside of school.

Friends had an important role in the identity development of children with respiratory assistance [9,17]. Children reported that friends were supportive in helping with challenges they faced in relation to their identity and respiratory assistance [9] and similarly, they reported that friends supported the development of their sense of self [17].

3.3.2 Social Isolation

Children with respiratory assistance described experiences of social isolation [5,15–18]. In one study children related their sense of isolation to the restrictions being dependent on respiratory assistance placed on their ability to do things [16]. For many of the children, managing respiratory difficulties was an everyday activity, requiring frequent medical input and often necessitating spending extended periods of time in hospital. In Noyes's study [5], some of the older children had spent up to 6 years in hospital. This prolonged period in hospital meant that children missed out education, had limited social contacts and limited opportunities to play. A prominent theme emerging from this study was that children felt socially isolated [5].

Some children were aware of differences in their ability to engage in activities in comparison to other children. Children reported not being able to engage in activities that their friends were doing, such as nights out [16]. In Earle's study [6], the one child who required respiratory assistance at school reported feeling sad and frustrated with not being able to engage in activities with others. In another study [15] some of the children reported being socially excluded whereas one child, who required ventilation 24 hours-a-day, showed little awareness that their social life was any different to the social lives of other children. These findings suggest that exposure to other children without respiratory assistance influenced how children with respiratory assistance viewed their social life.

Children reported knowing few other people with similar health conditions [16,18]. Spratling [18] described how, when children were asked if they knew other people with a tracheostomy, their answers suggested they did not know of other children with similar health conditions and were alone in their experiences of respiratory assistance. This experience of being "the only one" was associated with the children feeling isolated from others [18]. In research exploring children's experiences of chronic illness, such as diabetes or asthma, a consistent finding has been the importance children place on relationships with other children with chronic illness (e.g. [21]). What is notably absent from the studies in this review is children's experiences of peer relationships with other children with similar health conditions.

3.3.3 Never Alone

Whilst children reported experiencing social isolation, they also described the seemingly contradictory feeling that their respiratory assistance meant that they were never alone [9,16,17]. Many children with respiratory assistance require nursing support in all their

activities, such as at school, at bed time and during social activities. Some of the children reported that the constant presence of a nurse made it difficult for them to be themselves [17] and viewed not being able to be left alone as intrusive [16] and feeling like they had lost their privacy [9]. Children reported that the constant presence of nurses made it difficult to spend time alone with family members and restricted their ability to engage in social activities such as sleepovers [9]. The experience and feeling of never being apart from others, typically carers, may have further exacerbated children's experiences of not being seen as "normal" and as discussed previously, the lack of privacy appeared to have made it more difficult for children to develop a sense of self.

3.4 Service Delivery

The attachment children had to healthcare providers served as a protective factor for several children. The role of nursing staff in providing education and awareness of respiratory assistance was highlighted. Such awareness raising could help to mitigate some of the difficulties experienced by children.

3.4.1 Relationships with healthcare providers

The quality of the relationship with healthcare providers was a theme in many of the studies [5,6,17]. Children reported valuing the input they received from the medical staff and the hospital, with some describing a strong attachment towards the hospital who supported their medical needs, viewing the hospital as a "home away from home" (p.276, [6]). For one chronically-ill child, it was suggested that the confidence he had in his caregivers supported him through difficult times in his life [6].

Some children reported negative experiences with healthcare providers and some

described what they would find helpful from medical staff [5,17]. In Noyes's study the children, who had spent extended periods of time in hospital, reported that they were not given the opportunity to express their views or opinions and that treatment focused on their medical needs, often not taking in to account their social needs such as spending time with family [5]. As discussed in the theme, 'Perceptions of Self', children had a strong desire to be seen as "normal" and "ordinary" and they gave suggestions about how this could be achieved. In one study, children spoke about a desire for nurses to spend time talking to them about who they were as an individual rather than focusing solely on their medical needs [17]. They said that if nurses were able to spend time getting to know them this would help them to feel more comfortable and more able to express their feelings [17].

As discussed previously, a key part of identity work for children with respiratory assistance is focused around their desire to be seen as "normal". These findings suggest that by having discussions about their interests, rather than focusing solely on their medical needs, nursing staff can play an important role in children's identity development by helping them to see themselves as an individual distinct from their medical needs.

3.4.2 Education and Awareness

The importance of education and awareness of respiratory assistance were discussed by children in several of the studies [9,16,18]. As noted previously, a common finding of this review is the importance children place on being seen as "normal", possibly more so than other children without respiratory assistance [6,9,15–17]. In one study children reported that if others were educated and aware of the experience of needing respiratory assistance they believed that this would help people to see them as "normal" [16]. More specifically, children described how educating others about their tracheostomies helped with building

relationships with other children [18]. In Kirk's study there was discussion around how lesser known medical technologies, such as respiratory assistance, have not yet been normalised within children's social networks, leading to children with these technologies experiencing difficulties in managing their identity, and facing challenges related to concealment and disclosure of their medical technology [9].

Taken together, these findings indicate the importance of providing education about and raising awareness of, respiratory assistance to help with normalising children's experiences and supporting them with managing challenges related to their identity and self-presentation. The nursing profession was highlighted as being key to increasing the understanding of respiratory assistance [17,18]. Suggestions were made to incorporate teaching about children with medical technologies into nursing training programmes and for nurses to provide training to school populations (e.g. teachers, school nurses and students) in order to educate others and raise awareness of respiratory assistance [17,18].

4. Conclusion

This review has focused on children's experiences and views of living with respiratory assistance and four main themes have been presented about respiratory assistance in terms of their understanding of it, their identity, social experiences and service delivery experiences. The children in the studies were able to articulate and express their experiences, both positive and negative, of living with respiratory assistance. What was apparent throughout all the studies was the children's resilience to the difficulties they had experienced.

To date, the quality and quantity of the research focusing on the child's experience of living with respiratory assistance is limited. Most studies exploring children's experiences of such technology have focused on the parents' own experiences or their views of the child's

experience. As a result, there is still a limited understanding of these children's experiences across the illness trajectory and more specifically, for example, how the length of time with respiratory assistance impacts on a child's experience.

The studies in this review highlight how children and young people can provide valuable insights and information which can help inform understanding and future service provision. It is important to ensure that in future research children with communication difficulties are engaged, including those for whom English is not their first language, to ensure that more children have the opportunity to express their views and experiences.

With the continued advances in medical technology and the shift in care provision from the hospital to the community, it is likely that the number of children with respiratory assistance will continue to increase. It is therefore important that more research is conducted in which children's experiences of living with respiratory assistance are explored in order to inform future service provision. Specifically, in-depth explorations are needed to increase understanding of whether time and illness trajectory impact on children's experiences. Furthermore, such research would support the development of evidence-based interventions aimed at optimising the quality of life of children who require respiratory assistance, both at home and at school.

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Chapter 2 – Empirical Paper

Involved yet invisible: Parents' Experiences of Caring for a Child with a Tracheostomy

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Reference to a website:
[4] Cancer Research UK, Cancer statistics reports for the UK. http://www.cancerresearchuk.org/aboutcancer/statistics/cancerstatsreport/, 2003 (accessed 13.03.03).
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Abstract

Objectives The numbers of children with a tracheostomy being cared for in the community are increasing yet there is little research investigating the impact these caring responsibilities have on parents. This qualitative study aimed to explore experiences of parents caring for a child with a tracheostomy across the trajectory of care.

Methods Semi-structured interviews were conducted with seven parents of children who had received a tracheostomy at least 12 months prior to the interview date. Interviews were analysed using IPA, a qualitative approach was used to explore how people make sense of their lived experiences.

Results The analysis revealed three super-ordinate themes: "Coming to terms with a tracheostomy" explored how parents experienced the initial stages, from shock, to uncertainty to gaining control through tracheostomy training. "Medicalisation of your life" reflected the unrelenting need to be caring, the conflicting parental and carer roles, and the ways in which parents adjusted to and coped with their lives being dominated by caring. "Tracheostomy Transformation" illustrated parents' journeys to becoming confident in caring, advocating for their child and experiencing personal growth and change.

Conclusions The findings raise questions as to whether parents' emotional needs are being met, and suggest parents could benefit from additional support from healthcare providers. More research is needed, specifically, longitudinal studies exploring parent's adjustment to tracheostomy care, from first finding out to the stages before de-cannulation, as well as studies exploring the impact on all family members, particularly siblings.

Keywords: parents, experiences, tracheostomy, caring, psychosocial, adjustment.

1. Introduction

Advances in medical care have led to an increase in the number of children being supported by medical technologies most commonly mechanical ventilation, including tracheostomy and oxygen therapy, enteral and parenteral nutrition, intravenous drug therapies and peritoneal dialysis and haemodialysis [1]. These medical advances have meant that children, who previously would typically spend extended periods in hospital, are now able to transition home and be cared for in the community, usually by their parents or carers. In recent years, the impact these caring responsibilities have on parents has gained increasing interest. Parents caring for a child with a tracheostomy make up a sub-group of this population.

Children with tracheostomies require constant supervision from an adult who has been fully trained and who has specialist knowledge and skills in tracheostomy care and management. To transition from hospital to the community, the child's parents, or carers, must be taught and deemed competent in the following: stoma care, suctioning, tape changes, tube changes and resuscitation skills and emergency care [2]. Only when a parent is deemed "tracheostomy competent" would discharge to the community be considered.

The parental responsibility to continue delivering this skilled level of care has been found to impact on parents' emotional wellbeing, health, social experiences and family life [3,4]. Whilst some research has included the impact of tracheostomy care, few studies have focused exclusively on the experiences of caring for a child with a tracheostomy. A recent literature review exploring the experiences of parents caring for a child with a tracheostomy highlighted the lack of in-depth quality research in this area [5]. Furthermore, few studies have explored the parental experiences across the trajectory of care, from first finding out to caring at home. The absence of such research limits the understanding of the parental caring

experience and makes planning services more challenging due to the lack of evidence guiding healthcare professionals.

The aim of this study was to explore parents' experiences of caring for a child with a tracheostomy at different stages of the caring process, specifically, prior to the child receiving a tracheostomy, immediately after the tracheostomy and whilst caring for their child at home. The reason for the focus on parental experiences and not child, was firstly due to the level of responsibility on parents caring for their child with a tracheostomy. Secondly, many children with a tracheostomy are too young (e.g. those receiving a tracheostomy soon after birth) to be able to provide detailed accounts and insights into their experiences, therefore seeking the views and experiences of parents was considered most appropriate.

By gaining an increased understanding of parents' experiences across the trajectory of care, the study aimed to provide evidence to guide healthcare professionals who are supporting these children and families. To the authors knowledge, this is the first qualitative study exploring parents' experiences of caring for a child with a tracheostomy, exclusively.

2. Methodology

2.1 Methodological Approach

Interpretative phenomenological analysis (IPA) was used due to its flexibility and focus on participants' lived experiences [6]. The IPA approach assumes participants are experts in their experiences and focuses on gaining insights into how participants make sense of and interpret their experiences.

The researcher plays an active role in the interpretation and the dynamic process between researcher and participant is a key part of the IPA approach. To make sense of the participants' lived experiences IPA recognises that this interpretation is influenced by the

researcher's own experiences and conceptions. This two stage interpretation is known as double hermeneutics; essentially participants are trying to make sense of their experience and the researcher is trying to make sense of the participants trying to make sense of their experiences [6]. This process of double hermeneutics is viewed as an important element in interpreting participants' experiences.

2.2 Participants

Studies using IPA typically involve a small, purposively selected, homogenous participant group, to allow in-depth interpretation of a specific group [6]. Parents of children who had received a tracheostomy at least 12 months previously and had been cared for at home for at least 6 months prior to the study start date were invited to take part. Parents were recruited from an NHS specialist children's hospital.

Following receipt of ethical approval (Bangor University, Wales Research Ethics Committee, HRA approval and local hospital approval; Appendix 1-6) nursing staff, working with children with tracheostomies, gave information regarding the study and opt in forms to potential participants (Appendix 7). Participants who expressed an interest in taking part through returning the opt in forms or notifying the nursing staff were provided with more information and the opportunity to discuss the study in more detail. Seven participants expressed an interest in taking part and nobody declined to participate. Demographics of participants who took part can be seen in Table 1.

2.3 Participants Demographics

Parent	Relationship to child	Child	Child's Diagnosis	Child's Age at interview	Child's Age at Tracheostomy	Time cared for at home
Tom	Father	Freddy	Down Syndrome	3	1 year	15 months
Shane*	Father	Jason	Malrotation and Volvulus	4	6 months	19 months
Tracey*	Mother	Jason	Malrotation and Volvulus	4	6 months	19 months
Katie	Mother	Isla	Rare genetic condition†	23 months	5 months	15 months
Henry	Father	Tilly	Rare genetic condition†	4 years	1 day	3.5 years
Elizabeth	Mother	Noah	Oesophageal atresia	23 months	2 months	18 months
Lucy	Mother	Ally	Rare genetic condition†	13 months	2 months	6 months

*Shane and Tracey were interviewed together
†To protect parents' and child's anonymity specific details of the child's diagnosis have been omitted.
NB. For purposes of confidentiality and anonymity all names have been changed.

Table 1. Participant demographics

2.4 Data Collection

A semi-structured interview format was selected to allow participants the opportunity to explore their own experiences whilst also allowing the researcher to respond to participants' insights and reflections with further questioning. The interviews were guided by an interview schedule as suggested by Pietkiewicz and Smith [7]. The interview schedule was

developed through discussion with a specialist nurse in the field and parents of children with a tracheostomy (Table 2; see appendix 8 for a detailed interview schedule including prompts).

Interview Schedule

1. Can you start off with you telling me a little bit about (child's name)?
2. Can you tell me about how it was first discussed that your child needed a tracheostomy?
3. Can you tell me about your experience of tracheostomy training?
4. Can you tell about your experience of having a child with a tracheostomy?
5. Can you tell me about your experiences of transition from hospital to home with (child's name)?
6. Can you tell me about your experience of caring for your child with a tracheostomy at home?
7. How has your experience of caring for your child changed or not changed over time?
8. Can you tell me about what your expectations are for (child's name) since receiving the tracheostomy?
9. What impact do you feel having a child with a tracheostomy has had on your family?
10. What things did you value/think were important for you and your child since receiving a tracheostomy?

Table 2. Interview schedule

Topics in the interview were arranged chronologically covering the entire experience from first finding out their child needed a tracheostomy, to being trained in tracheostomy care, to transitioning home and caring for their child at home.

Participants were interviewed at a date and time that was suitable to them, typically this was during a visit to the specialist hospital. Prior to the interview, rapport was developed to help participants feel more comfortable and relaxed with the researcher and during the

interview. Participants were reminded of the study's aim, given the opportunity to ask questions about the study and made aware of their right to withdraw at any time during or after the interview. The researcher provided assurances of confidentiality and anonymity and permission for the interviews to be recorded and written consent were obtained (Appendix 9).

Participants were interviewed on one occasion. The duration of the interviews ranged between 40 minutes and 90 minutes and were conducted by the lead researcher across a five-month period from November 2016 to March 2017. After the interview, the recorder was turned off and participants were given the opportunity to ask any questions they had about the study. Participants were thanked for their involvement and the researcher ensured that each participant was not distressed and was aware of how to access further support. No participants withdrew from the study. The researcher made field notes during and following the interview, recording non-verbal gestures made by participants, any interruptions or stoppages during the interview, and their own reflections of the interview.

2.5 Data Analysis

Data analysis followed the IPA process outlined by Smith, Flowers and Larkin (2009). Having transcribed the interviews verbatim, the first interview was read several times in its entirety to allow the researcher to become familiar with the data. The researcher annotated the interview transcript with exploratory comments and initial interpretations in the right-hand margin. The transcript was reread and emerging themes were captured in the left-hand margin (see appendix 10 for an analysed extract), after this was completed all the themes were listed. Connections and differences between the themes were explored and similar themes were grouped together. Throughout checks were made to ensure the themes

corresponded to what the participants had said. A master list of super-ordinate themes was developed and emerging sub-themes were arranged into groups under each super-ordinate theme. This process was repeated for each transcript and the master list of super-ordinate themes and sub-themes expanded.

The super-ordinate themes and sub-themes were supported by verbatim quotes to ensure that the themes were representative of the participants' responses. The list of super-ordinate themes and associated sub themes changed several times throughout analysis and write-up.

To ensure reliability and validity of the IPA analysis field notes were written after each interview, providing the interviewer's reflections of their feelings about the interview and a reflective diary was completed throughout the research. The field notes and the reflective diary were consulted during data analysis. The co-authors (J.W a health psychologist and L.W a clinical psychologist) read the transcripts separately and checked the themes for relevance to ensure that they were grounded in the data.

3. Results

Three super-ordinate themes and associated underlying themes emerged from the data (Table 3). All themes were interlinked and signify the complex and emotional trajectory of caring for a child with a tracheostomy. These themes were presented as a narrative account and are supported by verbatim interview extracts from the seven participants[^]. See appendix 11 for an overview of the themes as they applied to each participant.

Super-ordinate Themes	**Underlying Themes**
1. Coming to terms with a tracheostomy	*"Taken out of our hands"; No choice in the decision making* *"Huge black wall"; Facing the unknown* *"Steps forming"; Gaining clarity and control*
2. "Medicalisation of your life"	*"Its constant"; The unrelenting responsibility* "*Wear the different caps"; Juggling the conflicting roles* *"You pull your socks up and you crack on"; Adjustment and coping*
3. Tracheostomy Transformation	*"Confident doing it ourselves"; Persevering yet forgotten* *"Opens your eyes"; Reflections on personal change*

Table 3. Superordinate and subordinate themes

The following transcript conventions have been used in the extracts:

[…] Words removed to shorten quote
… Short pause
(*text*) Verbal/non-verbal gestures by the participant
[*text*] explanatory information included by author
(name) Participant's name

[^]To comply with NWCPP guidelines, lengthier quotes from participants have been included in a suitable tabular form within the body of the text. These tables have been numbered from 4-29.

3.1 Themes

Superordinate Theme 1: Coming to terms with a tracheostomy

The urgent need for their child to have a tracheostomy left parents feeling like they had no choice in the decision to consent to a tracheostomy. They dealt with this lack of choice by disregarding their own emotional experience and prioritising the needs of their child. After their child received a tracheostomy, prior to tracheostomy training, parents were faced with several unknowns and uncertainties. Becoming tracheostomy trained alleviated these unknowns and allowed parents to work towards their goal of returning home.

"Taken out of our hands"; No choice in the decision-making

Prior to their child receiving a tracheostomy, parents described feeling like they had no choice in the decision to consent to a tracheostomy. All parents described how being told by the medical team that their child needed a tracheostomy was unexpected and shocking; "dropped the bomb shell" (Tom). Parents placed their trust in the medical teams and followed their advice; "they reckon the best thing was a tracheostomy so we consented to that" (Katie). They viewed the medical team as knowing what was best for their child and did not question their view of their child's prognosis. In most cases, due to their child's immediate need for a tracheostomy and the emergency of the situation, parents were left with little time to process or weigh up the decision in consenting to a tracheostomy, for example:

> "If he doesn't have a trachy, he is going to die. You have no option. You have no choice. So…ok, we're then all of the sudden gonna be thrust and thrown into this…situation errmm we have absolutely no control of" (Tom)

Table 4.

Tom described the fast pace at which everything unfolded and the sense of emergency and responsibility with needing to consent to a tracheostomy. Parents shared similar experiences of the sense of responsibility, that their child's life was in their hands. Faced with the possibility of his child's mortality, Tom described there being "no other route" suggesting a loss of free choice, that there was no other option than for his child to have a tracheostomy. This loss of choice in the decision to consent to a tracheostomy was described by most parents:

> "then unfortunately she had to do an emergency tracheostomy, that was like the only option, so we didn't have any time to think about or prepare, it was like like, "right, we gotta do it, sign the consent" and it was done…like really quickly" (Lucy)

Table 5.

The speed at which the events unfolded required Lucy to, without hesitation, consent to a tracheostomy. The immediacy of her child's need for a tracheostomy meant that she was unable to process her own feelings- an experience shared by all parents, for example:

> "I I jus you know I guess I just took it in my stride because….what else can you do? If he needed a, if he needed to have a tracheostomy then that's what he had to have. I would have to deal with it." (Elizabeth)

Table 6.

Elizabeth did not reflect on her feelings towards the tracheostomy, however prioritised her son's need. Using the expression "have to" suggests that this is what Elizabeth believed to be her moral responsibility as a parent, to accept the tracheostomy and "deal with it". Disregarding and ignoring their own emotional experience appeared to be a way of coping with the situation and served as a protective factor for several of the parents.

"Huge black wall"; Facing the unknown

After their child received a tracheostomy and prior to tracheostomy training, parents were faced with the uncertainty of what life entailed for them, their families and for their child. Tom used a metaphor of a black wall to describe his adjustment to his son's tracheostomy:

> "I remember one evening errr…at home with my dad, […] I said to him, "I can't do it, I don't know if I can do it". So you know, you, you, you're left standing in front a…huge…black…wall *(emphasised*), that's got no grip on it whatsoever and errr…it's, it's all oiled so there's absolutely no traction and you're not getting up that wall. And you can't see the top of it" (Tom)

Table 7.

