Data supplements

Data Supplement 1. Reporting recommendations for qualitative research methods in COS development

Table 1. Reporting recommendations for qualitative research methods in COS development, as developed by Jones *et al.* .

1	Research aims and relationship with broader COS development process	See section introduction
2	Sampling approach	See section methods
3	Type of data collection methods (e.g. interviews, focus groups, combination); content and derivation/ justification (e.g. topic guide)	See section data collection
4	Analytical approach and justification	See section data analysis
5	Sample characteristics and participants numbers	See section participants
6	Findings related to outcome domains (concordant with research aims)	See section results
7	Report approaches to ensuring rigour (e.g. multiple perspectives on the data, respondent validation) and consider reflexive content	See section data analysis and discussion
8	Discuss the strengths and limitations of the approach	See section strengths and limitations

Data Supplement 2. Standard Operating Procedure for LMiCs

Standard Operating Procedure (SOP) for COHESION Interviews in Low- to Middle-Income Countries

Who? Potential participants are parents whose infants have been diagnosed with and received treatment for neonatal encephalopathy or birth asphyxia, or other family members who may care for the infant. Infants will have been born at 35 weeks' gestation or later, where this can be confirmed or estimated, with a birth weight considered healthy for each location (preferably 2.5kg or above). We will recruit a minimum of 5-6 participants in each country.

Process for identifying participants

Steering Group members for COHESION, members with experience in the area of neonatal encephalopathy research, will identify Gatekeepers in each respective country. Gatekeepers will consist of researchers or healthcare professionals working in the area of neonatal encephalopathy. The Gatekeepers will act to identify potential participants through their local knowledge in their particular country.

Translation of information for recruitment of parents for whom English is not their first language

The following documents need to be translated from English to the local language in the area in which the interviews are being carried out:

- Participant Information Leaflet
- Consent Form
- Interview Schedule

Two researchers fluent in both English, and the local language and dialect of the region in which the interviews are taking place will support the translation of the above documents. One

of these individuals may be the research assistant conducting the interviews. The process for translating these documents is:

1. The documents are translated from English to the local language and dialect by one researcher.

2. The translated document is back-translated to English by a second researcher independently (this person will not have seen the original, English language version of the documents)

3. Two members from COHESION (FQ and LB) will compare the back-translated documents against the original English language documents using the "compare" feature in Microsoft word. Each will categorise any discrepancies independently as either acceptable or problematic. Acceptable discrepancies will be those where the meaning is not altered. Problematic discrepancies will be those, which alter the core meaning of the content. If this arises, the reviewers will compare the forward translated and back-translated documents against the original English document to see where the discrepancy arose.

4. Any discrepancies between the original English document and the back-translated document will be discussed with the two researchers who are fluent in both languages.

Audio recording of the Participant Information Leaflet: The researcher conducting the interviews will audio-record the translated Participant Information Leaflet and Consent form. This can then be played for potential participants who may have literacy challenges and ensure that adequate information is given to potential participants before consent is considered. Participants who agree to participate will sign (either through writing or annotating with an 'x' depending on literacy levels) the consent form and return it to the interviewer prior to commencing the interview. A copy of the signed consent form will be sent to the COHESION research team at the earliest opportunity.

Interviews

Research assistants or healthcare professionals with experience in interviewing will conduct the interviews. The interviewer will conduct the interviews in the native language using a structured interview schedule. All interviews will be audio recorded and recordings transcribed. The transcripts will be translated into English by one researcher. The translated transcript will be back-translated independently by a second researcher and compared against the recording. Any discrepancies will be resolved between both researchers. The final translated transcript (in English) will be returned to the COHESION research team.

The interviews will follow a semi-structured format, where participants will initially be prompted by open questions to encourage discussion, followed by additional questions, which will be informed by the *a priori* domains that emerge from the systematic review. The interview schedule may develop iteratively during the interview process.

Distress Protocol

We have developed a *Distress Protocol* document outlining steps for the interviewer to undertake in the event of the interviewee becoming distressed during the process of the interview. This is a separate document in English that does not need to be translated, as it intended for the interviewer to use.

Additional Information

Please note that the COHESION team will, subject to a priori agreement on costs, pay the interviewer and other researcher involved in translating the documents and interview transcripts, for their time and work for audio-recording the Participant Information Sheet and Consent Form, conducting the interviews and translating the transcripts back into English.

