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**Key words: qualitative study protocol, conversation analysis, parents, hydrocephalus, decision-making**

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Rationale for study/ background

Design

Sample strategies

Analytical strategies

Ethical issues

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Design

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Design

**What is already known about this topic?**

- Children with shunted hydrocephalus have frequent admissions to hospital for potential shunt malfunction
- Listening to parents is key when trying to establish a diagnosis of shunt malfunction
- Policy drivers highlight the need to involve parents in the care of their sick child
- Parents often feel engaging with healthcare professionals is focused on the provision of information but they would like to be more involved in the decisions made about their child's care

**What the paper adds?**

- The paper provides an example of a qualitative research protocol
- The study design is a novel approach in health care with few studies having explored professional/parent consultations at a micro-interactional level, using conversation analysis
- The study will evaluate the significance that healthcare practitioners place on parents' concerns in the context of diagnosing shunt malfunction
- The study will describe parents and healthcare professionals' perceptions and experiences of the consultation when making a diagnosis of shunt malfunction
- The study will examine parents' involvement in the decision making processes during parent-professional consultation.

## **Abstract**

### *Aim*

To outline the protocol for a study aimed at exploring parent's involvement during professional-parent interactions and decisions about their child's care in the context of suspected shunt malfunction.

### *Background*

Hydrocephalus is a long-term condition treated primarily by the insertion of a shunt that diverts fluid from the brain to another body compartment. Shunts frequently malfunction and parents of children with shunted hydrocephalus are responsible for recognising and responding to shunt complications. Parents feel that interactions with professionals when they seek healthcare advice for their child do always not encourage active participation in care decisions.

### *Methods*

The study design is based on qualitative methodologies: a combination of conversation analysis applied to consultation recordings of professional-parent interactions when a child is admitted to hospital with suspected shunt malfunction and semi-structured follow-up interviews with the same participants within two weeks following the consultation.

### *Sample*

This is a prospective study and participants will be purposefully selected. Parents of children who have been admitted to hospital with suspected shunt malfunction and healthcare professionals responsible for the initial assessment of the child will be invited to participate.

### *Discussion*

The study will identify how decisions about a child's care are negotiated between parents and healthcare professionals at key stages of the care pathway. In addition, examining interactions between healthcare professionals and parents may identify approaches that support or hinder parents' contributing to the decision-making processes when they seek advice from healthcare professionals.

(Word count 236)

## **Introduction**

A strong driver of United Kingdom (UK) health policy focuses on the need for services to be patient, or in the case of children, child and family-centred (Kennedy 2001, DH 2001, Modernisation Agency 2002, DH/DfES 2004, DH 2004). In relation to people with long-term conditions, health policy emphasises the need to actively involve patients in the management of their condition, and to value their expertise (DH 2001). This shift in the direction of health service delivery requires healthcare professionals to work collaboratively with patients (DH 2001, Modernisation Agency 2002, DH 2004). When the patient is a child working in partnership with parents when making decisions about a child's healthcare is fundamental to the provision of family-centred care. Two of the principles underpinning the UK National Service Framework for children relate to: the empowerment, self-management and support of the child and family, where the child has a health related problem; and ensuring care delivery considers the child and family's overall experience (DH /DfES 2004).

Despite policy initiatives, within the UK and internationally, advocating that healthcare professionals engage with parents, research suggests that parents often feel that their interactions with healthcare professionals are not child and family-centred (Espezel and Canam 2003, Alderson et al 2006, Payot et al 2007). Professional/parent communication appears to be primarily aimed at information giving and establishing good rapport (Espezel and Canam 2003). Evidence suggests that parents feel decision-making processes are based primarily on the provision of information and ensuring consent/assent for treatment rather than encouraging active participation in decisions (Able-Boone et al 1989, Payot et al 2007). Although evidence suggests patients are not actively encouraged to be involved in their care, concepts relating to involvement and participation are poorly described (Thompson 2007). This paper will outline the protocol for a study which aims to explore how healthcare professionals involve parents when making clinical decisions in the context of suspected shunt malfunction in children.