Tom's metaphor of a "huge black wall" suggests that after his son received a tracheostomy he was faced with a lot of unknowns and that he struggled to see any way forward. Tom described a sense of powerlessness and uncertainty in his ability to cope and care for his son's medical needs. Similarly, Lucy described her experiences after her daughter received a tracheostomy:

> "I was like a different person, I wasn't sleeping, I was throwing up […] I was getting palpitations and I like couldn't breathe properly, a really, really bad time, there was very small periods of time that I hate to admit but I didn't see any way out, I kind of, I was saying to my mum "maybe it would be better if she died (*said quietly*), I don't feel…like…she's going to have any quality of life if she's got this trachy and this heart problem" and I couldn't see her ever getting better, I thought it was just such a bad…downhill turn and not good for her to have this trachy …and I just…I didn't let myself get attached to her either after I found it really hard to bond with her, erm, yeah, that trachy was my down fall." (Lucy)

Table 8.

Lucy described a sense of regret that she felt with her daughter having a tracheostomy. The unknowns surrounding the tracheostomy impacted on Lucy's physical and mental health and made it difficult for her to form an attachment with her daughter. Several parents questioned what having a tracheostomy would mean for their child, "are we ever gonna hear him?" (Tracey) and this uncertainty evoked feelings of fear. Lucy further highlighted the difficulties she experienced in the stages following her daughter receiving a tracheostomy, describing it as "overwhelming", "living like an actual nightmare" and that she "wasn't living at all, I just existed", suggesting a sense of trauma and detachment from her daily life. Whilst Lucy could recall how she felt following her daughter receiving a tracheostomy, this was not the case for all parents:

> "The whole experience was, it just was traumatic, you know, a a so….there just was a lot going on *(emphasised)* erm….you know its difficult to….to go back and understood understand how I processed everything because it…you you just kind of keep going." (Elizabeth)

Table 9.

Like Lucy's experience, Elizabeth suggests she was living on auto-pilot, that she was just existing, without focusing or thinking about what was happening. Elizabeth's difficulty to recall how she felt after her son received a tracheostomy suggested that, due to the trauma of the situation, she did not process her own emotional experience and possibly disregarded it. Several parents were unable to recall how they felt after their child had received a tracheostomy, suggesting that parents had similar experiences, that they did not process or acknowledge their own emotional experience.

"Steps forming"; Gaining clarity and control

Gaining a sense of clarity to overcome the unknowns and to work towards achieving their goal of returning home was achieved through tracheostomy training. For Henry, training allowed him to "start kind of understanding how to move forward". Parents described an eagerness to begin the tracheostomy training in order to transition from hospital to home:

> "I just wanted to learn […] I lived in the accommodation which was opposite the wing of the hospital […] so…my idea was the quicker I got trained up to look after him, the quicker I could hopefully get him home, get him well, you know, I'm his mum I want to be looking after him, I want to be doing his things" (Elizabeth).

Table 10.

Prior to tracheostomy training, Elizabeth described a sense of feeling out of control, that she was unable to fulfil her parental role and care for her child. Several parents spent extended periods of time in hospital with their child with a tracheostomy which they described as living "in a void" and a "bubble". The implications of this on their daily lives meant that they felt "separated" from their families and had limited opportunity to spend time with their other children. Becoming tracheostomy trained, often referred to as "trachy competent", was viewed by the parents as a means to return home and to regain a sense of "normality" for themselves and their children. Whilst parents expressed a fear associated with being tracheostomy trained, "it was frightening cos you're playing with your child's life" (Tracey) for most parents their goal to return home superseded their fears and anxieties towards training:

> "If you're not going to do it, you can't expect, you can't expect other people to come and do it and[…]…obviously you want your baby to come home with you as soon as possible from the hospital and…if anything did, for god god forbid did go wrong at

> least if you get the training you know what to do […] As long as you know what to do if anything does happen if he starts to choke or if anything like that does happen then at least you know what to do" (Shane)

Table 11.

Shane's use of the second person pronoun suggests he generalised his viewpoint to other parents; that it is a parent's moral responsibility to overcome their fears of the unknown and to care for their child. This idea of parental moral responsibility was shared by other parents, for example, Tom said "the parents have got to do it", suggesting parents implicitly assumed that it was their responsibility to care for their child. Despite some parents experiencing difficulties with training, describing it as "horrible", and "worrying", all parents underwent and completed tracheostomy training, suggesting their parental responsibility to care for their child was given priority over their emotional experience and response to training. For Shane and several parents, being tracheostomy trained provided a sense of security that they "know how to look after" (Lucy) their child.

Gaining mastery in tracheostomy care was gradually developed through achieving a series of training "milestones". These milestones included suctioning, tape changes and what was described as the "pinnacle", tube changes. As training progressed and each milestone was achieved parents described the unknowns and the uncertainties dissipating; "all of a sudden there's some steps forming in front of you…and then as the steps grow bigger the top of the wall comes down" (Tom). Using the metaphor of "steps forming", training was viewed by parents as a process of becoming more aware of what life with a child with a tracheostomy would be like. As parents gained more clarity, they were able to regain a sense of control:

> "they let us off the ward *(smiles),* cos we were ok with suctioning and we'd both done the tube change, we still had another tube change to do, and they said "ok we'll let you go off the ward and you can be gone for half an hour" and it was like *(inhales as in excitement)* "freedom, freedom, yeah- we got out of here!" (Tom)
>
> Table 12.

This quote illustrates the level of control the hospital had in deciding when a parent was deemed ready to return home. For most parents, staff within the hospital decided when the parents were ready to return home. The excitement and sense of relief expressed by Tom implies the significance and importance of being able to "get out of the hospital" and to return home. Gaining mastery in tracheostomy care was viewed positively by parents, "I feel like really important!" (Lucy), evoking feelings of pride in their achievements and confidence in their abilities to look after their children.

Superordinate Theme 2: "Medicalisation of your life"

There seemed to be a shift in the eagerness and excitement to return home when parents finally did return home. Care at home was described as unrelenting and isolating, further perpetuated by the difficulties in gaining support. Parents described a juggle and a conflict between their parental and carer roles. Acceptance, avoidance and disregarding their own emotional experience were common ways of coping with the medicalisation of their lives.

"Its constant"; The unrelenting responsibility

Transition in care from the hospital to the community meant that parents assumed all caring responsibilities. Caring at home was described as "constant", "needing to keep an eye

on her all the time" and "24-hour care". For some parents the realisation of the ongoing and constant need to be caring did not become apparent until they had returned home:

> "what you don't realise until it actually happens when you're on your own is the after care and the amount of of work that you have to to put in. I wasn't aware of that until I guess, maybe when I got home…[…] you still have the support here in the hospital don't you? You have a little, a little hub of people, blanket, and then, when you're at home, then its day and night" (Elizabeth)

Table 13.

Elizabeth implies a loss of the sense of safety she felt in the hospital from the support from staff and feelings of being alone in the unrelenting caring responsibilities. Several parents described similar experiences during transition from hospital to home, that they only became aware that the caring responsibilities were "all on us" when they had returned home. Elizabeth reflected on the impact of her caring responsibilities:

> "its impacted my life hugely I can't go anywhere, I can't do anything, where I go, Noah goes, where Noah goes I go erm…even to the point of showering, going to the toilet, I cannot leave him unattended" (Elizabeth)

Table 14.

Parents described similar experiences to Elizabeth, of their lives being dominated by caring which resulted in "a lot of sleepless nights" (Henry), spending very little time together as a couple, not being able to engage in activities of interest to them and having very little free time to do things for themselves. Challenges related to time for self and personal privacy were further complicated by carers coming into their homes. Henry reflected on the experience of having carers coming into his home, "it's just it's a bit…weird erm…cos you kind of, you, you're not able to, kind of, to be yourself in your own home". The need for Henry to share his home

environment with carers and no longer having space that was his own impacted on his identity. Similarly, Lucy described parts of her home as becoming medicalised describing it as "Ally's little hospital", highlighting how caring dominated their home environment.

The constant and persistent need for caring and the inability to be apart from their child resulted in a loss of social experiences and sense of social isolation. This dichotomy between never being able to be alone and the sense of loneliness was expressed by several parents, for example Tom described his experience of caring as being, "quite lonely at times". Such loneliness and constant caring seemed to be exacerbated by other peoples' (family members, friends and carers) reluctance to provide caring support. The challenges in finding support and respite with caring for their children made it even more difficult for parents to be able to have time away from caring responsibilities, for example:

> "they're all very nervous about the trachy […] they just panic about the whole thing, it makes them feel uncomfortable, you know and… I don't know, I think it's, again I think it's the psychology of it, I think everyone's just like "that's the airway" and they're just panicking if, if they can't do it or if they don't do it then…you know it's…so they, they don't, you know. So we don't really have anyone, friends or family that will do it, besides me and Sam [*husband*]" (Katie)

Table 15.

Katie suggests that friends' and family members' anxieties about caring for her daughter, were attributed to the unknowns and lack of awareness around tracheostomy care. Katie's repetitive use of "you know" may signify her reluctance to articulate the outcome if they do something wrong. She implies that other people are fearful of caring for her daughter as they view it as a huge responsibility, that her daughter's life is in their hands. As nobody else was

willing to take on the responsibility, Katie and her husband were unable to get a break from caring. Several parents spoke of challenges in gaining support and being "the only ones" who were able to provide care for their children, meaning that caring responsibilities were unrelenting. Additionally, there seemed to be parallels between friends and family members' reluctance and community carers' reluctance to be trained. Participants expressed how senior members of community staff attempted to train carers to no avail: "they had to train them [*the carers*] up but none of them managed to do it" (Elizabeth). Such fear and reluctance in others resulted in parents being all consumed with the responsibility of caring for their child, which further exacerbated feelings of social isolation.

"Wear the different caps"; Juggling the two conflicting roles

Parents described themselves as needing to adapt and switch between distinct and separate roles of parenting and caring. This juggling of the two roles and the conflict parents experienced was particularly evident for parents with other children, which included six out of the seven parents interviewed.

The parental role was described as "fun", "spontaneous" and being able to engage in activities without restriction whereas the carer role required parents to be "organised", "four or five steps ahead" and assess and manage "risk" as illustrated by Tom:

> "it's also time for eventuality, I know that because I have to plan t..to do the school run, to go out for lunch, I need to know that his change bag has got a fully charged machine in it, that it's got all the relevant emergency box I'll have to take with me, make sure that that's stocked up and I've got catheters erm….to be a bit more organised but only with him, I still keep the spontaneity with my daughter" (Tom)

Table 16.

Tom's quote highlighted the sense of rigidity in the carer role, the need to be organised and prepared for potential medical emergencies, risk assessing every situation. Tom alludes to the juggle and distinction between his carer and parental roles; solely being spontaneous with his daughter (without a tracheostomy) and strictly organised with his son with a tracheostomy. Juggling both the caring and parental role appeared to elicit tension for parents.

> "I haven't been able to do […] we've not been able to take our children to the beach because sand and tracheostomies don't really mix very well erm and so the impact on obviously my eldest daughter is, I often think I'd quite like to take her to the beach and just do normal, you know, summer holiday type things" (Henry)

Table 17.

Henry alluded to a conflict between his carer and parental role, with the carer role taking precedence. Several parents made reference to such conflict and the distinction between the parent role as "fun" and "normal" and the carer role as "organised" and "prepared". Parents expressed difficulty in simultaneously wearing "different heads" or "caps", emphasising the juggle between the two distinct roles and how "balancing everything can be a bit stressful". The significance of the caring role taking precedence was further illustrated by parents' narrative of being vigilant and having to ensure their child's safety; "children they like want to play tag and things […] we have to be quite careful to stop Tilly running around the house cos its quite dangerous" (Henry). Such prioritisation of the caring role seems to limit opportunities of spontaneity and play, two key characteristics attributed by parents whilst describing their parental role. Tom discussed the impact that prioritising his carer role had on his daughter without a tracheostomy:

> "at the end of the day you're a 7 year old little girl that doesn't get to go swimming as much as she'd like to, I'm fully aware of that and as a parent it, it upsets me that maybe she's not getting all that she could get, purely because of the trachy" (Tom)

Table 18.

Tom appeared to imply a level of resentment towards the tracheostomy because of the restrictions it places on everyday activities for the whole family. Such restriction and conflict between roles elicited a sense of parental guilt towards their other children; "I feel guilty to Phoebe [*elder daughter without a tracheostomy*]" (Lucy) and "You've got that side of guilt I suppose, you're always thinking "am I doing too much with her, not enough with him?" (Katie).

"You pull your socks up and you crack on"; Adjustment and coping

Parents discussed ways they adjusted to the medicalisation of their lives. In all the interviews parents demonstrated a resilience to the difficulties they had experienced and described similar coping strategies which helped them manage day-to-day, for example: "I take each day as it comes and I don't look too far in to the future because it's too much to take in, it's kind of, you know, deal with the immediate problem" (Elizabeth). Elizabeth described a pragmatic approach to dealing with the challenges in caring for her son. Several parents spoke of taking each day at a time and alluded to an avoidance of planning or thinking about the future as it was "too much" for parents to contemplate and too uncertain. Whilst some parents avoided thinking about the future due to the uncertainties, other parents found it helpful thinking positively about the future:

> "I always take a view like […] optimistic view, that at some point in the future, you know things will get better, and she might be able to, at some stage, get of rid of her tracheostomy" (Henry).

Table 19.

For Henry fostering hope helped him manage with the daily demand of caring for his daughter. Parents expressed a need for "acceptance" and acknowledged their need to persevere; "you pull your socks up and you crack on" (Elizabeth) as a mechanism of coping; "[…] they say, "how do you cope with it?" and we just cope like you would if it was a normal baby without a trachy in, you just gotta get on with it…just get on with it" (Shane). Both Shane and Elizabeth describe a pragmatic, solution-focused approach to caring. The "just get on with it" mentality was expressed by many parents, suggesting a need to minimise or disregard their own emotional experiences and focus on caring for their child. Katie further illustrated this strategy; "I think it's just how you accept it, you know, you can dwell on it or you can just get on with it" (Katie). Katie's coping strategies included acceptance, avoidance and her tendency to "get on with it", a common narrative among parents. This suggests that they often acted on auto-pilot, lacking time to think or reflect on their experience. Such tendency to function on auto-pilot may be protective and serve as a coping strategy in avoiding their (parental) emotional experience.

Superordinate Theme 3: Tracheostomy Transformation

Parents expressed how their expertise in caring allowed them to advocate for their child. They reflected on their personal transformation and growth they had experienced through their tracheostomy journey.

"Confident doing it ourselves": Persevering yet forgotten

Parents' confidence in caring, their acceptance and perseverance allowed them to take on a role of advocating for their children. The vital role parents played in their child's lives, both caring and advocating responsibilities, meant that parents were often "forgotten". As their journeys progressed parents' confidence in caring for their child grew and parents assumed an "expert" role. Whereas at the beginning of their journeys parents placed trust in the medical teams, as parents became more experienced they were often required to step in and direct medical professionals as illustrated by Henry:

> "we had to deal with an emergency situation and I think I [*emphasis*] dealt with it and I was telling the consultant what to do so [*laughs*] erm because I'd seen it before and I knew what to do […] so it's almost, it's like you become, you do become the expert in in in what's best for Tilly, what works well what, you know, what doesn't work well" (Henry).

Table 20.

Henry's laughter implies some amusement however this may mask some apprehension with perceiving to know more than medics. Henry described the responsibility of being involved in all aspects of Tilly's care and voicing what was in her best interests. Parents therefore expressed a growth in their self-confidence in caring for their children; "we felt a bit more confident, a lot more confident doing it ourselves" (Shane). Such confidence was evident when parallels were made to being an advocate. Parents described attempts in ensuring sufficient care was offered:

> "you either have to carry on trying to advocate what you know is going to be safe and correct for her or you just give up and I think you get to a point, and I think some parents may give up because they just can't be bothered to fight anymore" (Henry)

Table 21.

Henry's use of the words "advocate" and "fight" describe a sense of persistence in ensuring the appropriate level of community support was received. This analogy of a "fight" suggests two possible outcomes, winning and losing. Parents' persistence in the "fight" and advocating facilitated their child's needs being met by services. This vital role parents played in the overall care of their child often left them feeling forgotten. Parents shared how "it's all on us", capturing the weight of responsibility in caring for their child's medical needs and needing to be "very selfless". The sense of being forgotten seemed to be exacerbated within the hospital setting:

> "[…] healthcare professionals are so focused on their job and what they have to do for that child they seem to forget, at times, that there is a parent connected to that child." (Tom)

Table 22.

Tom captured how the focus being on his child left him feeling ignored and forgotten. The need to be "very selfless" and the feeling of being "forgotten" likely left parents feeling invisible.

"Opens your eyes"; Reflections on personal change

All parents expressed an aspect of change resulting from their experiences; "it's changed me, definitely" (Elizabeth). When parents adopted the caring role, they described changes in needing to be "more organised", "a little more sensible" and "very patient". Several parents reflected on a positive psychological change that resulted from their experiences. They shared how they experienced a changed sense of self and how they had "learnt a lot" about themselves. The experience of caring for a child with a tracheostomy ultimately changed parents' outlook on life as illustrated by Lucy:

> "I think it's made me appreciate life so much more that maybe I took it for granted before, whereas now…you do have, I know it sounds like a cliché, but live everyday like it's your last" (Lucy)

Table 23.

For Lucy, being faced with her child's mortality elicited a greater appreciation for life. Similarly, other parents described becoming a "stronger person" and "becoming less fearful"; doing things they would not have done prior to their child having a tracheostomy, "a year later I jumped out of a perfectly good aeroplane with a parachute on my back" (Tom). Tom shares a sense of accomplishment in seizing every opportunity and embracing his fearlessness. This mirrors Lucy's sense of living each day to its fullest given that her experience (of caring for her daughter) also heightened her awareness of mortality "I do see death […] I'm just more aware of it". Parents also expressed being more empathic as illustrated by Elizabeth:

> "on a different level other things upset me more […] I guess you understand more what other people go through, you know, its its its upsetting because I know now what it's like and how it hard it can be erm to have a child who is very poorly erm and its its just heart breaking […]cos you've got no way of getting out of that situation, erm, it just opens your eyes up to to you know, to to that and and…it's just sad that children have to go through that really." (Elizabeth)

Table 24.

Elizabeth's reference to "just opens your eyes up" indicates how this has likely made her more aware of illness, its permanence and the likelihood of death.

4. Discussion

The three superordinate themes conceptualise the tracheostomy journey for parents from hospital to ultimately being the sole carer at home. The tracheostomy journey elicited the question as to whether parents' emotional needs were being met. The present study provides valuable information to an understudied area, offering a number of unique insights into parents' experiences of caring for a child with a tracheostomy.

This is the first study to offer an in-depth exploration and insight into the parental experiences of caring for a child with a tracheostomy across the trajectory of care. Furthermore, no studies have employed IPA methodology with this population, therefore the present study is unique in its approach to exploring the parents' lived experiences.

To the authors knowledge, this is the first study to explore parents' experiences in the early stages, prior to their child receiving a tracheostomy. Finding out their child needed a tracheostomy was shocking and unexpected. Parents saw themselves as having no option in the decision to consent to a tracheostomy and placed their trust in the medical professions advising them. This is consistent with previous findings where family members, who cared for a child supported with a ventilator or positive pressure device at home, experienced a loss of free choice when consenting to medical procedures when they believed the alternative was that their child would die [8]. In the present study, parents felt overwhelmed after their child had received a tracheostomy and contemplated the caring responsibilities they needed to assume. They did not question this responsibility however, but assumed it was a parent's responsibility to provide care for their child. These findings support Ricoeur's theory that the "mere existence of a child, who is entrusted to our care, is an obligation and renders us responsible through the child's fragility" (p.261) [9,10].

Parents' accounts demonstrated that caring for a child with a tracheostomy was unrelenting and isolating. The constant need to be caring and the experience of isolation is consistent with previous findings of caring for a child with medical technology [5,11]. Parents described having little time for themselves and like participants in other studies they felt "intruded on" by having carers in their homes [1]. The lack of respite opportunities exacerbated parents' feelings of social isolation. Similarly, studies have found that parents caring for children with complex medical needs were unable to have any respite and consequently "felt trapped" [8].

Parents described a conflict between managing two different roles: parent and carer. This is consistent with other findings where parents' caring for ventilator-dependent children described roles of "affectionate parents" and "medical carer" which led to an ambiguity in their social identity [1]. In the present study parents described the carer role as needing to take priority. Similarly, in interviews with parents of children dependent on medical technology, parents made a clear distinction between being a "parent" and a "carer" and described how the caregiving role often dominated their parenting experiences and daily lives [12]. A further added value of the present study was that parents expressed guilt towards needing to prioritise the carer role. They felt guilt towards their other children, because they worried they were missing out, highlighting a potential area for future research and intervention.

For most parents taking each day at a time served as way to cope with the challenges of caring. In other research, parents have identified focusing on day-to-day living as a way of managing with difficulties associated with caring [13]. Throughout the narratives, parents demonstrated prioritising their child's needs and disregarding their own, expressed as a need to "just get on with it". This emotional regulation strategy of ignoring their own emotions has

been reported in other studies of parents' experiences of caring for their medically dependent children as well as a strategy employed by healthcare professionals during clinical procedures [14,15].

The progression of their tracheostomy journey led to an increase in parental confidence. Parents needed to take on an advocate role for their children and like participants in other studies they needed to "fight to get needs met" [16]. Parents' growth in confidence and becoming an advocate for their children has been found in other studies [17]. The parents and medical professionals focus on the child's needs left parents feeling forgotten. The dominance of caring, feelings of social isolation and being forgotten highlight the importance in offering support to these parents, an area of need highlighted in several studies [13]. Other studies have found that supportive nursing staff and meeting other parents with similar experiences was helpful for alleviating some of the challenges associated with caring [18–20].