Data Supplement 3. Participant Information Leaflet

Consent form

COHESION (Core Outcomes in Neonatal Encephalopathy)

Participant Information Number: _____ (to be completed by researcher)

Declaration of the participant- please tick (□) the relevant box	YES	NO
I have read or have been read the participant information sheet for this interview and I understand the contents.		
I have had the opportunity to ask questions and all my questions have been answered to my satisfaction.		
I understand that my participation is voluntary and that I am free to withdraw at any time, without giving reason and without any negative consequences.		
I agree to the interview being audio recorded.		
I agree that the audio recording of the interview will be stored securely in the National University of Ireland, Galway, for a period of seven years after the completion of this study.		

Storage and future use of information: I give my permission for information collected about me to be stored or electronically processed for the purpose of research and to be used in related studies or other studies in the future but only if the research is approved by a Research Ethics Committee.		
I give permission to be contacted in the future about other studies I may be interested in participating in.		

Participant name: _____

Participant signature: _____

Date: _____

Statement by the researcher/person taking consent

I have, to the best of my ability made sure that the participant understands what is involved in taking part in this study and that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Researcher / person taking consent:

Name of person taking consent: _____

Signature of person taking consent: _____

Date: _____

Data Supplement 4. Interview Guide

COHESION Interview Guide

Interview Schedule

I. Introduction

II. The participant will be reminded of the purpose of the COHESION study.

III. The participant will be given the opportunity to ask questions about the COHESION study.

IV. The participant will be asked if they are still willing to take part.

V. The participant will be asked if they agree to having the interview audio/video recorded.

VI. They will be asked to fill in the consent for and to sign it and to give to the signed form to the interviewer.

VII. In the case of interviews carried out by teleconference, they will be prompted to provide consent via email attachment of the signed consent form prior to commencement of the video/ audio interview.

VIII. The specific questions will be asked of the participant.

I. Introduction

You are very welcome to our interview session today and we are very grateful that you have taken the time to participate in our focus group session. This session is part of a study we are carrying out to develop a "Core Outcome Set". (May insert slot to show POPPIE video explaining core outcome sets in plain language). One of the main delays in the improvement and progression of care for patients

with a particular disease is the differences in what things researchers look at to see a treatment works or not. These 'things' are called outcomes. If different outcomes are measured in different trials, they can't be compared and this slows progress in knowing how to improve patient care. Another problem is that often the research carried out does not incorporate the values and opinions of patients and care-givers and often prioritises the values of clinicians. The development of our Core Outcome Set (COS) will:

- Standardise what should be measured in trials for treating Neonatal Encephalopathy (Birth Asphyxia).
- Incorporate the opinions of Parents and care-givers of children with Neonatal Encephalopathy (Birth Asphyxia) (and have an expertise which is often overlooked).

II. The participant will be reminded of the purpose of the COHESION study.

Our COS aims to find people's opinions on what measures they think are most important and that should be measured when doing research on treatments for Neonatal Encephalopathy (Birth Asphyxia). We will compile a list of outcomes that will then be used to develop a questionnaire which we will circulate to a wider group. We really want your experiences to influence these outcomes.

III. The participant will be given the opportunity to ask questions about the COHESION study.

Before we begin, have you any questions?

IV. The participant will be asked if they are still willing to take part.

We would like to take this opportunity before we begin to make sure you are still happy to take part in this interview. If at any stage you'd like a break (or the questions asked are too difficult to answer), please just let us know.

V. *The participant will be asked if they agree to having the interview audio/video recorded.*

We'll be recording this interview (sound and/or video) and storing the recording safely until the study is complete. We will not mention names or anything that individually identifies you in anything we do.

If you do not wish for the interview to be video recorded we can offer audio recording instead.