## **Background**

Hydrocephalus is a long-term condition normally identified in early childhood where there is excessive cerebrospinal fluid in the ventricles of the brain. The main treatment for hydrocephalus is the insertion of a permanent ventricular shunt. A shunt is a device that diverts excessive fluid from the ventricles to another body compartment, commonly the peritoneum. The drawbacks of inserting a shunt to treat hydrocephalus are high complication rates, particularly shunt malfunction, and the likelihood of a child requiring at least one shunt

revision (Drake et al 1998, Tuli et al 2004). The signs and symptoms of shunt malfunction include headache, vomiting, drowsiness irritability, bulging fontanelle in infants, altered levels of consciousness, problems with vision, poor appetite and an inability to perform usual skills or activities (Kirkpatrick et al 1989, Watkins et al 1994, Garton et al 2001, Barnes et al 2002). A combination of vomiting, drowsiness and headache are highly predictive of shunt malfunction but are the same presenting symptoms of many childhood illnesses, particularly viral infections (Watkins et al 1994, Barnes et al 2002). Shunt malfunction results in the child requiring hospitalisation and surgery to revise the shunt in order to prevent severe neurological complications or death occurring (Watkins et al 1994, Iskandar et al 1998). The responsibility for monitoring the child's condition, identifying the symptoms of shunt malfunction and responding accordingly are primarily the role of parents.

The first stage of this research project, now completed, was a qualitative interview-based study to explore and understand parents' experiences and perceptions of living with a child with shunted hydrocephalus. The study findings suggested parents develop considerable expertise in managing their child's long-term condition, and are able to differentiate between the signs of potential shunt malfunction and common childhood illnesses in their child. However, the study also found that when seeking advice from healthcare professionals about suspected shunt malfunction, parents' knowledge about their child was not always acknowledged, nor were they encouraged to contribute towards decisions about their child's care. Recommendations from research relating to the diagnosis of shunt malfunction in children have stressed the need for healthcare professionals to value and listen to parents' concerns (Watkins et al 1994, Iskandar et al 1998, Garton et al 2001, Barnes et al 2002). However, no study appears to have explored or evaluated the significance that healthcare practitioners place on parents concerns when diagnosing shunt malfunction in children. A detailed examination of the interactions between healthcare professionals and parents may identify approaches that support or hinder parents' contributing to the decision-making processes when they seek advice from healthcare professionals in the context of suspected shunt malfunction.

## **The study**

### *Aim and objectives*

The aim of the study is to explore parent's involvement and contribution to the decision-making process during professional-parent interactions when a child is admitted to hospital with suspected shunt malfunction.

The specific objectives are to:

1. Explore how parents engage with healthcare professionals when they suspect their child has a shunt malfunction;
2. Explore how health professionals respond to and evaluate information from parents, including tacit knowledge, when making a judgement about whether a child's shunt is malfunctioning;
3. Identify whether or not the judgements of parents and professionals are similar in respect of diagnosing shunt malfunction;
4. Determine how decisions are negotiated at each stage of the care pathway;
5. Describe parents' perceptions and experiences of their encounters with professionals when they suspect their child has a shunt malfunction;
6. Describe healthcare professionals' perceptions and experiences of their encounters with parents when making decisions about the care of a child with suspected shunt malfunction.

#### *The study setting*

In the UK, children with hydrocephalus have their acute care managed by one of the regional children's neurosurgical services. Parents and healthcare professionals invited to participate in the study will be recruited from a regional children's neurosciences ward within a UK National Health Service acute hospital trust. A range of healthcare professionals have contact with children with hydrocephalus admitted with suspected shunt malfunction including: children's nurses and medical staff (paediatric house officers, paediatric neurologists, neurosurgical registrars and paediatric neurosurgeons). Healthcare professionals who have contact with the child and family during the child's initial assessment will be invited to participate in the study.

#### *The study design*

In order to meet the study objectives the design will employ mixed methods, based primarily on qualitative methodologies. The qualitative methods will comprise a combination of conversation analysis (CA) applied to audio recordings of consultations between parents/child and healthcare professionals, and semi-structured follow-up interviews with the same participants (parents and healthcare professionals). The semi-structured interviews will include a modified version of the OPTIONS scale, a validated tool consisting of key statements relating to decision-making tasks using a five point rating scale, in order to evaluate the extent to which clinicians involve patients in decision-making (Elwyn et al 2005). Review of routinely collected audit data (clinical presentation and admission outcomes) will also be undertaken to identify whether the judgements of parents and professionals are similar in respect to

diagnosing shunt malfunction. A primarily qualitative approach is indicated for two reasons: first the study will focus on an area where there is limited/no evidence (a comprehensive literature review failed to identify any published research exploring the decision-making process during professional-parent encounters for suspected shunt malfunction). Second, as the study aims to explore the interactions that occur between healthcare professionals and parents when making clinical decisions in the context of a child's admission to hospital, an approach which incorporates a micro-interactional element using CA methods alongside broader qualitative methods is particularly appropriate.