All parents reflected on how they had changed through their experiences. Some parents described a sense of personal growth and positive psychological change that resulted from their experiences. Similarly, several studies have found that parents of children with serious paediatric illnesses identified aspects of post-traumatic growth [21].

There are some limitations with the current study which need to be considered. The themes developed within the study were not discussed with the participants, therefore they were unable to support or modify the interpretations. The process of triangulation with the other researchers, tracheostomy specialist nursing staff, and initial interpretations being checked with subsequent participants aimed to ensure validity of the findings and to ensure that the findings were grounded in the participants' experiences. Although the sample size of the present study was small, this is typical for an IPA study with a unique population and is

the recommended sample size for doctoral thesis projects [6]. Furthermore, whilst the study was homogenous with respect to the age of the child (pre-school), in line with an IPA-based study, the challenges of caring for an older child were not explored.

Understanding parents' experiences of caring for a child with a tracheostomy is crucial for service development. There is a need for longitudinal studies exploring parents' adjustment to tracheostomy care, from first finding out to the stages before de-cannulation, as well as considering the impact on the family, particularly siblings. All the children of the parents in this study were pre-school aged so it is important that future research explores the experiences of transitions to school, particularly for those children who require a tracheostomy long-term. Recent research has highlighted the lack of data from male caregivers [3]. The present study has offered insights into the experiences of both female and male parental caregivers and future research could explore differences between male and female caregivers. This study provides a useful starting point for future research and provides evidence for improving services for parents caring for a child with a tracheostomy.

Suggestions for clinical practice implications arising from this study include integrating an assessment of parental coping into clinical practice, providing additional support with transition from hospital to home and establishing a parent support network for parents to be able to connect with other parents at different stages of their tracheostomy journey.

Evident from the findings in this study is the enormous contribution parents make to the lives of their children with a tracheostomy, often sacrificing their own needs to care for their children. It is important that the parents are not forgotten; that their needs (as well as their child's) are considered and that appropriate support is offered.

To assess parents' needs, routine assessment of parental functioning, including their physical and emotional health, is needed throughout the tracheostomy trajectory. Such an

assessment would help to identify parents who are struggling and need additional support. The value of using a structured assessment tool has been identified in previous research [22]. Assessment of parental functioning could be carried out at routine clinic appointments. In addition to identifying parents who are experiencing significant difficulties, routine assessment would give healthcare professionals the opportunity to discuss options in gaining appropriate support, signpost to other resources and help to ensure that parents' needs are met. Findings showed that the carer role took priority and parents expressed guilt to their other children, it is therefore important that healthcare professionals consider the needs and experiences of each family member and the family as a whole and provide appropriate support.

The findings in the present study indicate that parents were not aware of the shift in responsibility from hospital to home. Parents described caring at home as being "constant", unrelenting and isolating suggesting a need for additional support with transition from hospital to community. Support with transition would help to ensure that parents are coping with the increased responsibility. Previous research has highlighted the challenges in generalising skills learnt in hospital to the home environment [14] and the importance of gaining support from healthcare providers [17]. It is important that parents are supported with the transition home and are given opportunities to maintain and develop their skills in tracheostomy care to ensure confidence and capability in their caring responsibilities. Tracheostomy care specialists are well placed to liaise with and provide consultation and training to community healthcare professionals supporting these parents.

Research has highlighted the value of parents supporting one another, for example, being able to share with each other what works well [20]. Furthermore, in a study of parents caring for a child with chronic kidney disease, it was found that meeting other parents was a

source of emotional support [18]. In the present study parents described feeling socially isolated, and forgotten, suggesting a potential value in parents meeting with other parents caring for a child with a tracheostomy. One possible approach may be for nursing staff in hospitals where tracheostomies are performed and managed to create a 'buddy system' of parents who are willing to discuss their experiences. Parents at the start of their tracheostomy journey could be offered the opportunity to meet and speak with these parents. This could provide parents with an invaluable opportunity to discuss their anxieties around the unexpected, normalise their experiences as well as discuss what works well for them. Additional social contact could help with parents' experiences of social isolation.

5. Conclusion

Qualitative exploration of parents' experiences of caring for a child provides valuable information for future research and service development. In summary, the current study raises an important question as to whether parents' emotional needs are being met, highlighting an area requiring further consideration. Considering the increasing number of children with a tracheostomy being cared for in the community, further research is needed to help support and enhance service provision for the whole family.

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Chapter 3 – Contributions to Theory and Clinical Practice

Contributions to Theory and Clinical Practice

The thesis explored the experiences of living with and looking after children with respiratory assistance. The literature review summarised the qualitative studies exploring children and adolescents' experiences of living with respiratory assistance. An empirical paper explored parents' experiences of caring for a child with a type of respiratory assistance, specifically a tracheostomy. This final chapter integrates findings from the literature review and empirical study to consider implications for future research, theory development and clinical practice. Following this are personal reflections on conducting this research.

Implications for Future Research and Theory Development

The title "Unheard Voices" reflects a theme that emerged from both papers; that often the children and parents were unheard. This reflection is based upon the sparse research with this population. The literature review found only seven qualitative studies exploring the experiences of children and adolescents with respiratory assistance. It is recommended that more studies are conducted exploring the needs, experiences and quality of life of this group. Further complicating their lack of voice in the literature, many children with respiratory assistance, such as a tracheostomy, are unable to speak without a speaking valve. As individuals with respiratory assistance sometimes have difficulties with communicating, it is important that future research considers ways of engaging these individuals. Using technological communication aids, visual tools, observations and adopting ideas from other research such as the use of visual framework symbols (Murphy, 1998; Rabiee, Sloper, & Beresford, 2005) could help with identifying the needs and experiences of individuals with communication difficulties.

To the author's knowledge, the empirical paper was the first in-depth qualitative study to explore parents' experiences of caring for a child with a tracheostomy across the trajectory of care. Therefore, there is a need for more research, specifically, longitudinal studies exploring parents' adjustment to tracheostomy care, from first finding out to the stages before de-cannulation. Findings from the empirical paper demonstrated that the parents' narratives focused primarily on the needs of their children, not on their own. They described needing to advocate and "fight" on their behalf, demonstrating the powerlessness of their children. The dominance of caring responsibilities left parents unable to meet or voice their own needs and they were subsequently left feeling "forgotten". This lack of children and parents' voices in the literature highlights the need for more research to be conducted with this population.

Based on the findings from the empirical paper it is suggested that parents' emotional needs are being unmet, however there is very little research addressing parents' experiences and needs when caring for a child with a tracheostomy making it difficult to develop services. Specifically, little is known about the experiences of level of emotional distress, parenting distress, quality of life and resilience of parents of children with a tracheostomy. Given the sparse literature in the field, there is a need for more research, with a larger number of parents to inform service delivery.

It is recommended that future research employs a prospective longitudinal study using an embedded mixed methods design to explore parents experiences and unmet needs. Similar research has been conducted with parents of severely injured children and it is recommended that a future study follow a similar protocol (Foster, Curtis, Mitchell, Van, & Young, 2016). It is recommended that the study would combine qualitative data, in the form of face-to-face semi-structured interviews with parents and quantitative data on child and parental quality

of life (QoL), parenting stress, emotional distress and resilience at four different time points; acute hospitalisation, 6, 12 and 24 months. It is recommended that around 40 parents of children with a tracheostomy aged 0-12 years be recruited from specialist children's hospitals in the U.K. where paediatric tracheostomies are carried out.

The research would have several aims including; 1) explore parents' experiences of parenting a child with a tracheostomy in the acute hospitalisation phase, at 6, 12 and 24 following receiving the tracheostomy, 2) identify parents' unmet needs and factors that contribute to, or impede, needs being met during the time following their child receiving a tracheostomy and 3) measure child and parent quality of life, parental emotional distress, parenting stress and resilience during acute hospitalisation, and at 6, 12 and 24 months following receiving a tracheostomy. Such research would help to address an existing gap in the literature and provide guidance for service delivery for these families.

Despite focusing on different perspectives (parent and child) similar themes emerged from both papers. These included experiences of social isolation, medicalisation of their lives, and a loss of privacy. Both parents' and children's lives were consumed by caring for others or being cared for. These similar findings from both papers can be considered in the context of Bowen's family systems theory which views the family as a system, where a change in one individual is considered to affect all individuals in the family system (Bowen, 1993). Little research has explored the impact on each family member, including siblings, highlighting a potential area for future research. In the context of siblings, the empirical paper found that parents were required to prioritise their caring responsibilities and reported feelings of guilt towards their other children (without a tracheostomy). Parents worried that their other children were "missing out" and felt guilty for needing to spend most of their time caring for their child with a tracheostomy. In the context of Bowen's Family Systems theory (Bowen,

1993), these findings suggest that parents caring responsibilities would have impacted on siblings of children with a tracheostomy, highlighting a potential area for further research.

The parents' narratives of needing to spend more time caring suggests that children with a tracheostomy were treated differently to their brothers or sisters without a tracheostomy. Previous studies of parents with children with a chronic illness have reported this parental differential treatment of siblings (Quittner & Opipari, 1994). For example, it has been found that parents are more tolerant with their children with a physical illness in comparison to their children without (Walker, Garber, & Van Slyke, 1995). This parental differential treatment (PDT) in the form of parental affection, control or types of support, has been consistently linked with emotional and behavioural problems in children (Scholte, Engels, de Kemp, Harakeh, & Overbeek, 2007) and with the quality of sibling relationships (Buist, Deković, & Prinzie, 2013). Studies have found that it is often the sibling without physical health needs, receiving less attention from parents, who experiences psychosocial difficulties (Scholte et al., 2007). Future research could explore the link between parental differential treatment, the quality of sibling relationships and wellbeing in children with respiratory assistance and their brothers or sisters.

Both papers referred to identity and respiratory assistance. The empirical paper suggested that parents struggled with their changing identity which resulted from their caring responsibilities and the literature review highlighted some of the challenges of identity development in children with respiratory assistance. A key finding of the literature review was that children with respiratory assistance have the same developmental needs as all children. Erikson's stages of psychosocial development postulate that the task for adolescence is focused on the development of self-concept, sexuality and separation from parental attachment (Erikson, 1963). Evident from the literature review, respiratory

assistance greatly impacted on the lives of young people, which complicated the tasks of identity development in adolescence (Kirk, 2010; Sarvey, 2008; Spratling, 2012). Findings from the literature review indicated that some children's attempts to "fit in" with a peer group were challenged due to the visibility of the respiratory assistance (Kirk, 2010). Furthermore, dependence on a parent or carer for the management of their respiratory assistance and the resulting lack of privacy and control impacted on adolescents' attempts at striving for independence (Spratling, 2012). Previous studies have suggested that parental control during adolescent development are linked to an increase in problem behaviours in adolescence (Holmbeck, 2002). Given these findings, future research could explore whether parental control is related to problem behaviours in children with respiratory assistance. Such research would be beneficial in understanding how best to support these young people during an important stage of their development.

It has been suggested that identity development plays an important role in an individuals' adjustment and ability to cope with chronic illness (Holmbeck, 2002). Research found that adolescents with congenital cardiac disease with a diffused identity (also known as a weak sense of identity) were at risk of experiencing problems with treatment adherence and a range of psychosocial difficulties (Luyckx, Goossens, Van Damme, & Moons, 2011), suggesting that identity development influences psychosocial and illness-specific functioning in chronically ill adolescents. With respect to adolescents with respiratory assistance, future research is recommended to explore whether identity development can influence adjustment and promote resilience in adolescents with respiratory assistance.

The empirical study found that parents were required to assume an additional role of caring. Parents in the empirical study and previous research have described challenges in managing the roles of "parent" and "carer" (Kirk, Glendinning, & Callery, 2005; Wang &

Barnard, 2004), highlighting an area for further research. Furthermore, most parents spoke of personal growth and a changed sense of self that resulted from their experiences. It is possible that this personal growth reported by parents could be considered in the context of post-traumatic growth (PTG). PTG is a phenomenon that has been observed in parents and children with serious paediatric illnesses. The experience of PTG may include greater personal strength, a recognition of new possibilities and a greater appreciation of life (Picoraro, Womer, Kazak, & Feudtner, 2014), experiences described by parents within the empirical study. It would be interesting to explore whether other parents of children with a tracheostomy describe similar experiences of personal growth and change. Future research could assess PTG with a larger group of parents of children with a tracheostomy to explore the prevalence, mechanisms, individual characteristics and support networks which may contribute to the experience of PTG.

The empirical paper found that for parents, the period of adjustment to their child's need for a tracheostomy was filled with uncertainty. Some parents reported significant difficulties soon after their child received a diagnosis, however the individual psychological factors that influenced parental coping are unclear. One suggestion could be that parental coping was influenced by their attachment style. Research has found that individuals with secure attachment styles manage stressful life events with little psychological distress (Mikulincer & Florian, 1998). In the context of childhood illness, it has been proposed that a parent's attachment style influences coping (Mikulincer & Florian, 1998). Previous research has found that a mother's attachment style can influence their psychological reaction to an infant receiving a diagnosis of congenital heart disease (Berant, Mikulincer, & Florian, 2001). Specifically, a secure attachment style was linked to relatively lower levels of distress (Berant et al., 2001). More recently, research exploring parental attachment style and stress, found

that attachment avoidance was associated with higher levels of stress in parents caring for a child with diabetes (Moreira & Canavarro, 2016). Research exploring attachment style and parental coping and adjustment in parents caring for a child with a tracheostomy would provide useful insights into resilience factors for this population.

It is important to note that whilst the two papers reported similar findings, the age range of the children differed in the studies. The empirical paper focused on parents of children aged between 13 months to 4 years, whereas the literature review explored studies capturing the views of children and adolescents aged between 4-18 years. It is important to consider how the age of the child with a tracheostomy impacts both the parents' and child's experiences. The empirical paper explored the experiences of parents of pre-school children not school-aged children. Future research is recommended to explore adjustment and challenges over time, such as starting school. Longitudinal research would allow exploration of changes over time, specifically, parents' and children's experiences of transition to school and experiences within the school environment. Findings from this research would help to identify what resources are needed to support these parents and children at different time points.

Implications for Clinical practice

Raising awareness and education

Healthcare providers need to be aware of the potential emotional impact of caring for a child with a tracheostomy. A starting point would be for the findings of this research to be disseminated to all staff working with parents of children with a tracheostomy as a way to raise awareness of some of the challenges experienced by parents.

The findings from both papers suggest that there is a need for greater understanding and awareness of respiratory assistance. In the literature review, children highlighted how greater awareness of respiratory assistance would help other people to see them as "normal" (Sarvey, 2008) and support them in building relationships with other children (Spratling, Minick, & Carmon, 2012). Furthermore, the empirical paper suggested that friends', family members' and community carers' reluctance to support with caring responsibilities was related to their lack of awareness of the care involved in a tracheostomy. These findings suggest that educating the school population, including teachers, support staff and students would be important to help children with respiratory assistance integrate and build relationships in the school environment. One suggestion may be for carers and nursing staff, experienced in respiratory assistance, to provide this education to the school population.

Educating community carers, family members and friends, with little experience of tracheostomy care and management, could help to reduce anxieties in caring for a child with a tracheostomy. Clinical nurse specialists, with their expertise in respiratory assistance, could offer training to less experienced medical staff and to the community teams where children are transferred to following receiving a tracheostomy. Such training could support parents and children with transitions from specialist hospitals to the community. Recent research highlighted the important role of healthcare providers in offering support to families caring for a child with a tracheostomy (Callans, Bleiler, Flanagan, & Carroll, 2016). Community carers trained in tracheostomy care could help to support parents in training family members and friends in tracheostomy care. Given that parents' narratives in the empirical paper focused on the "constant" and unrelenting need to be caring, additional support with caring could help give these parents opportunities for respite.

Medical Staff: Systemic working, transitions and identity development

All staff should adopt a systemic approach when working with these families and consider the impact on all family members including siblings. Assessment of parental functioning should form be part of routine clinical practice. At each clinic appointment in the specialist hospital, staff working with these families should routinely assess parental functioning, including physical and emotional health of each parent and when appropriate refer for additional support (e.g. Clinical Psychology) or signpost to other resources.

Clinical Psychologists should be involved in working with this population and form part of the multi-disciplinary team considering the psychological needs of these families. Furthermore, Clinical Psychologists should provide training to staff on systemic working and some of the emotional difficulties experienced by parents, and when required, provide further support and intervention to family members (parents, siblings or the child with a tracheostomy).

There needs to be more support for parents transitioning from hospital to caring for their child independently at home. It would be important for Clinical Nurse Specialists to support this transition by liaising with community teams prior to discharge to establish their level of knowledge and competencies in paediatric tracheostomies. When necessary, the Clinical Nurse Specialists should provide additional training in tracheostomy care to less experienced staff and carers. Furthermore, Clinical Nurse Specialists should support with transition by visiting the home soon after parents have been transferred to the community to ensure that skills learnt in the hospital are generalised to the home environment. Tracheostomy training “refreshers” should be offered periodically by Clinical Nurse Specialists to parents and community teams to ensure continued competence and confidence in tracheostomy care and management.

The findings highlighted an important role for medical staff to support the identity development of young people with respiratory assistance and to recognise and support the needs of all family members.

Findings from literature review revealed that children wanted to be seen as an individual separate from their physical health needs (Earle, Rennick, Carnevale, & Davis, 2006; Kirk, 2010; Noyes, 2006; Sarvey, 2008; Spratling, 2012) and nursing staff were indicated as key to supporting children and people's self-concept (Spratling, 2012). Therefore, these findings suggest that it would be important for staff working with these young people to engage in discussions about their interests separate to their respiratory assistance. Furthermore, findings from the literature review suggest that relationships with peers are an important source of support in the identity development of young people with respiratory assistance (Kirk, 2010; Spratling, 2012). Based on these findings, it would be important for staff to support young people with meeting and developing relationships with other young people.

The medicalisation of children and parents lives found in both papers suggests that living with respiratory assistance is all consuming and dominates the lives of all family members. In the empirical paper, all the parents described the crucial role they played in the lives of their children with a tracheostomy. Their daily lives were consumed by caring and several felt like they were forgotten, described in the literature as "invisible work" (Ray, 2002). As discussed in the empirical paper, routine assessment of parental functioning, including their physical and emotional health, throughout the tracheostomy trajectory would help to identify parents who are struggling and need additional support. This assessment could be carried out by healthcare professionals at routine clinic appointment for their child

with a tracheostomy and parents experiencing difficulties could be offered additional support.

Based on previous research and the findings discussed, it would be important for healthcare professionals to adopt a systemic approach when working with these families to consider the needs and roles of each family member including the young person, parents and siblings. Through adopting a systemic approach with these families, staff would be able to support family members' adjustment to respiratory assistance and ensure that additional intervention is offered when appropriate.

Peer Support for Child and Parents

A peer support network should be developed for parents caring for a child with a tracheostomy. Staff working in the hospitals specialising in paediatric tracheostomies should develop a "buddy system" of parents who are willing to discuss their experiences. Specifically, parents whose children are about to receive a tracheostomy, or have just received a tracheostomy, should be offered to opportunity to meet with or talk to these parents. Throughout parents' tracheostomy journeys, staff working in the specialist hospital should facilitate peer support with parents of children with a tracheostomy. An annual social event should be organised for families of children with a tracheostomy, this would give the opportunity for parents to meet others and share their experiences. This should be facilitated by the specialist hospitals who provide the care for children with tracheostomies and their families.

Children reported feeling socially isolated and knew few other young people with respiratory assistance. Establishing a peer support network for young people with respiratory assistance may help children to feel less isolated. Studies have found that children with

chronic illnesses highly value the support from peers with similar health conditions (Kyngäs, 2004). Online peer-support communities have been shown to empower young people with cystic fibrosis and helped them to express their feelings and strategies for living (Kirk & Milnes, 2016). Creating an online community for young people with respiratory assistance could be a starting point to help young people to connect with peers with similar experiences. This would be especially important for individuals with communication difficulties and whose mobility and activity levels are restricted by respiratory assistance.

In addition to children feeling isolated, parents also described feelings of social isolation which were exacerbated by the lack of support with caring. A meta-synthesis of family members' experiences when a child is ventilator-dependent highlighted the need for a professional co-ordinator with these families (Lindahl & Lindblad, 2011). In the context of empirical study, a community-based professional co-ordinator role could help to support with transition from hospital to the community, both in terms of preparing parents for the transition in caring responsibilities and ensuring that appropriate support (both with caring and emotional) is available in the community. Furthermore, a professional co-ordinator would be able to continue to monitor family adjustment to living with and caring for a child with a tracheostomy and if necessary, facilitate appropriate intervention for families who need additional support.

The Role of Clinical Psychology

Healthcare professionals have been identified as potentially playing a significant role in the support of children and families. Clinical Psychologists, with their knowledge and expertise across the developmental lifespan, of a range of psychological theory, assessments, formulation and evidence-based treatment approaches could offer training and consultation

to these healthcare professionals (Division of Clinical Psychology, 2010). Specifically, Clinical Psychologists are well placed to help increase healthcare professionals understanding of child development and ways to promote identity development in children and adolescents. Furthermore, Clinical Psychologists, with their knowledge and experience of systemic approaches, could offering training to help staff recognise and support the needs of young people with respiratory assistance and their families.