VI. *Participants will be asked to fill in the consent form, sign it and give the signed form to the interviewer.*

VII. *In the case of interviews carried out by tele/videoconference, participants will be asked sent the consent form by email prior to commencement of the video/ audio interview.*

VIII. *The specific questions will be asked of the participant.*

1*	*Why do you think your baby was admitted to the NBU/ NICU?*
2*	(Ask about their experience of their child (relation/ child they care for) being told of their diagnosis of Neonatal Encephalopathy)

	Do you know what diagnosis your son/daughter was given? Can you explain?
3*	*What treatment options were offered to your baby and how did you decide about undergoing treatment?* What information did parents/caregivers want about the treatment their child would be receiving, and what factors did they consider when deciding on treatment options
4*	*What treatment did your baby receive while in hospital?*
5	*What treatment did your baby receive after discharge from hospital?*
6*	*What effects has the treatment had/ is having?* Prompt for areas such as (physical health, mental health, effects on family/ relationships, developmental milestones etc.) Ask what parents/caregivers would consider the worst side effect their infant has experienced
7	*Does your baby have any lasting illness or problems? If yes what are they?*
8*	*What are your concerns for your child for the future?*

9	*Is there any information you wished you had received in hospital that you did not get? What?* i.e. were they given any information leaflets/ websites at the time of diagnosis or treatment
10	*Did the explanation and information given about the treatment your child received match your real experience?*
11*	*Is there any information or advice your healthcare provider shared with you that you do not agree with and/or feel was important?*
12*	If I say I am studying health outcomes, what does a health outcome mean to you? *How would you describe an **outcome**?* (In their own words)
13*	*What outcomes do you think are important to measure to give an idea of the health/ progress of your child?*
14*	*What matters most to you about the health of your baby?*
15*	*What about the impact of your baby's health on you?*
16*	*What about the impact of your baby's health on the other members of your family?*

17*	*In the research, researchers and doctors have looked into (**insert list of outcomes derived from systematic review**)* *What are your thoughts?* *Is there anything else you would like to add?*

Note: *Where the question has an asterix (*), these questions should be prioritised and must be asked; Where the question does not have this asterix, these questions are supplementary questions that could be used where additional participant prompting is required.*

Data Supplement 5. Distress Protocol for COHESION interviews

Signs indicative of stress that may occur during the interview process	**Procedure when participant displays signs of distress and questions to determine level of distress**	**Response or behaviour of participant in response to questions**	**Is the participant displaying signs of strong emotional distress and/or is there a concern for their safety? (YES/NO)**	**Is there a cause to believe the participant may be in danger? (YES/NO)**
Participant informs interviewer that they are experiencing a high level of distress.	1. Stop the interview. 2. Offer support to the participant and allow then time recover. 3. Determine the level of distress through the following questions: a. Would you like to share what you are thinking? b. Would you like to share how you are feeling?			

	c. Do you feel you are able to continue with this interview? d. Would you like to end this interview? e. Do you feel you would be able to go on about your day as normal after this interview? (For Interviewer): Do you think that the participant is experiencing emotional distress beyond what would be expected from this interview?			
Participant shows signs of emotional distress (e.g. crying, becoming agitated, loss of concentration etc.)	1. Stop the interview. 2. Offer support to the participant and allow then time recover. 3. Determine the level of distress through the following questions: a. Would you like to share what you are thinking?			

	b. Would you like to share how you are feeling? c. Do you feel you are able to continue with this interview? d. Would you like to end this interview? e. Do you feel you would be able to go on about your day as normal after this interview? 4. (For Interviewer): Do you think that the participant is experiencing emotional distress beyond what would be expected from this interview?			

Actions for the Interviewer:

1. If the distress displayed by the participant is what would be expected in an interview on this sensitive topic;

offer the participant support and the option to:

a. Stop the interview.

b. Give the participant a break from the interview.

c. Continue the interview.

2. If the distress displayed by the participant is **beyond** what would be expected in an interview such as this on a sensitive topic;

   a. Encourage the participant to follow up with his/her GP for support.

   b. Provide the participant with the number of the emergency room at the nearest hospital (location specific) and encourage the participant to make contact with this service if their distress is increased in the hours/days/weeks following the interview.

   c. Indicate that you (the interviewer), with the participant's permission, will follow up with/ contact the participant on the day following the interview.

   d. Notify the PI/Lead Researcher of the steps undertaken and the recommendations given to the participant.

3. If the distress displayed by the participant indicates they may be in immediate danger;

   a. Contact the local authorities, unless a family member can transport the participant to the nearest hospital.

   b. Indicate that you (the interviewer), with the participant's permission, will follow up with/ contact the participant on the day following the interview.

   c. Notify the PI/Lead Researcher of the steps undertaken and the recommendations given to the participant.