The principles of CA will be adopted to explore the in-depth decision-making processes occurring during professional-parent interactions. CA is a well established socio-linguistic methodology for analysing interaction. Based on the detailed analysis of audio-recordings of naturally occurring behaviour, it has been used extensively in many institutional settings, and has a strong representation in the healthcare arena (for example Chatwin, 2009; Plug and Reuber, 2007; Collins et al 2005). CA is particularly suited to exploring the negotiation of treatment decisions between patients and professionals because of its focus on the ongoing sequential developments of participants' talk as they interact together (Chatwin 2004). In addition to CA, semi-structured interviews will be conducted within one week after the consultations with each of the participating professionals and parents. The interviews will complement the analysis of the actual interaction by exploring participants' experiences and perspectives of the consultation process, in particular beliefs about parental involvement in the management of their child's care. Interview, in particular the OPTIONS scale, and audit data will also be used to identify whether the judgements of parents and professionals are similar in respect to diagnosing shunt malfunction.

It is anticipated that the time required undertaking the study will be 22 months:

- |  |           |
|--|-----------|
| 1. Refinement of the interview topic guide /<br>Briefings of senior nurses | 1 month   |
| 2. Undertake pilot study, make adjustments as necessary                    | 1 month   |
| 3. Collect main data and undertake preliminary data analysis               | 6 months  |
| 4. Data analysis   | 10 months |
| 5. Report writing and dissemination  | 4 months  |

### *Sample*

This is a prospective study and participants will be purposefully selected. All parents of children who have been admitted with suspected shunt malfunction to the children's neurosciences ward are eligible to participate. Healthcare professionals responsible for the

initial assessment of the child will also be invited to participate. In order to ensure coverage of a range of encounters between professionals and parents a sample of between 15 and 20 parents will be recruited. Due to the large amount of detailed interactional data that these encounters are likely to generate, this number is appropriate, and is in line with other CA based studies of this scope and depth (Chatwin 2004). The final sample size, in common with qualitative studies, will be determined by the emergent themes and data saturation (Coyne 1997, Higginbottom 2004).

## *Methods*

### Recruitment of participants

- a. Parent/s of children who are admitted to the children's neurosciences ward because of concerns relating to the shunt will be invited to participate in the study. Where the child is accompanied by their mother and father, both will be invited to participate. The senior nurse on duty at the time of the child's admission will provide parents with information about the study and ascertain their willingness to participate.
- b. Following the recruitment of parent/s, healthcare professionals involved in the initial assessment of the child will be invited to participate in the study. The senior nurse on duty will provide healthcare professionals with information about the study and ascertain their willingness to participate.

Recruitment procedures are reliant on the senior nurses working on the children's neurosciences ward to identify parents and healthcare professionals who are eligible to participate in the study. Effective communication with the ward will be achieved by building on existing links; the main investigator (JS) has formal well established links with the ward in her role as liaison lecturer for student nurses. Before recruitment of participants begins there will be formal and informal briefing with healthcare professionals who may be involved with the study. Formal briefings will occur at ward meetings, informal briefings will be opportunistic during usual ward visits. Individual briefings with the senior nurses will be undertaken to ensure they have a clear understanding of the project aims and recruitment procedures.

### Obtaining Consent

Due to the unpredictable nature of shunt malfunction, children are admitted any time during the 24 hour period. Therefore, it will not be possible for the main investigator (JS) to be available



to discuss the study with all potential participants. The senior nurses will take responsibility for obtaining consent from participants; they will provide eligible parents who might be potential participants with information about the study as soon as is practicable, following arrival on the ward. Parents will be allowed time to read the information and consider if they would like to participate prior to healthcare professionals undertaking the initial assessment of the child. In the unusual situation where the child is identified as requiring immediate emergency care, the senior nurse will use their clinical judgement in relation to if or when it is appropriate to provide parents with information about the study. Once parents have had an opportunity to read the information provided, the senior nurse will ascertain if they are willing to participate in the study and ask them to complete a consent form.