When appropriate, Clinical Psychologists could offer psychological intervention to young people with respiratory assistance and family members experiencing difficulties. Research has evaluated a range of different psychological interventions to support psychological adjustment and adherence in children and young people with chronic illnesses. (Drotar, 2006; Kahana, Drotar, & Frazier, 2008). One such study found that an adapted version of acceptance and commitment therapy (ACT) was linked to reductions in parental distress for parents of children with life threatening illnesses (Burke et al., 2014), suggesting that a similar approach might be effective with parents of children with respiratory assistance. It would be important for Clinical Psychologists to undertake routine audits and evaluations to support the understanding of the psychological needs of this population and the development of evidence-based interventions.

Reflective commentary

The following reflections are based upon my thoughts, feelings and experiences I noted in a reflective diary throughout the research. As recommended by Smith, Flowers & Larkin (2009) as part of the Interpretative Phenomenological Analysis (IPA) process, keeping a reflective diary enabled me to recognise what I was bringing to the research and to focus on the lived experience of each participant.

I was fortunate during this research to be able to spend time with staff, children and family members at a specialist children's hospital gaining an understanding of what happens when a child needs a tracheostomy. I spent a lot of time with a tracheostomy clinical nurse specialist and observed several medical procedures on the ward and observed the surgical team in theatre performing various surgical procedures on children with tracheostomies. I noticed how I felt in awe of the strength and resilience of the children and their families.

I spent a lot of time with a young boy who, because of throat cancer, needed to have a tracheostomy. The tracheostomy meant that he had lost his ability to speak. Spending time with the young boy, I fluctuated between feeling extremely sad that he had experienced so many difficulties in his short life yet also inspired by his resilience, the way he continued to smile and make jokes despite his illness. I reflected on how, like this young boy, most of the young children are probably unable to understand why it is they required a tracheostomy or why they needed to spend so much time in hospital away from their families and friends. I noticed how I would make comparisons between how differently children and adults respond to physical health difficulties. Often we, as adults, look for meaning in our experiences, question, "why us?" and worry about the future which can lead to a range of emotional responses including sadness, anger and anxiety. The children I observed, rather than questioning, searching for meaning or worrying about the future, they were very much focused on the here and now and they expressed their emotions often in relation to physical pain or frustrations with not being able to play.

I observed parents being trained in tracheostomy care and I noticed feeling anxious when watching a parent performing a tube change on their child for the first time. I witnessed the unwavering commitment and dedication of parents to their children and I noted how these parents looked strained and exhausted by what they had been through. These

experiences of spending time with and observing the medical team, children and families helped me to develop my understanding of a tracheostomy from a medical perspective. Important to my research, it gave me an insight into the medical journey of a child with a tracheostomy and their families. I was able to observe, first-hand, several of the experiences parents spoke about in their interviews. Gaining these insights was helpful to my research as my increased understanding of medical terminology gave more time in the interviews for further exploration of parents' feelings in relation to their experiences.

Conducting the interviews was a new and interesting experience for me. I initially found it challenging to switch from my role at a trainee clinical psychologist to a qualitative researcher. I noticed that some of the skills I have developed were useful for the process whereas some others I needed to carefully manage and adapt. For example, I found that my skills in active listening helped the parents to feel comfortable to talk in detail about the experiences, whereas the more interpretative stance I use in my therapeutic work might have influenced parents' interpretation of their experience so I needed to be mindful to allow the parents to speak about their experiences without potential contamination of my own view point. I found this to be quite difficult as I noticed how I am often drawn to interpretation and sense making of peoples' experiences. I found that making a note of my interpretations during the interview rather than verbalising them helped with this.

During data collection, there was one parent who I struggled to engage in the interview and she often gave one word answers to the interview questions. I reflected that possibly, for this individual, IPA was not the best approach as it requires an ability and willingness to express and reflect on your experiences. I considered how other research methods, such as a questionnaire or observation, might have more easily captured this parent's experience.

During and after each interview, I noticed how I felt overcome and inspired by the strength and resilience of each parent. I felt extremely grateful for their honesty, openness and willingness to disclose some of their most challenging experiences with me.

When transcribing the parents' interviews I was surprised at the differences between how a parent had expressed something and what they had said. Often the way in which they expressed something mismatched the emotion that was evoked through what they were saying. For example, parents' descriptions of their children's physical health needs were said in a matter of fact way. I reflected upon how in the interviews I often responded to how they said something rather than what they said and wondered how this might have felt for the parents being interviewed.

Interestingly, it was not until analysing the transcripts in depth that I became aware of how much avoidance and disregard parents gave to their own emotional experience. This strategy of "switching off" emotions appeared to be protective for parents and I reflected on the usefulness of this strategy. Whilst most parents' narratives implied that thinking about or expressing their own emotions was unhelpful, I was left wondering whether this was really the case. I questioned the function of this strategy to disregard their own emotional response. I wondered whether they thought that their emotions would get in the way of their caring responsibilities and if they felt unable to feel a certain way and care for their child at the same time.

Thinking in detail about the parents disregard of their own emotions, I considered my own use of this strategy and how effective it was. I reflected on how I often ignore my own emotional response in much of my clinical and research work. In my clinical role, I am regularly required to communicate distressing information to clients, whilst it is important to recognise how I feel, expressing the emotion I feel (e.g. sadness) is often unhelpful to the client. I have

noticed that my strategy to manage not expressing my emotions is to disregard them and "just get on with it". Interestingly, it is often the emotions I perceive to be negative that I disregard. These reflections on my own experiences left me questioning whether this was the experience for the parents I interviewed. Whether they disregarded or avoided "negative" emotions such as sadness and anger as these would interfere with caring responsibilities yet expressed emotions such as happiness and joy.

In relation to this disregard of emotions, I noticed that during various stages of my research I would fluctuate between listening to and ignoring my emotions, dependent on the task. For example, when I transcribed the interviews I would disregard my emotions as the task required me to listen to each word so it could be accurately transcribed rather than engage in the content. During the analysis, I reflected on how the more time I spent with the transcripts the less emotionally connected I felt to what each parent was saying. I wondered whether I had become de-sensitised to what the parents were saying, whether the words lost some of their meaning because I had spent so much time reading and re-reading the interviews. Being able to connect with the emotion of what the parent is saying is an important part of IPA. I found that referring to my reflective diary and reading how I felt at the time of the interview, reading the transcripts out loud and taking a break to allow myself time to look at the transcript with "fresh eyes", helped me to re-connect with their experiences.

Throughout the research and especially when developing themes, I noticed how I felt a huge responsibility to each of the parents I had interviewed. I wanted to make sure I was able to capture their experiences fairly and honestly and in a way in which they would want me to. In the early stages of developing themes, I felt overcome by this responsibility which was both helpful and unhelpful to the process of analysis. It was helpful in that I would often

refer to the original transcripts to make sure that each theme was grounded in their experiences. I would frequently challenge and question myself to ensure that each quote and theme adequately captured the experience of that parent. The responsibility I felt was unhelpful as I found it hard to be selective and reduce the themes. I noticed feeling a sense of guilt with not being able to capture everything everyone had said.

Overall, I feel very privileged to be able to conduct this research. Considering the role of Clinical Psychology and a psychological perspective in a setting dominated by medical perspectives has been an interesting and challenging experience. The research conducted in this field is typically undertaken by nursing staff rather than psychologists and I would often question what I, as a trainee clinical psychologist, could bring to this research. Through the process of completing my thesis, I have become aware how valuable it is for psychologists to engage in research where a psychological view is possibly underrepresented. I hope that in offering a psychological perspective of these parents' experiences, more in-depth research is undertaken and that services are more able to recognise and meet the psychological needs of this inspiring group of people.

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Appendices

Appendix 1: Bangor University Ethics Approval

Please note ethics approval was obtained in my maiden name: "Davies".

PRIFYSGOL BANGOR UNIVERSITY

16th August 2016

Dear Jessica,

2016-15682 Parents' experiences of caring for a child with a tracheostomy

Your research proposal number 2016-15682 has been review by the Psychology Ethics and Research Committee and the committee are now able to confirm ethical and governance approval for the above research on the basis described in the application form, protocol and supporting documentation. This approval lasts for a maximum of three years from this date.

Ethical approval is granted for the study as it was explicitly described in the application.

If you wish to make any non-trivial modifications to the research project, please submit an amendment form to the committee, and copies of any of the original documents review, which have been altered as a result of the amendment. Please also inform the committee immediately if participants experience any unanticipated harm as a result of taking part in you research, or if any adverse reactions are reported in subsequent literature using the same technique elsewhere.

Governance approval is granted for the study as it was explicitly described in the application and we are happy to confirm that this study is now covered by the University's indemnity policy.

If any new researchers joins the study, or any changes are made to the way the study is funded, or changes that alter the risks associated with the study, then please submit an amendment form to the committee.

Yours sincerely,

Katie Jones
School of Psychology Ethics Administrator

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Appendix 2: Confirmation of Bangor University Liability Insurance

Hasilwood House
60 Bishopsgate
London EC2N 4AW
Tel: 020 7847 8670
Fax: 020 7847 8689

TO WHOM IT MAY CONCERN

18th July 2016

Dear Sir/Madam

BANGOR UNIVERSITY
AND ALL ITS SUBSIDIARY COMPANIES

We confirm that the above institution is a Member of U.M. Association Limited, and that the following covers are currently in place:-

1. **EMPLOYERS' LIABILITY**

Certificate No.	Y016458QBE0116A/026
Period of Cover	1 August 2016 to 31 July 2017
Limit of Indemnity	£25,000,000 any one event unlimited in the aggregate.
Includes	Indemnity to Principals
Cover provided by	QBE Insurance (Europe) Limited and Excess Insurers.

2. **PUBLIC AND PRODUCTS LIABILITY**

Certificate of Entry No.	UM026/95
Period of Cover	1 August 2016 to 31 July 2017
Includes	Indemnity to Principals
Limit Of Indemnity	£50,000,000 any one event and in the aggregate in respect of Products Liability and unlimited in the aggregate in respect of Public Liability.
Cover provided by	U.M. Association Limited and Excess Cover Providers led by QBE Insurance (Europe) Limited

If you have any queries in respect of the above details, please do not hesitate to contact us.

Yours faithfully

Susan Wilkinson
For U.M. Association Limited

U.M. Association Limited
Registered Office: Hasilwood House, 60 Bishopsgate, London, EC2N 4AW
Registered in England and Wales No. 2731799

Appendix 3: IRAS Form - Ethics Proposal

IRAS Form | Reference: 16/WM/0381 | IRAS Version 5.3.1

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Parents' experiences of caring for a child with a tracheostomy v1

1. Is your project research?

(•) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
( ) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
(•) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ( ) Yes (•) No
b) Will you be taking new human tissue samples (or other human biological samples)? ( ) Yes (•) No
c) Will you be using existing human tissue samples (or other human biological samples)? ( ) Yes (•) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

[x] England
[ ] Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
◯ Scotland
◯ Wales
◯ Northern Ireland
◯ This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: if your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

◯ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ◯ No

6a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

◯ Yes ◉ No

Please see information button for further details.

6b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◯ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
The main researcher will be a student completing a Doctorate in Clinical Psychology.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

IRAS Form | Reference: 16/WM/0381 | IRAS Version 5.3.1

Integrated Research Application System
Application Form for Research involving qualitative methods only

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Parents' experiences of caring for a child with a tracheostomy v1

Please complete these details after you have booked the REC application for review.

REC Name:
West Midlands-Edgbaston

REC Reference Number:
16/WM/0381

Submission date:
04/08/2016

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Parents' experiences of caring for a child with a tracheostomy

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Ms	Jessica	Davies
Address	NWCPP, School of Psychology Bangor University Bangor, Gwent		
Post Code	LL57 2DG		
E-mail	psp504@bangor.ac.uk		
Telephone	01248388365		
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
Doctorate in Clinical Psychology

Name of educational establishment:
Bangor University

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Dr	Jo	Wray
Address	Centre for Outcomes and Experience Research in Children's Health, Illness and Disability		
	Great Ormond Street Hospital for Children NHS Foundation		
	London		
Post Code	WC1N 3BH		
E-mail	jo.wray@gosh.nhs.uk		
Telephone	02078297822		
Fax			

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	Liz	Whitehead
Address	Children's OPD Heulwen Unit		
	Ysbyty Gwynedd		
	Betsi Cadwaladr University Health Board		
Post Code	LL57 2PW		
E-mail	Liz.Whitehead@wales.nhs.uk		
Telephone	01248 384384		
Fax			

Please state which academic supervison(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Ms Jessica Davies	☐ Dr Jo Wray ☐ Dr Liz Whitehead

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ◉ Student
- ○ Academic supervisor
- ○ Other

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Miss Jessica Davies
Post	Trainee Clinical Psychologist
Qualifications	BSc Psychology Currently completing Doctorate in Clinical Psychology
Employer	Betsi Cadwaladr University Health Board
Work Address	NWCPP, School of Psychology Bangor University Bangor, Gwynedd
Post Code	LL57 2DG
Work E-mail	psp504@bangor.ac.uk
* Personal E-mail	
Work Telephone	01248 388365
* Personal Telephone/Mobile	
Fax	

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title Forename/Initials Surname
	Hefin Francis
Address	School of Psychology Brigantia Building Bangor
Post Code	LL57 2AS
E-mail	h.francis@bangor.ac.uk
Telephone	01248388339
Fax	

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	16HC15
Sponsor's/protocol number:	
Protocol Version:	
Protocol Date:	
Funder's reference number:	
Project website:	

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

◯ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A8-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

Background
Increasing numbers of children are now living with a tracheostomy, most of whom are being cared for in their own homes. As a result, parents have become involved in providing highly technical and intensive care to their children which was previously considered to be the domain of health care professionals. Research suggests that caring for a technology dependent child at home can be stressful, anxiety provoking and exhausting for parents and that it changes the meaning of parenting due to the need to provide nursing care for their child. However, to date there is little evidence about the specific impact of looking after a child with a tracheostomy at home despite the invasive, potentially life-threatening nature of the tracheostomy and the burden of responsibility placed on the parents.

Aim
The primary aim of the study is to explore and understand the experiences of parents/carers caring for a child with a tracheostomy at home. It is hoped that if we can understand more about parents' experiences of caring for a child with a tracheostomy such information will help clinicians to provide optimal, targeted support for families.

Methods
Parents of children who had a tracheostomy at Great Ormond Street Hospital at least 12 months previously and who have been caring for their child with a tracheostomy at home for at least 6 months will be eligible to participate. Six to eight eligible parents will be invited to participate in an interview to explore their experiences related to their child's tracheostomy. It is envisaged that interviews will last approximately 60-90 minutes and they will be audiorecorded for later transcription. Interview transcripts will be analysed to identify key themes related to their experiences.

The findings will be disseminated widely through presentations, publications and a report back to participants.

A8-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

Given the nature of the research there is a potential for some people to find some of the questions sensitive or distressing. Particular attention will be given to how the participant is coping during the interview and breaks and time out will be provided if necessary. The participant will also be offered the opportunity to postpone the interview should they feel unable to continue at that point in time. It will also be made explicitly clear to the participant that the interview can be terminated at any point for any reason by indicating to the interviewer that they wish to do so (the participant will not need to give a reason for terminating the interview). In the instance of interview termination reassurance and support will be provided to the participant and they will be provided with the contact details of a tracheostomy nurse specialist, who knows the participant, for additional support. The nurse specialist will be able to refer the participant on for further support if necessary. In addition, in the unlikely event that a participant becomes particularly distressed during or following an interview the researcher will contact the tracheostomy nurse if the participant indicates that they would like further support. If during the interview the participant gives information indicating that their child or someone

else's child is at risk of significant harm, the GOSH policy for safeguarding children and young people will be followed. If there is a concern of risk of harm to the participant the relevant GOSH policy will be followed. If the researcher is concerned about any risk of harm either to the participant or anyone else, then she is legally obliged to share this information with the appropriate people, (a contact person from the clinical team, and GP). The researcher will always try to discuss these concerns with the participant first, before doing anything. Furthermore, the researcher will seek supervision from her supervisor based at GOSH. Following the interview, the researcher will spend time finding out how the participant is feeling and check if there are any issues that need addressing. This will be done verbally immediately after the interview. Again in this instance, if the participant reports any concerns these will be passed on to the tracheostomy nurse specialist for additional support if appropriate.

It is also recognised that there are important considerations for the researcher. Firstly, if she undertakes any of the interviews at participants' homes she will follow the GOSH lone-worker policy and ensure that someone has details of where she is, contact details for her and information about the time of the interview. She will text her GOSH supervisor on arrival and on leaving the interview. There is also potential for some of the interviews to be distressing for the researcher so she will be able to debrief with her supervisor after each interview, should she need to. The researcher is based in Wales and will be travelling to GOSH to conduct the interviews. Given the distance it will be important that interviews are organised carefully to minimise the risk of cancellation.

Finally, there are potential issues related to the use of audio-recording and data protection. The researcher will ensure that all audio-recordings are downloaded onto a secure hospital password protected computer at the earliest opportunity and that the recording is wiped from the dictaphone. All data will be stored securely in accordance with the Data Protection Act and local GOSH policy.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply:*

- ☐ Case series/ case note review
- ☐ Case control
- ☐ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☐ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The primary objective is to explore and understand the experience, from a parental/care givers perspective, of caring for a child with a tracheostomy.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

n/a

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

More children with chronic medical conditions which impact on their respiratory function, requiring support from a tracheostomy, are surviving, largely due to advances in tracheostomy care and technology support. The vast majority of these children are now being cared for in their own homes and at school (Cooke, 2009). Consequently, parents have become involved in providing highly technical and intensive care to their children, previously considered to be the domain of healthcare professionals (Kirk, & Glendinning, 2002).
Clinical practice indicates that parents of children with a tracheostomy report being initially overwhelmed and concerned about their ability to provide the required tracheostomy care for their child (Flynn, Carter, Bray Donne, 2013). Research seeking to understand the experiences of being a parent to a technology-dependent child identified that this can alter the meaning of parenting, with parents describing themselves as having a role that had both parenting and nursing dimensions which creates a number of tensions for parents. The study suggested that professionals working with these families need to recognize the significant "emotional dimension" for parents and should provide the opportunity to "discuss their feelings about caregiving and what it means for their parenting identity and their relationship with their child" (Kirk, Glendinning, Callery, 2005).
This study suggested an important role for professionals in working with parents caring for a technology-dependent child, however the researchers did not explore specifically, parents' experiences of caring for a child with a tracheostomy. A recent review of the literature has highlighted the lack of in-depth research exploring parents' experiences of caring for a child with a tracheostomy (Flynn, Carter, Bray Donne, 2013). Therefore, a main aim of the current study is to contribute to the research in this field through gaining an in-depth understanding of parents' experiences of caring for a child with a tracheostomy. Recent research has also highlighted the lack of data from male parental caregivers (Joseph, Goodfellow, Simko, 2014). This study will therefore aim to recruit both male and female parental caregivers to gain further understanding of experiences from a range of perspectives.
By gaining an understanding of families' experiences of caring for a child with a tracheostomy across the trajectory of care, the study aims to provide evidence to guide healthcare professionals who are supporting these children and families. It is hoped that the insights gained from this study will be help to improve the care of families when children receive a tracheostomy in the future.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

The nature of the research methodology means that no specific hypotheses will be tested out in the research. Advances in tracheostomy care mean that many more children are being looked after in their own home, however little is known about the parents experience of caring for a child with a tracheostomy. Given the importance in including service users in the development of services and the fact that relatively little is known about the lived experience of caring for a child with a tracheostomy it is important to gain this understanding in order to shape future services effectively. It is for these reasons that the current project has been developed.

Stage 1:
Initial meetings will be held with the paediatric tracheostomy team at GOSH in order to promote the research amongst professionals and help identify suitable participants for the research. Professionals will be given clear exclusion/inclusion criteria and asked to identify potential participants.

Stage 2:
Once suitable parents/carers have been identified information sheets, including information about the study and reply slips for parents/carers interested in the research will be given either by post or in person at their routine clinic appointment in GOSH. Families interested in receiving further information about the study will be asked to complete the reply slip.

Stage 3:
Contact will be made with potential participants who have returned reply slips, expressing an interest to take part in the research. More information about the research will be shared with the parent/carer expressing an interest in the research and they will be provided with the opportunity to ask questions about the research. It will be made clear that their participation in the study is completely voluntary and it is their choice to decide if they would like to take part. They will be informed that the decision they make will not affect the standard of care their child receives from the NHS. Furthermore, they will be made aware that they can change their mind at any time and stop participating in the study.

Stage 4:
Once a participant has agreed to take part in the study, a time and a place to meet will be agreed. In most instances this will be at their next clinic appointment at GOSH, however if this is not feasible for the family, the researcher will

organise a more convenient option. This can be in the participant's own home or a mutually convenient location.

Stage 5:
At the time of the interview the researcher will begin by reviewing each aspect of the consent form with the participant including the use of audio recording and the right to withdraw at any time. Confidentiality will be discussed and the participant will be made aware of the limits of confidentiality, i.e. that what is discussed will remain confidential and their anonymity protected, however if the researcher is concerned about any risk of harm either to the participant or anyone else, then she is legally obliged to share this information with the appropriate people, (a contact person from the clinical team, and GP). The researcher will always try to discuss these concerns with the participant first, before doing anything. The participant will be asked to provide written consent before the interview begins.