Healthcare professionals working on the ward will have been informed of the study prior to its commencement, through formal and informal ward briefings. Information leaflets about the study will be available on the ward prior to and throughout the data collection period. The senior nurse will inform the healthcare professionals involved in the assessment of the child that parent/s have consented to participate in the study prior to ascertaining healthcare professionals willingness to participate. The senior nurse will obtain written consent from all healthcare professionals who participate.

#### Data collection

Data will be collected from four sources;

a. *Audio-recorded interactions between professionals and parents*

The audio recordings of the interactions will relate to the assessment of the child in order to establish a diagnosis (shunt malfunction or not), as part of usual care. Such interactions are usually brief, between 10-15 minutes. The potential interactions that could be recorded for each family are: parent - nurse interactions, parent - paediatric house officer interactions, parent - neurosurgical registrar interactions, parent - paediatric neurologist interactions and parent - paediatric neurosurgeon interactions. The number of interactions recorded will vary for each encounter and will depend on which healthcare professionals consent to participate, and whether junior staff need to consult with senior colleagues where there are uncertainties about the child's diagnosis.

As CA is based on the analysis of naturally occurring interactions a researcher will not be present during the recording of the parent - professional encounters. The senior nurses have already indicated their willingness to be responsible for setting up recording equipment. JS will provide training in the use of recording equipment for these nurses prior to the study commencing. A small, unobtrusive and simple to

operate hand-held digital recorder will be used. The senior nurse on duty at the time of the child's admission will be responsible for setting up the recording. The senior nurses will contact JS to inform her that a family has been recruited to the study either at the time of recruitment if the admission occurs during 8am - 8pm, or the following day outside these hours. This will enable JS to provide the senior nurses with support during the process of recruiting participants, gaining consent and recording the interactions. JS will visit the ward as soon as is practicable to: provide additional support to the senior nurses, collect consent forms, and check equipment is ready and paperwork is available for subsequent participants.

b. *Audio-recorded telephone interviews with parents*

Parents who indicate on the consent form they are willing to participate in an individual interview will be contacted by JS within a week following the child's discharge from hospital. A mutually convenient time will be arranged to conduct the telephone interview. Telephone interviews have been used successfully to investigate patient satisfaction with healthcare interventions and service provision (Wilson et al 1998). Telephone interviews are appropriate in situations where the questions are more focussed and likely to be of shorter duration compared to face-to-face interviews (Wilson et al 1998). The interview will focus on parents' perceptions and experiences of their encounters with professionals during their last visit for suspected shunt malfunction. The interview will be semi-structured using an interview topic guide (table 1). Interviews will be recorded (with participants' permission) and it is anticipated they will last approximately 15-20 minutes.

c. *Audio-recorded interviews with healthcare professionals*

Professionals who indicate they are willing to participate in the follow-up interview on the consent form will be contacted by JS within a week following the child's discharge from hospital. A mutually convenient time will be arranged to conduct a telephone interview. The interview questions will focus on healthcare professionals' perceptions about the factors that supported or hindered them in involving parents to contribute during the decision-making process. The interview will be semi-structured using an interview topic guide (table 1). It is anticipated that interviews will again be of 15-20 minutes duration. As with the parents, these interviews will be audio recorded with the permission of the participants.

d. *Audit data routinely collected by the ward staff*

Audit data collected routinely for all children admitted because of potential shunt malfunction will be reviewed for the children whose parents agree to participate in the study. Information will be extracted from the audit tool in relation to the child's demographic data, shunt history and the outcome of the child's recent admission to hospital.

Insert table 1

### *Data analysis*

There are a range of approaches available to analyse qualitative data, each having their own theoretical underpinning and specific purpose. As the key element of this study is the investigation of ongoing, naturalistic interaction, CA will be used to analyse the audio-recorded data i.e. data relating to interactions between parents and healthcare professionals. The analysis of these interactions will focus on how healthcare professionals engage with parents, how parents describe their child's symptoms and how treatment decisions are made. The four main stages of the CA method will be as follows: transcription of data (CA transcription is highly detailed and forms a central part of the analysis); locating discrete phenomena within the data that relate to the focus of the study (for example the dynamics of turn-taking and the characteristics of speech delivery during the sequences relating to decision-making); describing each discrete phenomenon in depth (identify patterns in the sequencing and the organisation of interactions), and finally returning to the original corpus to identify whether or not other instances of the phenomenon can be identified and described in a similar way (Hutchby and Wooffet 1998). This final stage will result in continual refining of the description of the phenomena of interest until a formal account is formed.

The principles of the framework approach, based on thematic analysis, will be used to analyse the individual interviews (Spencer et al 2003). The three stages of the framework will be followed; data management (transcription of the interview, familiarisation of the data through a process of reading and re-reading of the transcribed interview, identification of initial key themes or concepts from which data can be organised and sorting the coded data into the initial themes); descriptive accounts (mapping the range and diversity within the themes, refining themes and sub-themes until the 'whole picture' emerges); and explanatory accounts (interpretation of the themes and sub-theme, their development and associations). A quantitative approach will be used to analyse the OPTIONS scale and audit data using descriptive statistics such as frequencies, means and percentages. The OPTIONS scale will be used to identify congruence between parents and professionals' perceptions of the interaction. Interview and audit data relating to the outcome of the child's admission will be used to identify

whether the judgements of parents and professionals are similar in respect to the diagnosis of shunt malfunction

### *Pilot study*

A pilot study will be undertaken to test and where necessary refine the recruitment and sampling process and data collection methods. The pilot study will enable the senior nurses to become familiar with the recording equipment, recruitment approach and consent obtaining procedures. The pilot study will enable the interview topic guide to be tested and modified if required. The pilot study will follow the procedures already outlined. It is anticipated that the pilot study will involve two -three families and the healthcare professionals involved in the assessment of these children.

### *Issues of rigour*

Ensuring that the study accurately reflects the parent-professional interactions and participants' descriptions is essential if the findings are to be credible. The findings must be relevant, accurate, unbiased and sensitive to the participants. This will be achieved by having a clear audit/ decision trail, using 'thick' descriptions of the raw data, reflection, comparison and agreement of the findings between two or more researchers and researchers taking into account their own perspectives (Tobin and Begley 2004, Tuckett 2005).

### *Ethical issues*

The main ethical challenges for this study relate to: the acute nature of the child's admission to hospital does not allow for the usual period of 24 hours between being informed about the study and parents agreeing to participate; and reliance on senior nurses to provide potential participants with information about the study and taking responsibility for obtaining consent. The procedures for ensuring the senior nurses are aware of the ethical principles that must be adhered to have been described. The strategies applicable to this study in order to ensure ethical principles are maintained include:

- *Ensuring participants' rights are maintained*  
All prospective participants will have the right to decide whether or not to participate in the study. Parents will be informed that deciding to participate or not will not influence the care provided. It is likely that healthcare professionals will be invited to participate in the study more than once. The senior nurses will not assume that agreeing to participate once applies to each encounter.
- *Ensuring consent is an informed choice*  
In order to make an informed choice potential participants' will require adequate information about the study. The senior nurse will use their clinical judgement in

relation to when, or if in the case of the child requiring emergency care, it is appropriate to provide parents with information about the study. Although parents will not have the usually time period to decide whether to participate or not, the senior nurse on duty will allow parents time to read the study information before ascertaining if they wish to participate and subsequently obtain consent. Healthcare professionals participating in the study will have information about the study in advance of and during the data collection period. Healthcare professionals willing to participate in the study will be asked to complete a new consent form for each recorded encounter with a parent.

- *Ensuring participants are respected and treated sensitively at all times*

Privacy will be maintained during audio-recording of parent- healthcare professional interactions. Participants will be able to withdraw from the study, and if they wish to stop the audio-recording of their interaction, at any time. Individual follow-up interviews will be conducted at times suitable to participants. Participants will be able withdrawn from the individual interviews, and if they wish stop the interview, at any time. Any concerns/issues raised by participants during individual interviews will be handled sensitively by the researcher at the end of the interview. Systems will be put in place to refer participants to the senior ward sister, Association for Spina Bifida and Hydrocephalus advisor or consultant neurologist if necessary, and with participants' consent. Details of who to contact if participants have any concerns about the study will be provided in the information sheets.

- *Ensuring participants' information remains confidential*

The study involves collecting audio-recordings of participant interactions, recorded telephone interviews and ward audit data. The storage of audio data will meet the ethics committee recommendations, which included using a password protected lap top and ensuring recorded data will be destroyed within three months following transcription. Only members of the research team (JS, FMC, HB, JC) will have access to the original data, and participants will be referred to by a unique identifier. The chief investigator will be the only person who will have access to participants contact names and details. Anonymity will be maintained in subsequent reports and publications that arise as a direct result of the study. Data routinely collected from the ward in relation to the number of children admitted for potential shunt complications will be anonymised and referred to by the unique identifier. Participants will be informed of these procedures and assured that information will remain confidential both verbally and within the study information sheet.