Prior to starting the interview the participant will be asked to complete a demographics questionnaire. They will be told that if they are unsure about any question they should ask the researcher and if they do not feel comfortable with answering any questions then they can leave them blank. The purpose of the study will be reiterated and the focus of the interview will be introduced to the participant. Following this the audio device will be tested to ensure it is working correctly and then the semi-structured interview will be carried out. It is hoped that the semi-structured interview will allow some containment for the participant, however also provide the opportunity to explore in greater detail areas which may be of importance/interest. It is hoped that the flexibility of the interview agenda will allow for rapport building which will be important given the sensitive nature of the topic.
Participants will be interviewed in an in-depth semi-structured conversational style interview. The interviews are expected to last 60-90 minutes with breaks as required. On conclusion of the interview participants will be asked to reflect on their experiences of the interview, and given the opportunity to ask any further questions. They will also be informed that they may contact the researcher should they have further queries or concerns. Only one meeting between the participant and the researcher is likely to be required but if parents wished to extend the interview over two sessions this will be facilitated. The interviews will be audio recorded, provided the participant has given consent for this.

Stage 6: Recorded interviews will be transcribed and later analysed using interpretative phenomenological analysis (IPA).

Stage 7: Once all data have been analysed and written up, participants who expressed an interest in finding out about the results of the study will be provided with a summary document of the findings. This document will be written in language comprehensible to the lay person.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [x] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
Design of the research:
During the development of the project parents of children with a tracheostomy were consulted about their experience of caring for their child in addition to care they have received from GOSH. This provided valuable insights which highlighted the need for the project, contributed to the research topic and provided information which contributed to the development of the semi-structured interview guide. Furthermore, these consultations provided important insight into what needs to be taken in to account to ensure that parents feel comfortable with taking part in the study.

Undertaking the research:
The questions in the semi-structured interview will also be piloted with parents of children with a tracheostomy who are not involved as participants in the research project. Parents' feedback will inform any revisions to the interview guide.

Dissemination of findings:
Following completion of the study it is hoped that service users will contribute to the dissemination of the results. In particular, service users will be consulted to ensure that the results are communicated in a clear and effective way

that is understandable. Methods of dissemination will be explored with service users to ensure that the results can be accessed by a reasonable number of people.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A16. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [ ] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [x] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit: 70	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 6000 characters).

Parents of children (aged 1-18) with a tracheostomy are being recruited who meet the following inclusion criteria:
1.Their child received a tracheostomy at Great Ormond Street Hospital
2.Their child has had a tracheostomy for at least 12 months
3.The parent has cared for their child with a tracheostomy at home for at least 6 months
4.The parent and child have received care regarding the tracheostomy from the GOSH paediatric tracheostomy team
5.Parents are able to speak English sufficiently well to participate in an interview in English

A17-2. Please list the principal exclusion criteria (list the most important, max 6000 characters).

Parents of children who had recently undergone a tracheostomy and remained inpatients will be excluded due to not being able to answer the majority of questions within the interview. Previous research has excluded these participants due to the likelihood that quality of life was "influenced more by the coexisting medical conditions necessitating tracheostomy, rather than the procedure itself" (Hopkins, Whetstone, Foster, Blaney, Morrison, 2009). Parents of children with a rare condition will be excluded due to the risk that this makes the family identifiable. Furthermore, parents of children with a child protection concern or involved in an ongoing complaint against GOSH will be excluded due to potential conflict with the information being gathered.

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Seeking consent:	1	n/a	20 minutes	Jessica Davies (Trainee Clinical Psychologist), at Great Ormond Street or participant's own home Hospital (GOSH)
Demographics form	1	n/a	10 minutes	Jessica Davies (Trainee Clinical Psychologist), at Great Ormond Streetor participant's own home Hospital (GOSH)
Semi-structured interview	1	n/a	60-90 minutes	Jessica Davies (Trainee Clinical Psychologist), at Great Ormond Street Hospital (GOSH)or participant's own home

A21. How long do you expect each participant to be in the study in total?

It is expected that the time from consent to feedback of results will be 12 months.

The face to face contact with parents will be approximately 120 minutes in total, including giving participants the opportunity to ask questions, taking consent, completing the demographics form and the semi-structured interview.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

The risks to participants are considered to be minimal. However, given the nature of the research there is a potential for some people to find some of the questions distressing or sensitive. Particular attention will be given to how the participant is coping during the interview and regular breaks and time out will be provided. The participant will also be offered the opportunity to postpone the interview should they feel unable to continue at any point in time. It will also be made explicitly clear that the interview can be terminated at any point for any reason (the participant will not need to give a reason for terminating the interview) and that if there are any particular questions that the participant does not wish to answer they do not have to do so. In the instance of interview termination reassurance and support will be provided to the participant and they will be provided with the contact details of a tracheostomy nurse specialist, who knows the participant, for additional support. The nurse specialist will be able to refer the participant on for further support if necessary. In addition, in the event that a participant becomes particularly distressed during or following an interview and requests further support the researcher will liaise with the tracheostomy nurse to facilitate this. Following the interview, the researcher will spend time finding out how the participant is feeling and check if there are any issues that need addressing. This will be done verbally immediately after the interview. Again in this instance, if

the participant reports any concerns this will be passed on to the tracheostomy nurse specialist for additional support.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

(•) Yes ( ) No

If Yes, please give details of procedures in place to deal with these issues:

Any parent who becomes distressed during the interview will be offered the chance to have a break from interviewing or terminate the session and will be provided with contact details for the tracheostomy nurse or local support services. If a parent specifically requests it, the researcher will make a referral to the appropriate services at GOSH (e.g. psychology, PALS). Once recording of the interview has stopped, parents will be invited to comment on their experience of taking part in the study and to voice any concerns. It has been suggested that this period of reflective discussion is important for participants who become distressed during the interview.

A24. What is the potential for benefit to research participants?

Direct benefits to research participants are likely to be minimal. However, participants may find sharing their experiences and telling their story helpful and a positive experience and may furthermore consider it beneficial to contribute to improved support for families of children with a tracheostomy in the future.

A26. What are the potential risks for the researchers themselves? *(if any)*

Interviews will take place at Great Ormond Street Hospital (GOSH) during working hours, however in cases where this is not possible and interviews take place in participants' homes, the local GOSH lone worker policy will be followed. In this situation the researcher will inform colleagues of where they are going and when they are likely to return. They will call a member of the supervisory team before and after the interview has taken place.

The opportunity to have a debrief and receive appropriate support will be provided to the researcher after the interview as it is recognised that some of the interviews may be challenging or distressing.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

Initial meetings will be held with the paediatric tracheostomy team at GOSH in order to explain the research to the team so that they can identify suitable participants for the research from the tracheostomy database. Professionals will be given clear exclusion/inclusion criteria and asked to identify potential participants. Once suitable parents/carers have been identified information sheets, including information about the study and reply slips for parents/carers interested in the research will be given either by post or in person at their routine clinic appointment in GOSH. Should they be interested in receiving further information they will be asked to complete the reply slip and return it to the researcher. There are approximately 2000 families caring for a child with a tracheostomy receiving treatment from GOSH. Approximately 4-10 participants will be sufficient for the research.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

( ) Yes (•) No

Please give details below:

Only members of the paediatric tracheostomy team will screen for potential participants.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

Once suitable parents/carers have been identified information sheets, including information about the study and reply slips for parents/carers interested in the research will be given either by post or in person at their routine clinic appointment in GOSH. This initial contact will be made by professionals working with the family i.e. the tracheostomy team. They will be given the information sheet to read detailing information about the study, including potential benefits and possible risks.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Initial contact will be made by professionals working with the family i.e. the tracheostomy team. They will be given the information sheet to read detailing information about the study, including potential benefits and possible risks. Furthermore, the information sheet explains that their participation is not mandatory and will not affect the care they receive in any way.
Parents/carers, if interested, will be asked to complete the reply slip so that the lead researcher can provide them with more information (they will be provided with a stamp addressed envelope to return the reply slip). When the reply slip has been returned including their chosen method of contact and contact details the researcher will make contact with the family. When the researcher makes contact they will be given the opportunity to ask any questions related to the research. They will also be made aware that their participation in the research is not mandatory and will not affect the ongoing care they receive in any way. Furthermore, they will be made aware that, should they choose to take part they may withdraw from the research at any stage. Following this initial contact between the researcher and potential participant if the parent/carer confirms that they would like to take part in the research they will be given the consent form to initial, sign and date (see supporting documentation). The consent form will be explained verbally in addition to the written information to ensure that all information is understood. If a parent whose first language is not English has expressed an interest in taking part GOSH translation services will be utilised to communicate with the potential participant. Translation services will be used to translate information sheets/consent forms. Although forms will be translated into different languages participants will only be included if they are willing to be interviewed in English. This is because the researcher will only be able to analyse the work through the medium of English.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

Participants will be given as long as they need to decide to take part. They will be given the information sheet and will have at least 24 hours to decide whether or not they are interested in taking part in the study. If a potential participant wishes to take part in a study as soon as possible this will be facilitated.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or

written information given in English, or who have special communication needs? *(e.g. translation, use of interpreters)*

If a family whose first language is not English has expressed an interest in taking part GOSH translation services will be utilised to communicate with the potential participant. Translation services will be used to translate information sheets/consent forms. Although forms will be translated into different languages participants will only be included if they are willing to be interviewed in English. This is because the researcher will only be able to analyse the work through the medium of English.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- (●) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ( ) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ( ) The participant would continue to be included in the study.
- ( ) Not applicable – informed consent will not be sought from any participants in this research.
- ( ) Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A38. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)? *(Tick as appropriate)*

- [ ] Access to medical records by those outside the direct healthcare team
- [ ] Access to social care records by those outside the direct social care team
- [ ] Electronic transfer by magnetic or optical media, email or computer networks
- [ ] Sharing of personal data with other organisations
- [ ] Export of personal data outside the EEA
- [x] Use of personal addresses, postcodes, faxes, emails or telephone numbers
- [x] Publication of direct quotations from respondents
- [ ] Publication of data that might allow identification of individuals
- [x] Use of audio/visual recording devices
- [x] Storage of personal data on any of the following:
  - [x] Manual files (includes paper or film)
  - [x] NHS computers
  - [ ] Social Care Service computers
  - [x] Home or other personal computers
  - [ ] University computers
  - [ ] Private company computers

☐ Laptop computers

Further details:

A37. Please describe the physical security arrangements for storage of personal data during the study?

A standard operating procedure for confidentiality and data security will be drawn up prior to the study commencing that is understood by all members of the research team with access to the data. Field notes will be written in short hand
that does not indicate which participant was involved (i.e participant numbers and pseudonyms will be used). When field notes are transferred to electronic copies, the hard copies will be destroyed. Any identifying data in notes and any significant indicators, such as specific nurses who may often be mentioned by patients in interviews for example, will be given a pseudonym. Participant details will be kept separately from information about their pseudonym.

Data storage: all digital data including interview transcripts will be stored on password protected computers or encrypted memory sticks and after transfer of the recording from the digital recorder to a computer drive the digital recording will be deleted. All paper copies of data will be kept securely in a locked filing cabinet in a locked office by the research supervisor (Dr Jo Wray). Participant identifiers and consent forms will be securely stored separately to any hard copy data.

A38. How will you ensure the confidentiality of personal data? *Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

All data collected during the course of the study will be held in accordance with the Data Protection Act (1998). This means that it will be kept safely and will not be revealed to other people without the participant's permission. Furthermore the GOSH policy regarding confidentiality and data protection will be followed at all times.
Personal information such as addresses and emails: This information will not be known to the researchers until contacted by participants or participants have returned the reply slips with the contact details they would like the researcher to use (e.g. email or phone number). Contact details will not be shared with anyone outside the research team.
Use of audio/visual recording devices: A digital recorder will be used to record the interviews. Written consent will be sought (as documented in the consent form) and the participants will be asked again for verbal consent to record the interview immediately prior to the interview commencing. When the interview has finished it will be securely downloaded onto a secure, password protected GOSH NHS computer. To ensure anonymity the file will be given a number and to enhance security, once the download to the GOSH computer is completed the original interview will be deleted from the digital recorder. Once the digital recordings of the interviews have been downloaded onto a secure GOSH computer, the interviews will be transcribed. All interviews will be anonymised when the researcher listens to and transcribes the interview. Each transcript will be password protected and given a number which can be linked to participants only via the consent forms (which will be stored in a locked cabinet in GOSH). Publication of direct quotations from participants: All direct quotes from participants, when written up for publication or internal reports, will be made anonymous using either a pseudonym or participant number. Potential identifiers (such as names of professionals or places) will also be removed. Parents of children with a rare condition will be excluded due to the risk that this makes the family identifiable.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

No-one outside the direct care team will have access to participants' personal data until participants have agreed that the researcher can contact them. At that point the researcher will have contact details for the participants. Once participants have consented to providing their personal data to members of the research team this will be restricted to the person conducting the interviews.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

Once the interviews have been transcribed and pseudo-anonymised the data will be analysed either by the researcher and her university academic supervisor and GOSH supervisor. Neither supervisor will have access to anything other than pseudo-anonymised transcripts. Analysis will be carried out by the researcher +/- her academic supervisors either at Bangor University or GOSH.

A42. Who will have control of and act as the custodian for the data generated by the study?

	Title Forename/Initials Surname
	Miss Jessica Davies
Post	Trainee Clinical Psychology
Qualifications	BSc Psychology, Currently completing Doctorate in Clinical Psychology
Work Address	North Wales Clinical Psychology Programme
	School Of Psychology
	Bangor University
Post Code	LL57 2DG
Work Email	psp504@bangor.ac.uk
Work Telephone	01248388365
Fax	

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ◉ 3 – 6 months
- ○ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

A44. For how long will you store research data generated by the study?

Years: 5
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

All data collected during the course of the study will be held in accordance with the Data Protection Act (1998). Any questionnaires, audio recording of the interview and transcripts of the interview will be given an identification number, so only the researcher will know whose data belongs to whom. The interview will be anonymous since any identifiable information will be deleted when the researcher listens to and transcribes the interview recording. Participants will not be identified in any report or publication of the results of the research.

All paper copies of information provided by participants will be kept securely in a locked filing cabinet that will only be accessible to members of the research team. Similarly, the electronic audio recordings of the interview and any other electronic information such as the interview transcripts will be saved on an encrypted memory stick or on the GOSH computer.
On completion of the research, all of the interview recordings will be wiped clean. However, paper copies of the transcripts of the interviews and completed questionnaires will be stored securely in a locked cabinet in a locked filing cabinet by the Research Supervisor (Dr Jo Wray) for up to 5 years, at which point they will be securely destroyed. At the end of the study all data held on anything other than a GOSH computer will be securely deleted.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives

for taking part in this research?

◯ Yes ◉ No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

◯ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

◯ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

A48-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

◯ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

◯ Yes ◉ No

Please give details, or justify if not registering the research.
The research will not be registered on a public database as it is not publicly funded. It will be registered on the GOSH database and once complete it will be available in the University of Bangor library. It is the intention of the lead researcher to ensure that the work will be written up for publication in a scientific journal.

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☑ Internal report
- ☑ Conference presentation
- ☑ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by independent Steering Committee on behalf of all investigators

☐ No plans to report or disseminate the results

☐ Other (please specify)

Written information about the overall findings will be provided to: participants if they requested this and to healthcare professionals involved in the care of the participants.

A62. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

No identifiable personal data will be used when publishing the results. All quotes will anonymised.

A63. Will you inform participants of the results?

◉ Yes ○ No

Please give details of how you will inform participants or justify if not doing so.
At the end of the interview participants will be asked if they would like feedback on the findings of the research. If they are interested, the researcher will note their chosen method of communication of the findings (e.g. email, letter, telephone). Once the data have been analysed and the internal report written, participants will be sent a copy of the report of the findings if they had said that they would like a copy. This report will be written in a way which is understandable to the lay person and free of scientific jargon. All terminology will be clearly defined within this report.

6. Scientific and Statistical Review

A64. How has the scientific quality of the research been assessed? *Tick as appropriate:*

☐ Independent external review

☐ Review within a company

☐ Review within a multi–centre research group

☑ Review within the Chief Investigator's institution or host organisation

☑ Review within the research team

☑ Review by educational supervisor

☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The NWCPP has received and approved an initial proposal for this study. The research team comprises of a number of experienced researchers in the field of psychology. The research will also be reviewed by members of the School of Psychology's ethics board at Bangor university before being submitted for wider NHS ethics and R&D approval.

The study has been reviewed by Great Ormond Street's research committee.

The study has also been reviewed within the research team by the two supervisors and the lead researcher undertaking their doctoral qualification. This is an ongoing process as the research will continue to be discussed by the research team through to completion of the study and through the completion of regular "progress reports" as per NWCPP policy.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A69. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:

Total international sample size (including UK):

Total in European Economic Area:

Further details:
Using qualitative methodology 4-10 participants will be recruited into the study in total.

A80. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

It is usual for qualitative research to involve recruitment of small numbers of participants in order to facilitate a deep analysis of the interviews. It allows researchers to recall individual accounts, and this helps reduce the loss of any subtle nuances between each individual's account.
Morse (2010) provided an overview of the recommendations for sample size in qualitative research and suggested that a study using interpretative phenomenological methodology interviewing each participant, in depth, over a longer duration (60 minutes +), produces a large amount of data for each participant and therefore needs fewer participants in the study (Morse, 2000). Typical sample sizes for these studies range from 1 to 10 persons. In addition, Smith, Flowers and Larkin (2009) recommend that researchers should recruit between 4-10 participants when conducting research for Doctoral level qualifications using Interpretative Phenomenological Analysis. Therefore, in keeping with typical qualitative studies, the proposed study aims to recruit between 4-10 participants.

References:
Morse, J. M. (2010). How different is qualitative health research from qualitative research? Do we have a subdiscipline?. Qualitative Health Research.

Morse, J. M. (2000). Determining sample size. Qualitative health research, 10(1), 3-5.

Smith, J. A., Flowers, P., & Larkin, M. (2010). Interpretative Phenomenological Analysis: Theory. Method and Research London: Sage.

A82. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Data will be collected through semi-structured interviews and will be analysed following a specific form of thematic analysis known as interpretative phenomenological approach (IPA). IPA requires a small and homogenous sample of individuals who provide in-depth information on the subject being studied.
IPA is an approach used to find out how individuals are perceiving the particular situations they are facing, and how they make sense of their personal and social world. The focus of IPA is gaining detailed, in-depth insights into the lived experience of a particular phenomenon, focusing on thoughts, feelings and an individual's interpretation of these. The approach places an importance on the researcher's own interpretation of a participant's interpretation of their personal and social world, leading to deeper analysis.

The approach was selected for the depth of information it can provide and for the partial structure which allows participants to raise all issues that are relevant to them, without the researcher imposing predetermined categories and expectations. The analysis of the interviews will be conducted manually, following, in part, the guidelines of Braun and Clark (2006), Smith, Flowers and Larkin (2009) and Smith and Osborn (2008). In order to promote the validity and credibility of the analysis, an independent rater (member of the research team) will review the data for discrepancies, overstatements and errors. Derived themes will be compared with the original transcripts to ensure that interpretations are grounded in participants' accounts, thus reducing researcher bias in the selection of themes for analysis. A final list of themes will be agreed after discussion of which themes best capture the interview data, to ensure the credibility of the final account.

References:
Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. Qualitative research in Psychology, 3, 77101.

Smith, J. A., Flowers, P., & Larkin, M. (2009). Interpretative Phenomenological Analysis: Theory. Method and Research London: Sage.

Smith, J. A. & Osborn, M. (2008). Interpretative Phenomenological Analysis. In JA Smith (ed) Qualitative Psychology. London, Sage. (2nd ed)

8. MANAGEMENT OF THE RESEARCH

A83. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Dr	Jo	Wray
Post	Senior Research Fellow/Health Psychologist		
Qualifications	BSc, MSc, PhD, DHP(NC), C Psychol		
Employer	Great Ormond Street Hospital for Children NHS Foundation Trust		
Work Address	Centre for Outcomes and Experience Research in Children's Health, Illness and Disability		
	Barclay House		
	37 Queens Square, London		
Post Code	WC1N 3BH		
Telephone	0207829 7822		
Fax			
Mobile			
Work Email	jo.wray@gosh.nhs.uk		

	Title	Forename/Initials	Surname
	Dr	Liz	Whitehead
Post	Clinical Psychologist		
Qualifications	DClinPsy		
Employer	Betsi Cadwaladr University Health Board		
Work Address	Children's OPD Heulwen Unit		
	Ysbyty Gwynedd		
	Gwynedd		
Post Code	LL57 2PW		
Telephone	01248 384384		
Fax			
Mobile			
Work Email	Liz.Whitehead@wales.nhs.uk		

	Title	Forename/Initials	Surname
	Ms	Jo	Cooke
Post	Clinical Nurse Specialist		
Qualifications	RSCN, MSc		
Employer	Great Ormond Street Hospital for Children NHS Foundation Trust		
Work Address	Great Ormond Street		
	London		
Post Code	WC1N 3JH		
Telephone			
Fax			
Mobile			
Work Email	jo.cooke@gosh.nhs.uk		

	Title	Forename/Initials	Surname
	Mr	Richard	Hewitt
Post	Consultant Paediatric ENT, Head & Neck and Tracheal Surgeon		
Qualifications	BSc DOHNS FRCS(ORL-HNS)		

Employer	Great Ormond Street Hospital for Children NHS Foundation Trust
Work Address	Great Ormond Street London
Post Code	WC1N 3JH
Telephone	
Fax	
Mobile	
Work Email	richard.hewitt@gosh.nhs.uk

A84. Details of research sponsor(s)

A84-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

If Other, please specify:

Commercial status:

Contact person

Name of organisation	Bangor University
Given name	Hefin
Family name	Francis
Address	School of Psychology
Town/city	Brigantia Building, Bangor
Post code	LL57 2AS
Country	UNITED KINGDOM
Telephone	01248388339
Fax	
E-mail	h.francis@bangor.ac.uk

Is the sponsor based outside the UK?

○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A85. Has external funding for the research been secured?

- [ ] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [x] No application for external funding will be made

What type of research project is this?

- (•) Standalone project
- ( ) Project that is part of a programme grant
- ( ) Project that is part of a Centre grant
- ( ) Project that is part of a fellowship/ personal award/ research training award
- ( ) Other

Other – please state:

A86. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A84-1) ? *Please give details of subcontractors if applicable.*

( ) Yes (•) No

A87. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

( ) Yes (•) No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A88-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Ms	Emma	Pendleton
Organisation	Great Ormond Street Hospital for Children NHS Foundation Trust		
Address	Great Ormond Street		
	London		
Post Code	WC1N 3JH		
Work Email	research.governance@gosh.nhs.uk		
Telephone	02079052485		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A88-1. How long do you expect the study to last in the UK?

Planned start date: 11/07/2016
Planned end date: 30/09/2017

Total duration:

Years: 1 Months: 2 Days: 20

A71-1. Is this study?

- (•) Single centre
- ( ) Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- [x] England
- [ ] Scotland
- [ ] Wales
- [ ] Northern Ireland
- [ ] Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?

( ) Yes (•) No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

[x] NHS organisations in England	1
[ ] NHS organisations in Wales	
[ ] NHS organisations in Scotland	
[ ] HSC organisations in Northern Ireland	
[ ] GP practices in England	
[ ] GP practices in Wales	
[ ] GP practices in Scotland	
[ ] GP practices in Northern Ireland	
[ ] Joint health and social care agencies (eg community mental health teams)	
[ ] Local authorities	
[ ] Phase 1 trial units	
[ ] Prison establishments	
[ ] Probation areas	
[ ] Independent (private or voluntary sector) organisations	
[ ] Educational establishments	
[ ] Independent research units	
[ ] Other (give details)	
Total UK sites in study:	1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The researcher will meet regularly with her supervisors throughout the study to match progress against targets and analyse data. Ad hoc meetings will also take place as required, particularly if there are any particular concerns - e.g. with recruitment. During the period of data collection the researcher will meet/speak to Dr Jo Wray after each interview to debrief and address any concerns. The wider research team will also meet twice during the project to monitor progress.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Bangor university will meet with potential legal liability of the sponsor for harm to participants arising from the management of the research. Please see attached sponsorship letter.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Bangor university will meet with potential legal liability of the sponsor for harm to participants arising from the management of the research. Please see attached sponsorship letter.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Bangor university will meet with potential legal liability of the sponsor for harm to participants arising from the management of the research. Please see attached sponsorship letter.

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

◯ Yes ◉ No ◯ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.*

Investigator identifier	Research site		Investigator Name	
IN1	(●) NHS site ( ) Non-NHS site		Forename Middle name	Dr Jo
	Country: England		Family name	Wray
			Email	jo.wray@gosh.nhs.uk
	Organisation name	GREAT ORMOND STREET HOSPITAL FOR CHILDREN NHS TRUST	Qualification (MD...)	PhD
	Address	GREAT ORMOND STREET	Country	UNITED KINGDOM
		LONDON GREATER LONDON		
	Post Code	WC1N 3JH		

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.
4. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 1998.
9. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:
   - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
   - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
   - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
   - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
   - May be sent by email to REC members.
10. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 1998.
11. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication *(Not applicable for R&D Forms)*

NRES would like to include a contact point with the published summary of the study for those wishing to seek further information. We would be grateful if you would indicate one of the contact points below.

◉ Chief Investigator

- ◯ Sponsor
- ◯ Study co-ordinator
- ◯ Student
- ◯ Other – please give details
- ◯ None

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Miss Jessica Davies on 04/08/2016 13:41.

Job Title/Post:	Trainee Clinical Psychologist
Organisation:	Bangor University/BCUHB
Email:	psp504@bangor.ac.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co-sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.
2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.
3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.
4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.
5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.
6. The duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*
7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.
8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by Mr Hefin Francis on 04/08/2016 13:52.

Job Title/Post:	School Manager for Psychology
Organisation:	Bangor University
Email:	h.francis@bangor.ac.uk

D8. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Dr Elizabeth Whitehead on 04/08/2016 14:15.

Job Title/Post:	Clinical Psychologist
Organisation:	BCHUB
Email:	liz.whitehead@wales.nhs.uk

Academic supervisor 2

This section was signed electronically by Dr Jo Wray on 04/08/2016 13:45.

Job Title/Post:	Senior Research Fellow
Organisation:	Great Ormond Street Hospital
Email:	jo.wray@gosh.nhs.uk

Appendix 4: Research Ethics Committee – Favourable opinion with conditions

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

WALES REC 7
PO Box 108
Building 1
St David's Park
Jobswell Road
Carmarthen
SA31 3WY

Tel: 01267 225045
Email: sue.byng@wales.nhs.uk

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

Miss Jessica Davies
Trainee Clinical Psychologist
Betsi Cadwaladr University Health Board
NWCPP, School of Psychology
Bangor University
Bangor, Gwynedd
LL57 2DG

31 August 2016

Dear Miss Davies

Study title:	**Parents' experiences of caring for a child with a tracheostomy**
REC reference:	**16/WA/0253**
IRAS project ID:	**206449**

The Research Ethics Committee reviewed the above application at the meeting held on 25 August 2016. Thank you for participating by telephone to discuss the application.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Ms Sue Byng, sue.byng@wales.nhs.uk. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below. .

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

1) The PIS should mention in the introductory paragraph that the study was being carried out as part of an educational qualification.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the

study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA Approval (England)/ NHS permission for research is available in the Integrated Research Application System, at www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations.

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

Ethical review of research sites

NHS Sites

The favourable opinion applies to all NHS sites taking part in the study taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Summary of discussion at the meeting

Social or scientific value; scientific design and conduct of the study

The Committee noted parents had been consulted during the development stage of the study in terms of the semi structured interview questions.
Mrs Davies explained she wanted to make sure the questions asked were appropriate and took into account all the experiences parents go through. Rather than conducting a parent forum she had asked families in the vicinity for their views about the questions.

Recruitment arrangements and access to health information, and fair participant selection

The Committee queried if there was a concern about potential for over recruitment and what would happen if too many people came forward.
Mrs Davies responded that she would not hand out too many information sheets to lots of families but if more interest was received than required, she would inform those families not required but inform them of the outcomes.

Favourable risk benefit ratio; anticipated benefit/risks for research participants (present and future)

The Committee asked what action would be taken if families experienced distress during the research.
Mrs Davies explained that her training and skills would assist in dealing with any instances of distress. If she needed further support she would signpost them to the clinical nurse specialist.

Care and protection of research participants: respect for potential and enrolled participants' welfare and dignity

The Committee noted the use of a home computer and sought reassurance on security issues involved in the use of a home computer with the data being held.
Mrs Davies explained she was based in Bangor but the research was being carried out in London. She explained the identifiable data would be transcribed on a Trust computer which would then be anonymised and coded and transferred to her home computer which would be password protected.

Informed consent process and the adequacy and completeness of participant information

The Committee would like the PIS to mention that the study is being carried out as part of an educational qualification.

Suitability of the applicant and supporting staff

The Committee queried what the key collaborators' roles were in the research.
Mrs Davies explained there was a clinical nurse specialist and the consultant who would have carried out the surgery

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Interview schedule	2	19 May 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
IRAS Checklist XML [Checklist_04082016]		04 August 2016
Letter from sponsor		16 August 2016
Non-validated questionnaire [Demographics]	2	19 May 2016
Participant consent form [Parent]	3	30 June 2016
Participant information sheet (PIS) [Parent]	2	19 May 2016
Research protocol or project proposal	3	30 June 2016
Summary CV for Chief Investigator (CI) [Jessica Davies]		04 August 2016
Summary CV for supervisor (student research) [Liz Whitehead]		13 June 2016
Summary CV for supervisor (student research) [Jo Wray]		04 August 2016

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The HRA website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website: http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

We are pleased to welcome researchers and R&D staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

16/WA/0263	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project.

Yours sincerely

pp. Dr John Buchan
Joint Vice-Chair

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*

"After ethical review – guidance for researchers"

Copy to: *Hefin Francis*
Ms Emma Pendleton, Great Ormond Street Hospital for Children NHS Foundation Trust

Wales REC 7

Attendance at Committee meeting on 26 August 2018

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr John Buchan	Retired Medical Practitioner / Joint Vice-Chair	Yes	
Dr Gareth Davies	Principal Public Health Intelligence Analyst/Chair	No	
Mrs Catrin Fischetti	Lead Mental Health Pharmacist	No	
Dr Anand Ganesan	Consultant Psychiatrist	Yes	
Mr Owen Hughes	Psychologist	No	
Mrs Sarah Jones	Clinical Trials Nurse	No	
Dr Raymond Jones	Lay member	Yes	
Dr Sumant Kundu	Consultant Haematologist	Yes	
Mr Derek Lassetter	Lay member / Joint Vice-Chair	Yes	
Mr Gareth Lewis	Principal Pharmacist	No	
Mr Chris Olchawski	Lay member	No	
Dr Girish Patel	Consultant Dermatologist	Yes	
Ms Sian Price	Lay member	Yes	
Dr Gopinath Selvaraj	Consultant Anaesthetist	No	
Dr Geoff Shellswell	Lay member	Yes	
Mrs Rosemary Whittemore	Lay member	No	
Dr Barbara Wilson	Expert nurse member	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Ms Sue Byng	REC Manager

Appendix 5: Research Ethics Committee – Acknowledgement of compliance with conditions.

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

Gwasanaeth Moeseg Ymchwil
Research Ethics Service

Ariennir gan Lywodraeth Cymru
Funded by Welsh Government

WALES REC 7
PO Box 108
Building 1
St David's Park
Jobswell Road
Carmarthen
SA31 3WY

Tel: 01267 225045
Email: sue.bymp@wales.nhs.uk

Please note: This is an acknowledgement letter from the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

Miss Jessica Davies
Trainee Clinical Psychologist
Betsi Cadwaladr University Health Board
NWCPP, School of Psychology
Bangor University
Bangor, Gwynedd
LL57 2DG

26 September 2016

Dear Miss Davies

Study title: **Parents' experiences of caring for a child with a tracheostomy**
REC reference: **16/WA/0263**
IRAS project ID: **208448**

Thank you for your email of 26 September 2016. I can confirm the REC has received the documents listed below and that these comply with the approval conditions detailed in our letter dated 31 August 2016

Documents received

The documents received were as follows:

Document	*Version*	*Date*
Participant Information Sheet [Parent]	3	26 September 2016

Approved documents

The final list of approved documentation for the study is therefore as follows:

Document	*Version*	*Date*
Interview schedule	2	19 May 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
IRAS Checklist XML [Checklist_04082016]		04 August 2016
Letter from sponsor		16 August 2016
Non-validated questionnaire [Demographics]	2	19 May 2016
Participant consent form [Parent]	3	30 June 2016

Participant information sheet (PIS) [Parent]	3	26 September 2016
Research protocol or project proposal	3	30 June 2016
Response to Additional Conditions Met [Email]		26 September 2016
Summary CV for Chief Investigator (CI) [Jessica Davies]		04 August 2016
Summary CV for supervisor (student research) [Liz Whitehead]		13 June 2016
Summary CV for supervisor (student research) [Jo Wray]		04 August 2016

You should ensure that the sponsor has a copy of the final documentation for the study. It is the sponsor's responsibility to ensure that the documentation is made available to R&D offices at all participating sites.

16/WA/0253 Please quote this number on all correspondence

Yours sincerely

Ms Sue Byng
REC Manager

Copy to: *Mr Hefin Francis*
Ms Emma Pendleton, Great Ormond Street Hospital for Children NHS Foundation Trust

Appendix 6: HRA Approval

NHS
Health Research Authority

Miss Jessica Davies
Trainee Clinical Psychologist
Betsi Cadwaladr University Health Board
NWCPP, School of Psychology
Bangor University
Bangor, Gwynedd
LL57 2DG

Email: hra.approval@nhs.net

13 October 2016

Dear Miss Davies

Letter of HRA Approval

Study title:	**Parents' experiences of caring for a child with a tracheostomy**
IRAS project ID:	**206449**
REC reference:	**16/WA/0253**
Sponsor	**Bangor University**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

IRAS project ID	208448

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application

IRAS project ID	206449

procedure. If you wish to make your views known please email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **206449**. Please quote this on all correspondence.

Yours sincerely

Miss Lauren Allen
Assessor

Email: hra.approval@nhs.net

Copy to: *Hefin Francis (Sponsor contact)*
Ms Emma Pendleton, Great Ormond Street Hospital for Children NHS Foundation Trust (Lead NHS R&D contact)

IRAS project ID	208448

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	Version	Date
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only)		18 July 2016
Interview schedules or topic guides for participants [Interview Schedule v2 19.5.16]	Version 2	19 May 2016
IRAS Application Form [IRAS_Form_04082016]		04 August 2016
Letter from sponsor		16 August 2016
Non-validated questionnaire [Demographics 19.5.16 v2]	Version 2	19 May 2016
Other [Statement of Activities]	2	13 October 2016
Other [Schedule of Events]	2	13 October 2016
Participant consent form [Parent consent form v3 30.6.16]	Version 3	30 June 2016
Participant information sheet (PIS) [Parent]	3	26 September 2016
Research protocol or project proposal [Tracheostomy Research Protocol v3 30.6.16]	3	30 June 2016
Summary CV for Chief Investigator (CI) [CV Jessica Davies 4.8.16]	1	04 August 2016
Summary CV for supervisor (student research) [Liz Whitehead CV 4.8.16]	1	13 June 2016
Summary CV for supervisor (student research) [Jo Wray CV 4.8.16]	1	04 August 2016

IRAS project ID	206449

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations, capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study: Hefin Francis (h.francis@bangor.ac.uk; 01248388339).

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	No comments
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The Statement of Activities and Schedule of Events will act as the agreement between the sponsor and participating NHS organisation.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study

IRAS project ID	208448

Section	HRA Assessment Criteria	Compliant with Standards	Comments
4.3	Financial arrangements assessed	Yes	No funding will be provided to the participating NHS organisation.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	No comments
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no objection received	Not Applicable	No comments
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There is one site type. Participants will be identified by the paediatric tracheostomy team. Interviews and completion of the questionnaire may take place at the participating NHS organisation or in participants' homes. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for

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IRAS project ID	208449

participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research.** • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
A Local Collaborator will be required at the participating NHS organisation to facilitate access arrangements for members of the external research team where needed. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Members of the research team who do not have a contractual relationship with the participating NHS organisation will require a Letter of Access to conduct study activity on NHS premises. Disclosure and Barring Service and Occupational Health checks will need to be in place where a Letter of Access is required.

IRAS project ID	208448

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

Appendix 7: Information Sheet for Parents/Carers

PRIFYSGOL BANGOR UNIVERSITY

Great Ormond Street Hospital for Children NHS Foundation Trust

Parents' experiences of caring for a child with a tracheostomy

INFORMATION SHEET FOR PARENTS OR CARERS OF CHILDREN WITH A TRACHEOSTOMY

We would like to invite you to take part in a research study which is being carried out as part of a Doctorate in Clinical Psychology. Before you decide if you would like to participate it is important for you to understand why the research is being done and what it would involve. Please take time to read the following information carefully. Talk to others about the study if you wish to help you decide if you would like to take part.

Why is the study being done?
The main aim of the study is to help us understand more about the experiences of parents/carers of children who have a tracheostomy. This information will be gained through interviewing parents/carers of children who have received a tracheostomy at Great Ormond Street Hospital (GOSH). If we can understand more about parents' experiences during this time, it will help clinicians provide the best support for children and their families.

Why have I been chosen?
We would like to speak to parents/carers who are caring for their child with a tracheostomy at home and receive ongoing input from GOSH. Furthermore, we would like to speak to parents/carers of children who received their tracheostomy at GOSH, have had a tracheostomy for the last 12-15 months and have been caring for their child at home for at least the last 6 months.

Do I have to take part in the study?
No. Your participation in the study is completely voluntary and it is up to you to decide if you would like to take part. Your decision will not affect the standard of care your child receives from the NHS. If you decide that you would like to take part, you will be asked to sign a consent form to show you have agreed to take part and will be given a copy of this. You can change your mind at any time and stop participating in the study. You do not need to give a reason for this. If you choose not to take part in the study this will not in any way affect the care received by you or your child, now or in the future.

What will I be asked to do?
If you decide to take part, we will ask you to meet with the researcher (Jessica Davies) on one occasion for approximately 60-90 minutes. This meeting can take place at Great Ormond Street Hospital, co-ordinating with your child's outpatient appointment, or at your home if you would prefer, at a time that is convenient for you. The exact length of the interview will vary depending on how much you feel you wish to say. We expect it to take around 60 minutes.

At the meeting you will be asked to fill out a brief questionnaire asking you to provide some background information, which will include questions such as: your child's

educational level, current use of support services, your family composition and your employment status.

An interview will then take place, in which the researcher will ask about your experiences of having a child with a tracheostomy, the impact on you and your family and what aspects of the care you have received were most important to you/your child. There are no right or wrong answers, and you are free to decline to answer any question. The interview will be audio recorded so that the researcher can have a record of what you have said.

Expenses and payments
Taking part in this study is voluntary and you will not be paid for your participation.

Are there any disadvantages or risks?
We do not anticipate there to be any risks in taking part in the study, although some people may feel uncomfortable when talking about their experiences. This is an understandable reaction to discussing a personal subject. If you become upset or distressed at any time you can take a break or end the interview completely. If you feel you need to speak to someone after the meeting, the researcher will refer you to a member of the clinical team who can help you.

What are the possible benefits?
We cannot promise the study will help you, but by taking part in this research you will be providing valuable information regarding your experiences of being a parent of a child who has a tracheostomy. Additionally, you may find it useful to share your experiences. We believe that what we learn from this study will help improve the care of families when children receive a tracheostomy in the future.

Will my taking part in the study be kept confidential?
Yes. All information collected about you and your child during the course of the research will be kept strictly confidential and known only to the research team. A copy of the consent form you sign and your completed questionnaire will be kept separately and securely in locked cabinets at GOSH. Additionally, a further copy of this signed consent form will also be placed into your child's medical records.

All data collected during the course of the study will be held in accordance with the Data Protection Act (1998). This means that we keep it safely and cannot reveal it to other people, without your permission. Any questionnaires that you fill in, the audio recording of the interview and transcripts of the interview will be given an identification number, so only the researcher will know whose data belongs to whom. The interview will be anonymous since any identifiable information will be deleted when the researcher listens to and transcribes the interview recording. You will not be identified in any report or publication of the results of the research.

All anonymised paper copies of information that you provide will be kept securely in a locked filing cabinet that will only be accessible to members of the research team. Similarly, the electronic audio recordings of the interview and any other electronic information such as the interview transcripts will be saved on an encrypted memory stick. On completion of the research, all of the interview recordings will be wiped clean. However, transcripts of the interviews and completed questionnaires will be stored securely in a locked cabinet by the Research Supervisor (Dr Jo Wray) for up to 5 years, at which point they will be destroyed. Additionally, paper copies of the signed consent forms will be stored separately and securely in a locked cabinet by the Research Supervisor (Dr Jo Wray) for a minimum of 2 years, at which point they will be destroyed.

Disclosure of information gained from the study will be shared only in exceptional circumstances. If the researcher is concerned about any risk of harm either to yourself or anyone else, then she is legally obliged to share this information with the appropriate people, (a contact person from the clinical team, and your GP). The researcher will always try to discuss these concerns with you first, before doing anything.

What will happen to the results of the study?
The results of the study will be written up in a thesis by the researcher (Jessica Davies) as part of a Doctorate in Clinical Psychology. Anonymised quotes from your interview may be used in the final report to help explain the key findings. The research may also be published in a journal, or presented at a scientific conference. You will not be identifiable in any of these.

At the end of the study, a summary of the results can be sent to everyone who took part if they wish and we also hope to make a summary of the findings available on the GOSH website. The results of the study will be reported for the group as a whole and you and your child will not be identified in any report/publication.

Who is organising and funding the research?
The study is being organised in partnership with the Paediatric Tracheostomy Care team at Great Ormond Street Hospital for Children NHS Foundation Trust. The study is being carried out by Jessica Davies who is a Trainee Clinical Psychologist at Bangor University. It will be supervised by Dr Jo Wray (Health Psychologist) at Great Ormond Street Hospital, and Dr Liz Whitehead (Clinical Psychologist) at Betsi Cadwaladr University Health Board, North Wales.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given a favorable opinion by the National Research Ethics Committee. Additionally, the study has received approval from the Research and Development department at Great Ormond Street Hospital and Bangor University's Psychology Department Ethics Committee.

What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions (see contact details below).

If you have any complaints please contact Hefin Francis at the School of Psychology, Bangor University, telephone 01248 388339.

If you wish to speak with someone independent of the study please contact the Patient Advocate and Liaison Service (PALS), Great Ormond Street Hospital, telephone 0207 405 9200 extension 7862 for support and advice.