## *Resources*

Standard equipment required to undertake qualitative interviews (telephone recording equipment and NVivo software packages) and quantitative statistical analysis software (SPSS) are available to support the study. Additional resources have been secured to support CA methodology including a wide screen PC, Sound Forge software audio editor, Zoom H4 portable stereo recorder, headphones and attendance at training courses in CA methodology.

## **Discussion**

Study protocols for systematic reviews are published extensively within evidence based healthcare collaborations. For example, the Centre for Reviews and Dissemination - the largest world-wide group engage exclusively in evidence synthesis in the health field ([www.york.ac.uk/inst/crd/](http://www.york.ac.uk/inst/crd/)), and the Cochrane Collaboration which aims to improve healthcare decision-making globally through systematic reviews of healthcare interventions ([www.cochrane.org/](http://www.cochrane.org/)), frequently undertake this aspect of dissemination. However, there appears to be a paucity of published study protocols dealing with other types of empirical research - particularly non-experimental designs and qualitative approaches (Donnelley et al 2008). Yet a study protocol is an integral part of the research process; it outlines the rationale for undertaking the work, the study design and the ethical, organisational and procedural issues that need to be considered. A study protocol is essential if funding and ethical approval are to be sought. In addition, the publication of a study protocol enables early dissemination of the proposed study (Donnelley et al 2008). Other reasons for producing a study protocol include: serving as a useful means with which to convince others a project is worthwhile, and the detailed process of planning and formalising what is involved to help ensure that study aims are realistic and achievable. Although there are few published examples of actual research protocols, guidance in relation to their structure and format are widely available for example: the UK's National Institute for Health ([www.rdinfo.org.uk](http://www.rdinfo.org.uk)), and North America's Atlantic Health Promotion Research Centre ([www.medicine.dal.ca/ahprc](http://www.medicine.dal.ca/ahprc)). Despite the wide range of methodological approaches and academic disciplines which might be encountered most study protocols tend to have a similar structure (table 2), and usually need to address the following questions: why is the research being undertaken; how will the study be conducted; and what is trying to be accomplished.

Insert table 2

The primary aim of the protocol we have outlined in this article is to consider how healthcare professionals work in partnership with parents when making clinical decisions about the care of

their child, in the context of suspected shunt malfunction. The study we propose will examine interactions between parents and healthcare professionals at a micro-interactional level, while simultaneously exploring both parents' and healthcare professionals' perceptions of consultation behaviour. In terms of this study, these will be consultations where the parent suspects that their child's shunt is malfunctioning. Despite policy drivers aimed at ensuring health services are child and family centred and that healthcare professionals work collaboratively with parents (DH/DfES 2004, DH 2004, DH 2001), there is little empirically derived interactional work dealing with the behavioural mechanisms by which this might be achieved. Certainly, there has been more general work focusing on inclusivity and participation in health care encounters (for example: Heritage and Stivers 1999, Entwhistle et al 2004, Collins et al 2005, Stivers 2001, Collins et al 2007). Although there is a growing corpus of micro-interactional research focusing on medical interaction and healthcare and particularly studies utilising conversation analysis as the primary method (for example Entwhistle et al 2004, Collins et al 2005, Collins et al 2007, Chatwin 2009), the idiosyncratic clinical environment that we are proposing to study with its complex multi-party dynamics has received no attention.

The study has several outcomes, and describing these clearly is a key part of the protocol: first it will describe how parents and healthcare professionals interact when making decisions about a child's healthcare in the context of suspected shunt malfunction. Second, it is anticipated that the findings of the study may influence the way healthcare professionals interact with and involve parents in the care of their child in the future. Third, the study has potential benefits for parents and healthcare professionals. For parents, the opportunity to share their views may have a therapeutic effect (Eggenberger and Nelms 2007). For professionals, the potential benefits may relate to a greater understanding of interactional factors that support or hinder parents' contribution to the clinical decision-making process when dealing with an ill child.