How do I contact members of the research team?
If you would like further information about taking part, please do not hesitate to contact Jessica Davies or Dr Jo Wray. Contact details are below.

Researcher:
Jessica Davies, Trainee Clinical Psychologist
North Wales Clinical Psychology Programme (NWCPP)
Bangor University
Bangor
Gwynedd

LL57 2DG
Tel: 01248 388365 (Please note: Please state that it is intended for Jessica Davies)
psp504@bangor.ac.uk

Dr Jo Wray (Research Supervisor):
0207 8297 822
jo.wray@gosh.nhs.uk

If you are interested in taking part.....
If you would like to take part, please contact Jessica Davies using the contact details provided above. Alternatively, if you would prefer Jessica Davies to contact you instead, then please complete the participant reply slip below and return it using the prepaid envelope. She will then call you and will answer any further questions that you may have about the study. If you want to participate in the study, Jessica will then arrange a convenient time to meet with you and conduct the interview.

Thank you for taking the time to read this.

(Tear off Slip) PARTICIPANT REPLY SLIP

- -

Understanding the experience of caring for a child with a tracheostomy

Please tick the box to show your response and give your contact details.

I have read the Participant Information Sheet and I would like to be contacted to arrange a time to meet with Jessica Davies ☐

My name is: ____________________

I would like to be contacted by (telephone, email, post?) ____________________

My telephone/mobile number is: ____________________

My email address is ____________________

My address is: ____________________

____

____

Please return this reply slip in the pre-paid envelope, or alternatively you can contact Jessica Davies on 01248 388365 (Please note: Please state that it is intended for Jessica Davies).

Appendix 8: Semi-structured interview schedule

Research title: Parents' experiences of caring for a child with a tracheostomy v2 19.05.16

Draft: Semi-structured interview schedule

Participants will have received an information sheet explaining the purpose of the research prior to the commencement of the interview. They will also have been provided with the opportunity to ask any questions related to the research. If they are happy to participate in the research they will have signed the consent form prior to starting the interview.

The following interview schedule will be used as a topic guide, however remain flexible in nature. The researcher will be responsive to the participant's comments/insights and consequently adapt and modify the ordering of the questions. In accordance with IPA techniques the researcher will question further and follow up novel insights or reflections.

P indicates possible prompt questions

The purpose of the study will be reiterated and the focus of the interview introduced.

1. **Can we start off with you telling me a little bit about (insert child's name)?**
   P- Can you tell me about the history of (insert child's name) health experiences that led them to needing a tracheostomy?

2. **Can you tell me about how it was first discussed that your child needed a tracheostomy?**
   P How did you feel when you first found out?
   P What were your initial reactions?
   P How did you feel about the risks and benefits?

3. **Can you tell me about your experience of having a child with a tracheostomy?**
   P Can you tell me about your experience on (ward name) when (insert child's name) had first received a tracheostomy?
   P Can you tell me about how you felt following your child receiving a tracheostomy?
   P What impact do you feel the tracheostomy has had on your child?
   P Can you tell me about your experience of learning to care for your child with a tracheostomy?
   P How did you feel about caring for your child with a tracheostomy?
   P What impact has caring for your child had on you?

4. **Can you tell about your experience of transition from hospital to home with (insert child's name)?**
   P Can you tell me about the support you received within the hospital?
   P How did you feel about returning home with your child?
   P How did your thoughts/feelings about returning home fit with your experience of returning home?

P Can you tell me more about your experience of caring for your child at home?
P Can you tell me about some of things that made your experience better or worse? (Staff, own coping resources, closeness to family & friends)

5. **Can you tell me about your experience of caring for child with a tracheostomy at home?**
   P Can you tell me about some of things that made your experience better or worse?
   Support? Family closeness? Own coping?
   P What impact has caring for your child had on you?
   P What impact do you think caring for your (insert child's name) at home has had on (him/her)?

6. **How has your experience of caring for your child changed or not changed over time?**
   P How do you feel now in comparison to how you felt when your child first received a tracheostomy?
   P How do you feel that time has impacted on your knowledge and experience of caring for your child?
   P Your adjustment to you child's health difficulties

7. **Can you tell about what your expectations are for (insert child's name) since receiving the tracheostomy?**

8. **What impact, do you feel having a child with a tracheostomy has had on your family?**
   P Your quality of life
   P Family dynamics
   P Practical and social circumstances eg employment
   P Siblings, other close family members

9. **What things did you value/were important for you and your child since receiving a tracheostomy?**
   P What advice would you give to another parent/carer of a child with a tracheostomy?

Appendix 9: Consent Form

Research Title: Parents' experiences of caring for a child with a tracheostomy v3 30.06.16

PRIFYSGOL BANGOR UNIVERSITY

Great Ormond Street Hospital for Children NHS Foundation Trust

CONSENT FORM FOR PARENTS

Parents' experiences of caring for a child with tracheostomy

Name of Researcher: Jessica Davies (Trainee Clinical Psychologist)

Name of Research Supervisors: Dr Jo Wray (Health Psychologist)
Jo Cooke (Clinical Nurse Specialist)
Dr Liz Whitehead (Clinical Psychologist)

Patient Identification Number for this study: .....

Please Initial Box

1. I confirm that I have read and understood the information sheet for the above named study dated 26/09/16 (version 3). I have had an opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐

2. I understand that my participation is voluntary and that I am free to withdraw myself from the study at any time, without giving any reason, without my child's medical care or legal rights being affected. ☐

3. I consent to an audio recording of the interview being made and understand that it will be destroyed after the research is complete. ☐

4. I am aware and understand that direct quotations said by me during the interview may be used in the thesis report or subsequent publications or presentations, but that these will be anonymised. ☐

5. I agree to take part in the above study. ☐

When completed: 1 for participant; 1 for researcher file; 1 for your child medical/electronic records.

6. I would like to receive a brief summary of the research findings following the completion of the study. ☐

_____	_____	_____
Name of parent/guardian (Print name)	Date	Signature
_____	_____	_____
Name of person taking consent (if different from researcher) (Print name)	Date	Signature
_____	_____	_____
Name of researcher (Print name)	Date	Signature

When completed: 1 for participant; 1 for researcher file; 1 for your child medical/electronic records.

Appendix 10: Analysed extract

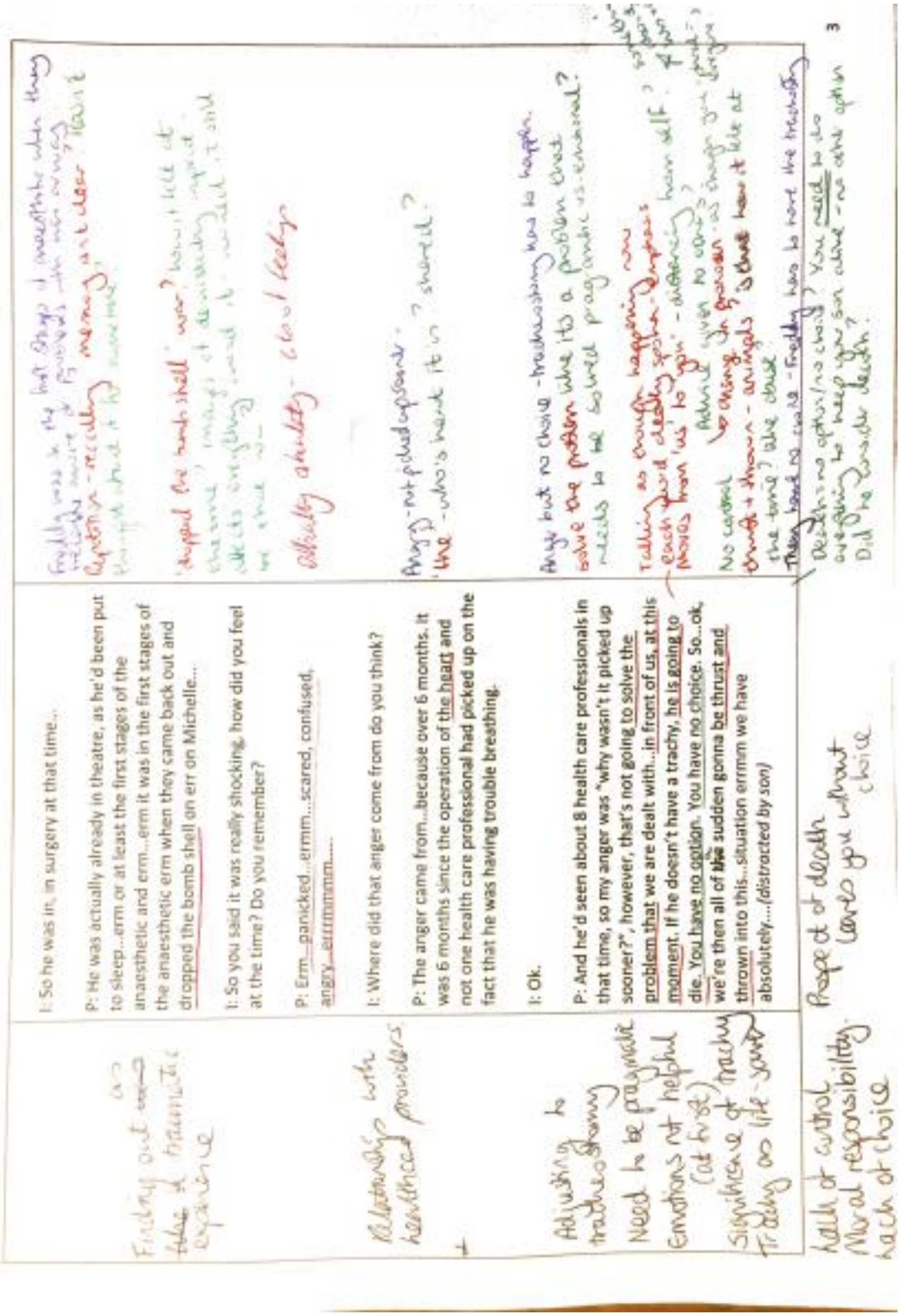
Right column – exploratory comments using the following key:

Notes in **blue** – descriptive

Notes in **red** – linguistic

Notes in **green** – conceptual

Left column – Emergent themes



I: So he was in, in surgery at that time...

P: He was actually already in theatre, as he'd been put to sleep...erm or at least the first stages of the anaesthetic and erm...erm it was in the first stages of the anaesthetic erm when they came back out and dropped the bomb shell on err on Michelle...

I: So you said it was really shocking, how did you feel at the time? Do you remember?

P: Erm...panicked...ermm...scared, confused, angry...errrmmmm....

I: Where did that anger come from do you think?

P: The anger came from...because over 6 months. It was 6 months since the operation of the heart and not one health care professional had picked up on the fact that he was having trouble breathing.

I: Ok.

P: And he'd seen about 8 health care professionals in that time, so my anger was "why wasn't it picked up sooner?", however, that's not going to solve the problem that we are dealt with...in front of us, at this moment. If he doesn't have a trachy, he is going to die. You have no option. You have no choice. So...ok, we're then all of the sudden gonna be thrust and thrown into this...situation errmm we have absolutely....*(distracted by son)*

Previous understanding of trachy Trachy as stage before death.	I: So had you heard about trachys before? Did you know... P: *(jumps straight in)* Oh yes. Yeah, a friend, a friend of ours had a trachy errr just before he passed away. I: Okay. P: So unfort...the psychology connected to...*(breathes in)* trachys....for myself *(looking at the floor)* was...erm....they...they are to sort to help people breathe. I understood what a trahcy was and how it worked erm *(looks down)* but unfortunately the person that it was erm urr put into, before hand, erm died of errr...*(pause)* cancer, throat cancer.	used term 'die' before now 'passed away' - softened? knew about trachys prior to son having one. Friend with trachy died of throat cancer. difficulty articulating doesn't use name Relates trachys to death? Or did so in the past? Son's trachy's death.
Trachy and fear Significance of time ~~Timing~~ clarity in time Significance of medical needs Role of specialist team	I: So how do you think you think that impacted on you when you were told that your son might need a trachy? P: Yeah, erm...possibly the fear I experienced was rel..related to knowing what my friend had been through... erm...the fear also as it started to unfold...as to what would happen, I mean it didn't happen straight away, it was 24 hours. They did a balloon dilation, they did some erm surgery to try and open up the air, the air way but unfortunately it just...kept...closing back up again...so...in this time we were explained about what a tracheostomy is, how it would work, ermm...the specialist nurse [name removed] was fantastic and her team.	Tracheostomy didn't happen immediately Specific time frame - vivid memory? 'the' not his as though it doesn't belong to him? his airway Were told about tracheostomies prior to son receiving it. Benefit of support from team.

Separation b/w child & medical illness ('the')

Planning/drive as coping (early steps)
Tracheostomy as significant threat.
Personal experience impacting coping/ process
Front as vulnerable child
Big bang
Feeling stuck/ trapped
Uncertainty.

I: So in that, so you were kind of told, he's going to have to have a trachy immediately, there was a bit of delay. How did you feel during that delay?

P: I guess we...we just to tried to think, ok, right the enormity of what's about to happen, how are we going to build this in to...erm...his development...and...lifestyle...and you know what...I, I, I have a er, I, I have a problem with having, with wearing a tie and having my top bottom done up and putting stuff around my neck...so all of a sudden I've now got to deal with...my own...problem trying to look after my boy...erm...and I remember one evening errr...at home with my dad, cos we were taking it in turns, and one evening at home with my dad erm, I said to him, "I can't do it, I don't know if I can do it". So you know, you, you, you're left standing in front a...huge...black...wall *(emphasised)*, that's got no grip on it whatsoever and errr...it's, it's all oiled so there's absolutely no traction and you're not getting up that wall. And you can't see the top of it erm...and slowly but surely...

I: I was going to say, what happened to that black wall then?

P: It shrank very quickly *(suctions Freddy)*

I: Did it?

P: Yeah. Yeah very quickly.

I: Can you tell me about a bit about then, the journey...so you had those kind of 24 hours of *(Tom*

No time to think or process Auto pilot Focus on child's needs Own emotions unhelpful Worry as wasting time Importance of trachy as hope. Significance of early stages. Significance of time Partial medical knowledge	*continues to suction Freddy)* all those emotions, the shock and then, then, it sounds like quite quickly saying, right, I need to, I need to think pragmatically about it... P: Absolutely, cos you haven't got time...to panic, you haven't got time to, to think about...your fears. The main e, the main essence is that your child needs to have breathing apparatus put in to their neck, so they can...breathe. They'll have a completely normal life, it's not going to...the chances are, it won't be forever erm it's a small fraction of his life...so all of this is going off, and you're thinking, you know...it's all, it's all firing off...and you're thinking hang on, I'm wasting time here...I'm wasting time, we, we are wasting time. I: And that was, kind of what you went through, in those first kind of 24 hours? P: Those first 24...48 hours. Yeah I believe it was...*(looks up-thinking)* they did the balloon dilation...came up to the operation, they did the hernia...did the balloon dilation on that day...we were left over night and most of the following day, spoke to ENT again and they said, "how has he been?" And actually he seemed to be worse than he was...beforehand. so we had to make a decision, erm...s,o I think it was, I think it was about 48 hours I had to...I had to...do full circle. So you make a decision. I: So, sorry, when did you make that decision then? I must have assumed you made that decision straight away, but you had that time to think about it?	No time to think - Pronouns you/your not my/I - why? Time? Need time to think? what is normal? is normal what is ... for children? what is valued? breathing apparatus not tracheostomy - sounds inhumane? moves from 'its not' to 'chances are' - from hopeful to reality? 'firing' - attach? attaching? thinking = wasting time? Waited 24-48hours, health deteriorated - needed the trachy - parents needed to make decision about the trachy. changing pronouns clarity to things full circle? why?

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Decision made for them. Moral responsibility	P: So, so we made the decision when... the ENT department came back in the day after and said "ok, it hasn't got any better, we have to do a trachy". We've got no choice, the decision was taken out of our hands.	Health did not improve, therefore Freddy needed a trachy. we made decision vs no choice. repetition - no choice (contradiction [illegible]) decision to 'no choice' [illegible] Moral dilemma [illegible] There is no choice? need to save child's life
Impact on change in info processing. Unable to take in information	I: And did..before that time, was that when you had the input from [specialist nurse] and the team or was that after that? Can you tell me what that was like, receiving that input?	
Number of staff involved in care. Information drip-fed.	P: During the, during our stay there, (I:Ok) the team...cos we were, we were on [ward name] *(points)*. We were on...Pe..(thinks) yeah, we were on [ward name] and the team sort of spoke to us bit by bit, and that was ev..everybody on the team. There was the HSA's, there was the nurses, there was [specialist nurse], there was ENT and they're slowly just drip feeding...what we will...eventually be doing.	All the team, daily informed them of what would be involved in trachy care. Repetition - recalling. Thought about before? First time spoken about. 'our stay' - like a hotel? 'drip feeding' as though unwell? patient? Parent becomes patient/needy? [illegible]
Parents as children. Parents as patient. Role reversal.	I: Right.	
Parental responsibility. Moral responsibility. Normality of trachy care. Sense of achievement/mastery.	P: Now, because the, the, there is no...in my mind, there is no I...there is no other option, there's nobody else who's gonna be able to do it for him; the parents have got to do it. We'll get all the help, all the support, all the training and it's something that you can do because people do it, thousands of kids, there's thousands of kids in the errr *(distracted by son)*...there's thousands of kids in the UK with, with trachy's...erm so ok, yeah, it's another string to our bow. There is still a big black wall, in front of you, and you still can't see the top of it but its less oiled.	'my' - shared feelings with wife or not? No choice - moral code/values = no choice - parent. 'have got to'. Tom believes parents should care for child. Will receive lots of support for it. Moral [illegible]? other people do it - therefore you can do it. repetition - emphasis - lots of others, so therefore ok? not alone? what would that mean to be the only? normality / role of normality?

Tracheostomy training as a skill. Process of coming to terms w/trachy

Shift in thinking - trying to see positives. Talking through process metaphor of Black wall. Black wall is smaller after conversation with nurses? Nurses/healthcare professionals supported them

	I: So are you saying that's your experience now or...that was when you were on the ward?	
	P: Erm...that that, that was when we were on the ward.	
Approach to being give info. about trachy	I: So their approach of, as you say, drip feeding you the information...how was that for you?	
Lack of control/choice Moral responsibility Reassurance from medical team Powerlessness.	P: Yeah, yeah, yeah, it was a bit more gentle erm we were told, that, you know, that, that this is something that...is going to happen. It has to happen. So whether we sign the consent form or not, it, it has to happen, however, you will not be left alone...you certainly won't be going home until you are 100% confident, competent. And if it takes 3 months, 6 months, a year, this is what we will do.	Tracheostomy has to happen but parents will be supported. contradiction gentle yet you have no choice it has to happen Choice? Repetition - emphasis. Sounds like no choice - what would happen if they didn't sign it - role of medical professionals in decision making - shift in power? Given reassurance will be supported. [illegible] with power?
	I: And how did that feel them saying that?	
Excessive thinking State of shock Time passing & processing	P: Erm...there, there's a lot of relief erm thousands of questions spinning around in your head but nothing, but nothing coming out of your mouth. Just day by day, minute by minute, hour by hour, you...come up with another question. Erm....so the, so the questions are answered...as, some questions weren't answered, cos it would be covered in training. Erm one second.	As time passes think of lots more questions. Shift in pronoun to 'you' - removes from self spinning - disorientated? sense of time? time distorted?
	Walks over to collect child.	
	P to child: Come here you! That's it, good boy! So you wait here, good boy. Ok?	

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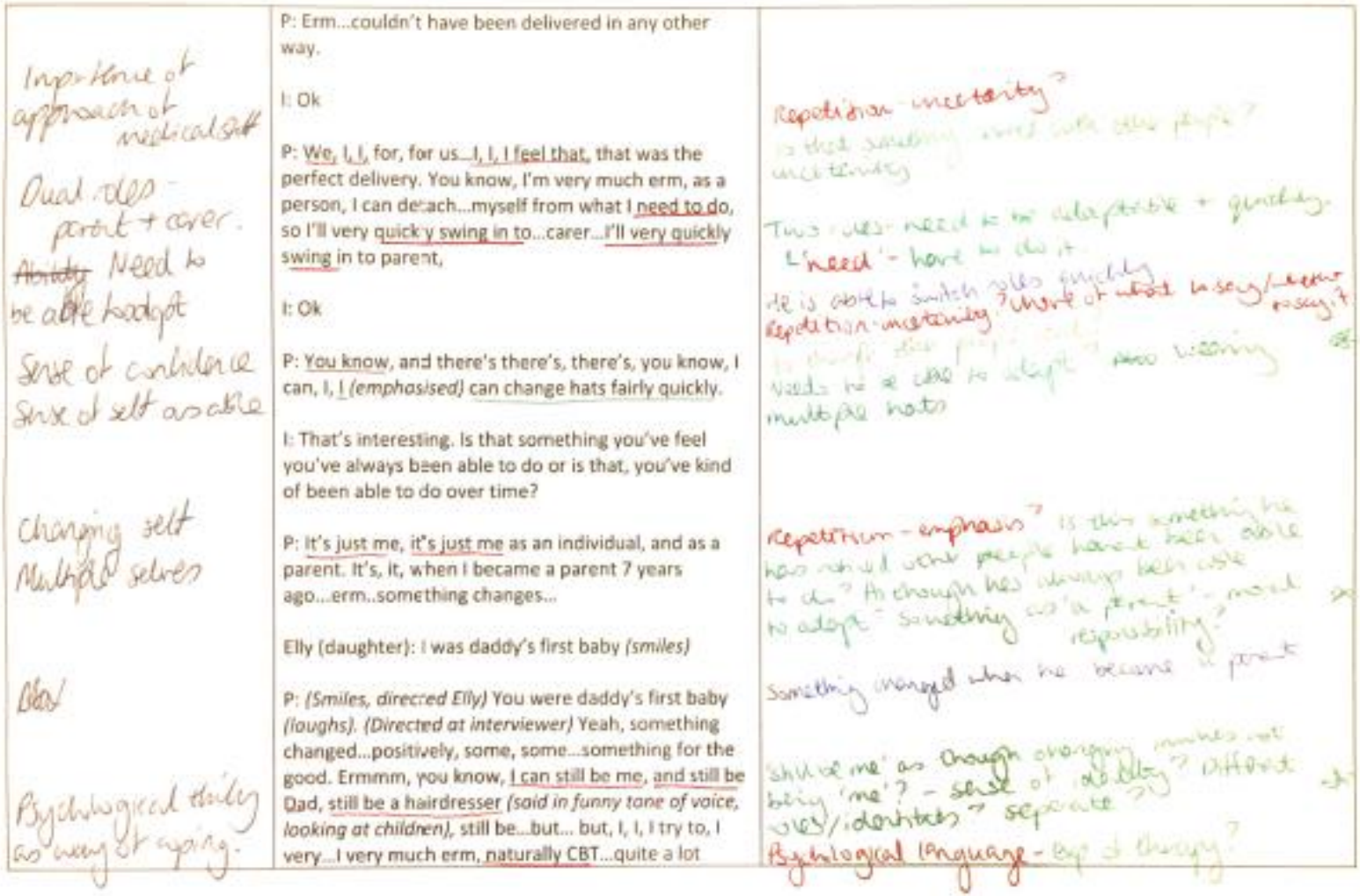
Significance of time Uncertainty & reassurance	Directed at interviewer: Please can you pause a second? *Taping paused whilst P collects child from corridor.* P: Erm...so, so as, as, as, as, minute by minute, hour an hour, hour by hour unfolds, then...you're starting to...all the questions you start firing out...erm...are, are being, are being answered. I: Are not being answered? P: No no, they are, they are being answered. *Child asks father something. Inaudible.*	Lots of questions come to mind over time. sense of time - repeated - precise every moment unfolds - like a mystery? significance/importance? new things being revealed? Questions being answered.
Drip-feeding information Fear Overwhelmed with information Parent as student Reassurance from medical staff. Person-centred approach to learning Medical staff aware of parents feelings (perceptive/mindful)	P: And [specialist nurse] *(suctions child)* is very good at not overloading us...with..cos she knows theres, theres so much to...theres, you, you, your brain's just swimming...with, with...information and *(suctioning)* obviously you've still got your fear factored, built in to that as well. So there's certain things that...she said, "yeah, we'll cover this, but only when...you're confident enough to cover it". They, they don't want to scare you before you've even started you're learning. I: How did you find that approach? P: I think the delivery was fantastic. I: Ok.	Information was not overloaded. Brain - 'you' - what does that mean? swimming - going ... as though everyone feels that way. Took time to be explained everything they - us vs. them? Parents vs healthcare; mindful of their ability - role of parent? knowledge? - at the pace - person-centred.

Role of medical staff
Importance of approach of medical staff.

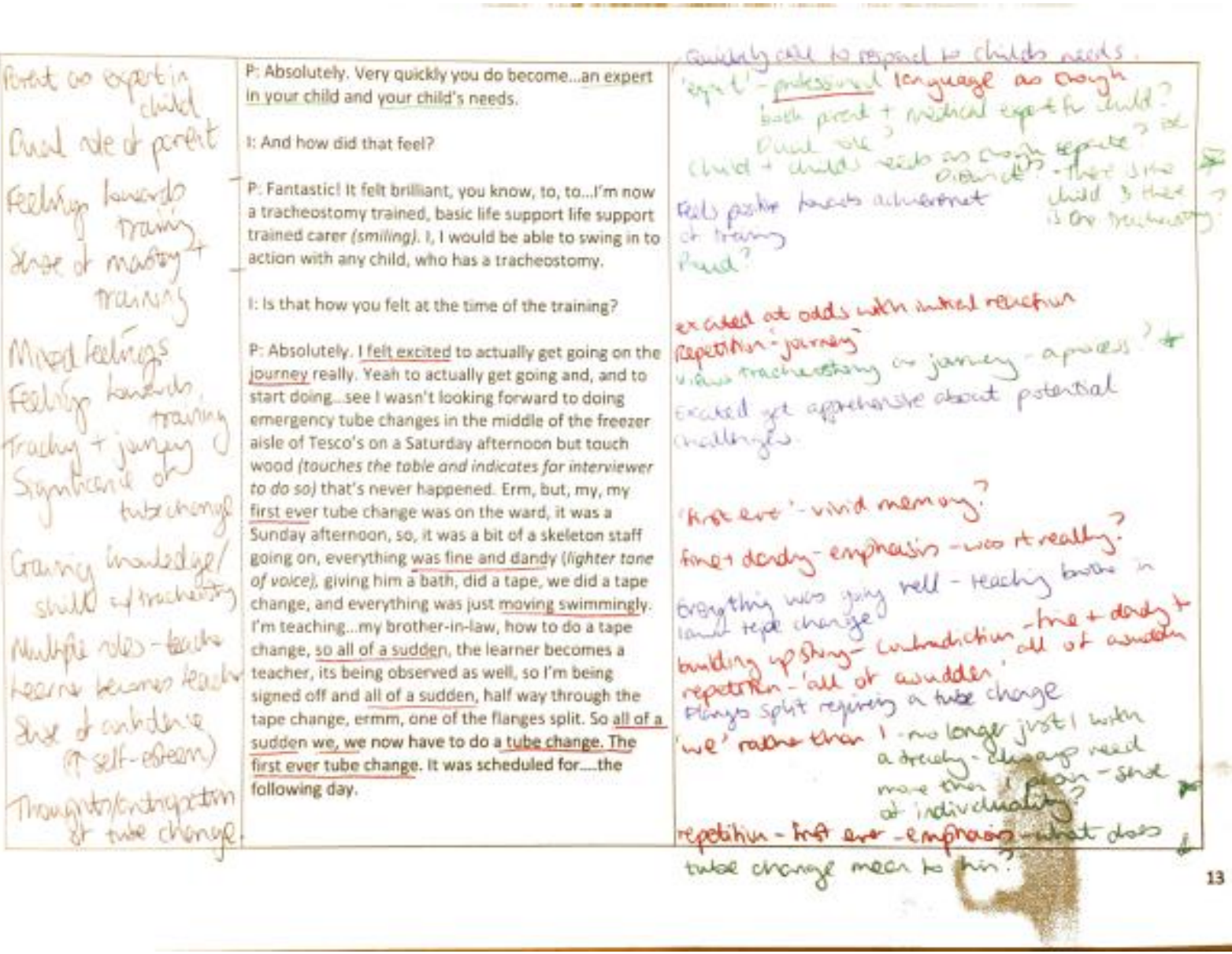
9



Importance of approach of medical staff Dual role - parent + carer. ~~Ability~~ Need to be able to adapt Sense of confidence Sense of self as able Changing self Multiple selves Dad Psychological theory as way of coping.	P: Erm...couldn't have been delivered in any other way. I: Ok P: We, I, I, for, for us...I, I, I feel that, that was the perfect delivery. You know, I'm very much erm, as a person, I can detach...myself from what I need to do, so I'll very quickly swing in to...carer...I'll very quickly swing in to parent, I: Ok P: You know, and there's there's, there's, you know, I can, I, I *(emphasised)* can change hats fairly quickly. I: That's interesting. Is that something you've feel you've always been able to do or is that, you've kind of been able to do over time? P: It's just me, it's just me as an individual, and as a parent. It's, it, when I became a parent 7 years ago...erm..something changes... Elly (daughter): I was daddy's first baby *(smiles)* P: *(Smiles, directed Elly)* You were daddy's first baby *(laughs). (Directed at interviewer)* Yeah, something changed...positively, some, some...something for the good. Ermmm, you know, I can still be me, and still be Dad, still be a hairdresser *(said in funny tone of voice, looking at children)*, still be...but... but, I, I, I try to, I very...I very much erm, naturally CBT...quite a lot

	anyway, to try and make my life a bit easier. It does help. It helps a great deal.	CBT helps make [illegible]
	Interruption, nurse walks in to take something from the room.	
	P: Erm, he's starting to leak a bit. *(directed at nurse whilst indicating towards child)*	
	I: Are you happy with us continuing?	
	P: Yeah, yeah, yeah. *(Adjusting childs tracheostomy)*	
	I: Erm...so I guess more, more generally, cos I've got some questions that are more general in terms of the specifics around transitions and things from hospital to home just trying to think what would fit well here...	
Tracheostomy care as a journey/ process/ stages	*Elly says something (inaudible)*	
	P: I'll tell you what, let me bring you back in to the journey.	'journey' - the - an experience / process/stages?
	I: That would be fab, I'm sure you'll answer a lot of the things.	
Significance of time	P: Ok, I'll bring you back in to the journey. Erm...we were here, as I said, 54 days in total. No I think it was about...I think it was about...54, 50, 52 [counting mentally]...I think it was probably about 48 days we were here from when we were first to...	'the journey' - as though shared - doesn't use personal pronoun - 'my' length of time in hospital recalls nurse exactly - vivid memory?
Vivid memory in early stages	I: That's a very accurate number.	

Role of services Number of people involved.	P: Yeah *(laughs)* because we were, we were transferred from here to our local hospital...I was, I was more than happy to take Freddy home but we needed, *(lots of background noise, toys dropped)* we needed the care package. So we'd been in contact here at...[hospital name] gave us our social worker, who then contacted our local authority.	Needed a care package in place before being transferred home.
	I: Yeah	
	P: So, they, they, they made the introduction before we got there. So wheels were set in motion before we got back to our local authority.	Involved in local authority prior to being transferred Repetition 'wheels' - in a car - those driving one car? out of control.
Sense of a journey	I: Ok.	
	P: Erm...but it was our local authority who were like, ok we need to get moving here...and it took them, it took them a couple of weeks.	It took the local authority time to organise things 'moving' - related to wheels - journey.
	I: To sort out what care you would receive when you were back home? So before that you had to stayed in hospital for longer?	
Process of learning Front as medical expert.	P: Yes, for just a little bit longer, probably an extra...10 days-2 weeks. The the the, we, we we, we could have come away from here a lot earlier....so... we've now, we've, we've now, we've now learnt about suctioning, we've learnt about tape change. That was all here.	Spent an extra time in hospital than needed - Present tense - as though telling about it now.
	I: How did it feel? You sound you're very well versed in the medical terminology...	



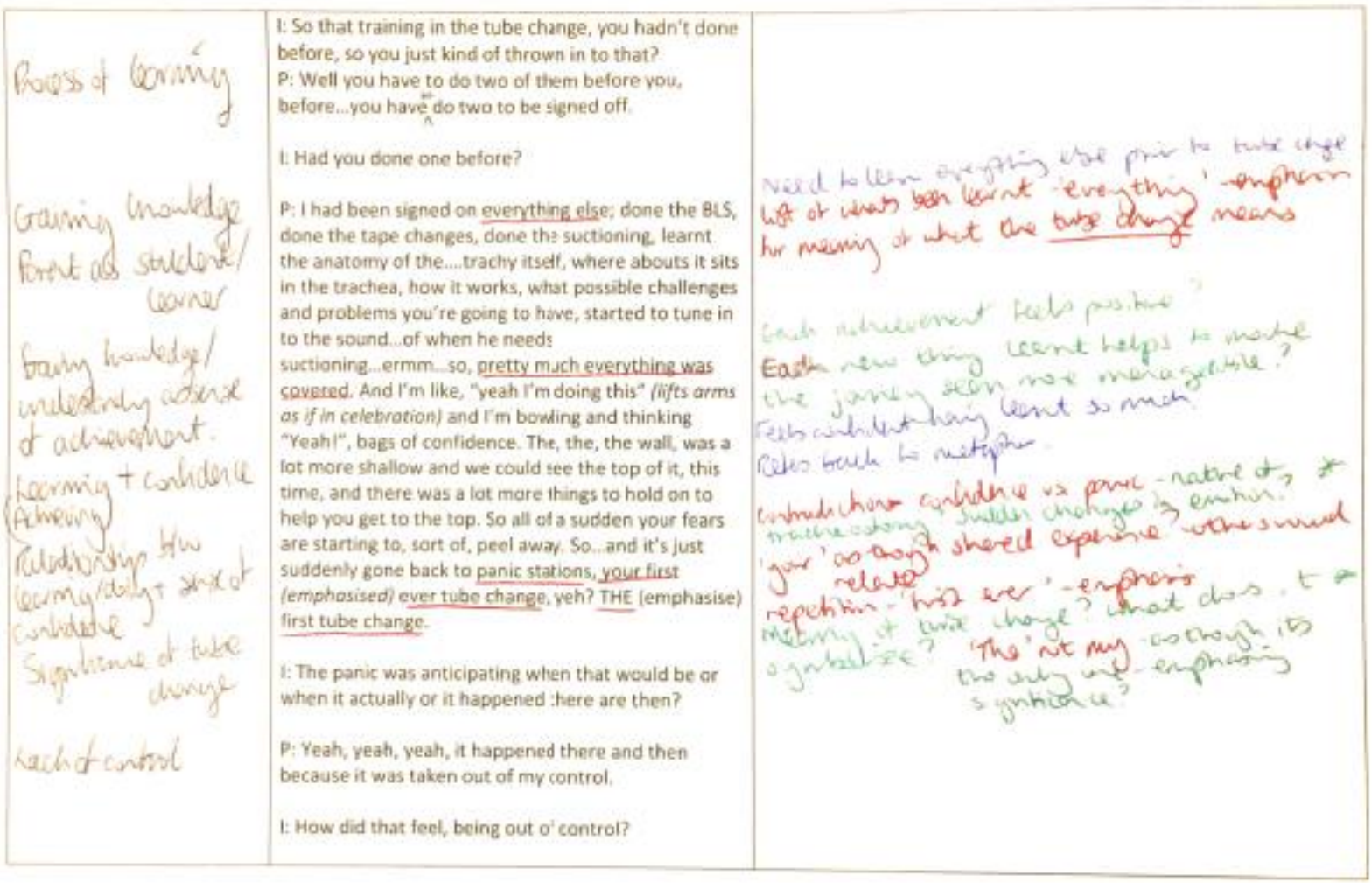
P: Absolutely. Very quickly you do become...an expert in your child and your child's needs.

I: And how did that feel?

P: Fantastic! It felt brilliant, you know, to, to...I'm now a tracheostomy trained, basic life support life support trained carer *(smiling)*. I, I would be able to swing in to action with any child, who has a tracheostomy.

I: Is that how you felt at the time of the training?

P: Absolutely. I felt excited to actually get going on the journey really. Yeah to actually get going and, and to start doing...see I wasn't looking forward to doing emergency tube changes in the middle of the freezer aisle of Tesco's on a Saturday afternoon but touch wood *(touches the table and indicates for interviewer to do so)* that's never happened. Erm, but, my, my first ever tube change was on the ward, it was a Sunday afternoon, so, it was a bit of a skeleton staff going on, everything was fine and dandy *(lighter tone of voice)*, giving him a bath, did a tape, we did a tape change, and everything was just moving swimmingly. I'm teaching...my brother-in-law, how to do a tape change, so all of a sudden, the learner becomes a teacher, its being observed as well, so I'm being signed off and all of a sudden, half way through the tape change, ermm, one of the flanges split. So all of a sudden we, we now have to do a tube change. The first ever tube change. It was scheduled for....the following day.



Process of learning

Gaining knowledge
Front as student/
learner

Basic knowledge/
understanding absence
of achievement.

Learning + confidence
Achieving

Relationship btw
learning/doing + start of
confidence

Significance of tube
change

Lack of control

I: So that training in the tube change, you hadn't done before, so you just kind of thrown in to that?
P: Well you have to do two of them before you, before...you have to do two to be signed off.

I: Had you done one before?

P: I had been signed on everything else; done the BLS, done the tape changes, done the suctioning, learnt the anatomy of the....trachy itself, where abouts it sits in the trachea, how it works, what possible challenges and problems you're going to have, started to tune in to the sound...of when he needs suctioning...ermm...so, pretty much everything was covered. And I'm like, "yeah I'm doing this" *(lifts arms as if in celebration)* and I'm bowling and thinking "Yeah!", bags of confidence. The, the, the wall, was a lot more shallow and we could see the top of it, this time, and there was a lot more things to hold on to help you get to the top. So all of a sudden your fears are starting to, sort of, peel away. So...and it's just suddenly gone back to panic stations, your first *(emphasised)* ever tube change, yeh? THE (emphasise) first tube change.

I: The panic was anticipating when that would be or when it actually or it happened :here are then?

P: Yeah, yeah, yeah, it happened there and then because it was taken out of my control.

I: How did that feel, being out o' control?

Fear + tube change	P: I was terrified. Absolutely petrified. Every vein in my body...was saying...cos I know that the nurse is going to come back with a tube in her hand and say...(P speaks to Elly: Can you go and get your brother please?) The nurse is going to come back and say, "who's gonna do this tube change?" *(laughs, smiling when talking)* And I know, that, I, I, I pictured it happening, and every vein in my body, and that's exactly what happened, she became in and said right, "who's going to do this change?" and every vein in my body was saying, "you, you, you, you, you!" what came out of my mouth was "me!" *(exclaims)*. I've gotta do it, at some point, and I just thought, you know what, I've got to do it. There's no point in putting off to tomorrow, what's going to happen now, today. And I did it and I did the change and it went smoothly, it was absolutely fantastic and then I fell apart. Once it was done and he was out of danger and that final tape was tied in, I then just....from out of nowhere, like a bolt in the blue, I just collapsed and fell apart.	two words to emphasise significance? Scared about prospect of doing tube change
Overwhelming experience of first tube change. Anticipation vs reality		Wanted to get the nurse to do it but said he would do it. How veins are communicating? overwhelming body experience? Emphasis Courageous. Self talk
Unexpected emotional reaction. Tube change as significant events. Meaning attached to tube change.		quick change from build up to - and I did it. Anticipation vs reality? Did the tube change - it went well but then 'fell apart' contradiction/mismatch - absolutely fantastic to 'fell apart'. bolt in the blue - unexpected? unravelled? emotionally? collapse - medical - who patient? who cared for?
	I: Why do you think that was?	
Emotion attached to tube change	P: Erm...probably about 2 or 3 week's worth of worrying, stress, anxiety, erm...there was relief that I'd actually done it.	Relief led to collapse needed to be... mismatch with excitement
	I: Worry, stress and anxiety about the tube change?	
Lack of time to process/think/connect w/ emotional experience.	P: Yeah. I randomly had made the entire situation as well. Cos I hadn't had a, I hadn't had a release. There wasn't that time to process it. Yeah, I mean, pushed in	Catapult? Been holding everything in? Tight? Why? Need to hold emotions in? Unable to express difficulties?

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Tube change/reality
Challenge without choice
Parental responsibility/expectation
Tracheostomy journey
Tube change as the ultimate achievement/goal
What achieving tube change symbolises
Trapped in hospital
Shift in what normality is
Anticipation vs. reality of home

the deep end you sink or swim. I'm going to have *(emphasis)* do a tube change on him.

I: Can you tell me more about what it means to you to do a tube change?

P: Doing your first tube change, I think the more people you interview, the focus will be on the first tube change. Erm…

I: What does that tube change mean to you?

P: It, it, it's the pinnacle, I think it's the milestone of…I've done all of the other things that have been listed but this is the final. It means that I can do a tube change on my son and it means…I can take him home *(slight laugh)* and get out, get out of the hospital *(smiles and laughs)*. I want, I want, you know, I want…we can get out of the hospital, Elly can have some normality in her life. Erm, and we can…and Freddy can get some normality in his life erm and we can start to work towards a new, a new normal….and new normals are what it's all about *(looking at children)*.

I: So can you tell me a bit about…how did that transition go then, from the pinnacle of the tube change, to then ok, we're going to be moving home?

P: When, when, when we came home I was actually, I felt a lot less…concerned…or worried cos I, I know we can do this.

I: Was that when you were at home?

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Appendix 11: Themes as applied to each participant

	Coming to terms with a tracheostomy			"Medicalisation of your life"			Tracheostomy Transformation	
Participant	*"Taken out of our hands"; No choice in the decision making*	*"Huge black wall"; Facing the unknown*	*"Steps forming"; Gaining clarity and control*	*"Its constant": The unrelenting responsibility*	*"Wear the different caps"; Juggling the conflicting roles*	*"You pull your socks up and you crack on"; Adjustment and coping*	*"Confident doing it ourselves"; Persevering yet forgotten*	*"Opens your eyes"; Reflections on personal change*
Tom	✓	✓	✓	✓	✓	✓	✓	✓
Shane	✓	✓	✓	✓	✓	✓	✓	
Tracey	✓	✓	✓	✓	✓	✓		
Katie	✓		✓	✓	✓	✓	✓	✓
Henry	✓	✓	✓	✓	✓	✓	✓	✓
Elizabeth	✓	✓	✓	✓		✓	✓	✓
Lucy	✓	✓	✓	✓	✓	✓		✓

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