Some of the greatest challenges in undertaking this study are practical ones, in particular, how to gather data in a timely and ethical manner. The protocol has described how the main ethical issues relating to the study will be addressed, which include ensuring: participants rights about deciding to participate or not are maintained and obtaining consent in a timely and appropriate manner; participants receive adequate information about the study; participants are treated with sensitivity and respect at all times and; participants information remains confidential. The study has undergone a rigorous review process and has obtained both NHS research ethics committee and local site specific (hospital trust) research and development approval.

The findings of the study will be disseminated in several ways. Key findings will be conveyed to the local healthcare professionals through presentations at team meetings and neurology seminars. The study methods and results will inform teaching in undergraduate and postgraduate healthcare programmes. Wider dissemination will be undertaken through national and international conference presentations and publications in peer reviewed professional and research journals as well as through national support networks such as the Association for Spina Bifida and Hydrocephalus.

## **Conclusion**

A study protocol is an integral part of the research process. This paper outlines a study protocol describing the procedures that will be followed when investigating how healthcare professionals work in partnership with parents when making clinical decisions about the care of their child, in the context of suspected shunt malfunction. The protocol described how mixed methods, primarily based on qualitative methodologies will be employed to meet the study aims and the particular ethical challenges when participants are recruited in the immediate period following hospital admission.

(Word count 4 936)



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**Table 1: Interview topic guide**

**1. Parents' interview topic guide (provisional)**

<b><i>Focus</i></b>	<b><i>Example of questions</i></b>
Concerns about child	<ol style="list-style-type: none"> <li>1. What made you think your child's shunt was malfunctioning? (Prompt - On this occasion how likely did you feel that your child's shunt was malfunctioning?)</li> <li>2. Thinking back to the time just prior to this hospital admission, what that prompted you to seek healthcare advice for your child? (Prompt - On this occasion did you seek advice from anyone else including other healthcare professionals prior to your arrival on the ward?)</li> </ol>
Involvement in decisions about the child's care	<ol style="list-style-type: none"> <li>1. Thinking back to the time of the hospital admission, how did healthcare staff respond to your concerns? How did this compare to previous experiences?</li> <li>2. How did healthcare staff take into consideration your views about your child's changed condition? How did this compare to previous experiences?</li> <li>3. To what extent do you want to be involved decisions when your child has a suspected shunt malfunction?</li> <li>4. Did you feel you were involved you in decisions about your child's care in relation to this last admission? (Prompt - ask for examples). Is this different from previous experiences?</li> </ol>
	Do you have anything you would like to tell me about in relation to your child's admissions to hospital?

**2. Healthcare professionals' interview topic guide (provisional)**

<b><i>Focus</i></b>	<b><i>Example of questions</i></b>
Initial assessment	<ol style="list-style-type: none"> <li>1. What do you think prompted parents to seek advice from healthcare professionals about their child?</li> <li>2. At the time of the initial assessment how likely did you feel that the child's shunt was malfunctioning? (Prompt - What did you base your decision on?)</li> </ol>
Decision-making processes	<ol style="list-style-type: none"> <li>1. Do you feel parents should be involved in treatment decisions when a child is acutely unwell, such as suspected shunt malfunction? (Prompt - How do you feel parents can be involved in decisions about their child's care?)</li> <li>2. Do you feel parents can make informed decisions when their child is acutely unwell, such as suspected shunt malfunction?</li> <li>3. How do you involve parents in treatment decisions relating to the care of the child?</li> <li>4. How do you feel parents' knowledge, experience and expertise can be used in relation to diagnosing shunt malfunction?</li> </ol>
	Do you have anything you wish to add?

**Table 2: Design of a study protocol**

<b><i>Focus</i></b>	<b><i>Content</i></b>
Title	Must be clear and outline topic area, participant group and design
Investigators	List all study contributors
Background	Summary of current literature/ current evidence Identify gaps in the literature/state need to undertake the study/rationale State the hypothesis or research questions Study outcomes (linked to the study aims)
Aim	State aim and concise objectives
Study setting	Outline the study population, inclusion and exclusion criteria
Study design	Describe the methodological approach
Methods or procedures	Outline sampling strategies Describe recruitment processes Describe process for gaining consent Describe data collection tools/ interventions
Data analysis	Describe analytical procedures and data analysis software
Rigour	Describe how issues relating to reliability and validity will be addressed
Ethical issues	Describe the key ethical issues that apply to the study and how these will be addressed
Plan of action	Provide a detailed order and timeframe for the study
<b>Resources</b>	Outline all costs: Staff salaries Equipment cost and sundries Estates costs