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Local Site Lead:

Chief Investigator: Dr Sophie Bertaud
Ethox Centre
Nuffield Department of Population Health
University of Oxford
Big Data Institute, Old Road Campus
Oxford, OX3 7LF
Email: sophie.bertaud@ethox.ox.ac.uk

PARTICIPANT INFORMATION SHEET

Supporting families before birth: a qualitative study of parents' and health care professionals' experiences

We would like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information and discuss it with others if you wish. *If there is anything that is not clear, or if you would like more information, please ask us.*

What is the purpose of the study?

When parents face the difficult news during pregnancy that their baby is affected by a serious health condition, they rely on health care professionals for advice and support. This research aims to better understand the experiences of the families and health care professionals in this situation and to examine the ethical considerations in providing supportive care to families before birth. The research findings will lead to recommendations for professionals who support families before birth in order to enable compassionate supportive care for more families in the future.

Why have I been invited?

- You have been invited to participate because you are a health care professional with experience caring for families when they receive a diagnosis of a life-limiting or potentially life-limiting condition in their baby during pregnancy.

- We are intending to involve approximately 15 parents and 30 health care professionals in this study.

Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part, you will be asked to sign a consent form next time we see you. You will have the opportunity to discuss the study and ask any questions you may have. You can withdraw at any time without having to give a reason. Your legal rights will not be affected by agreeing or refusing to take part.

What will happen to me if I decide to take part?

If you decide to take part, there are two parts to this study:

Part One involves:

- Audio-recording antenatal consultations: a member of the healthcare team or a researcher will plan to audio-record the conversations that take place between parents and healthcare professionals after a baby is diagnosed with a life-limiting condition in pregnancy. This will involve the use of a small audio-recorder that will be present in the room.
- Short interviews after antenatal consultations: After each consultation you are involved in, a member of the research team will contact you to conduct a short interview (approximately 15 minutes duration). This interview will be audio-recorded and the researcher will ask you a few questions about your experience of the most recent consultation. This can take place in person, online or via telephone depending on your preference and we can choose a time that is convenient to you.

Part Two involves:

- A longer interview after the end of the patient's pregnancy (approximately 60 minutes in duration). This will be an opportunity to ask you more in-depth questions about your experience. This can take place in person, online or via telephone depending on your preference and we can choose a time that is convenient to you.

  AND/OR

- Participation in a focus group (approximately 90 minutes in duration): This will be a group discussion with other healthcare professionals who care for families when a baby is diagnosed with a life-limiting condition in pregnancy. We will discuss your experience of providing care in this context and ask how you think support for families could be improved in the future. This will take place either in person or online.

We would be delighted for you to take part in both Part One and Part Two of the study but if you would prefer to only participate in either Part One or Part Two this is also a possibility. If you participate in Part One and Two of the study we would anticipate that you will be involved in the study for a total time of around 6 to 12 months.

Are there any possible disadvantages or risks from taking part?

We recognise that caring for families during pregnancy when a baby is diagnosed with a life-limiting or potentially life-limiting condition can be a stressful and upsetting experience. Therefore, some people will find answering the questions in the interviews emotionally upsetting and talking about your experiences may be distressing for you.

What are the possible benefits of taking part?

There is no expected direct benefit to you by taking part. However, the information we learn from this study will help us to improve our approach when caring for parents in the future. Some participants who have taken part in studies like this one have found that the chance to talk about their experience was helpful to them personally.

Will my General Practitioner/family doctor (GP) be informed of my participation?

We do not routinely plan to inform your GP that you are participating in a research study. If you feel you may benefit from additional support from your GP, then you can let us know at the time of consenting to participate in the study and we will arrange to write to them.

What support will be available to me during the research study?

If at any time during the study you feel that you are finding participating to be upsetting or uncomfortable, please let the researcher know. If you are taking part in an interview or focus group you will be invited to skip over that question or to take some time out of the interview/focus group or to end the interview/focus group entirely. After the interview or focus group has ended you may find that the discussion you had has brought up some painful or upsetting emotions. The researcher will be available afterwards to talk to you about this if you would like and you are welcome to get in touch with the research team at any point. We will also be able to offer you specific psychological support if you need it and we can give you details of additional ways to access information and support outside of the research study.

Will my taking part in the study be kept confidential?

All information which is collected about you during the study will remain confidential. We will not access your personal medical notes as part of this study.

We will only use personal data such as names, dates of birth, addresses or telephone numbers where this is necessary to contact you or to send you vouchers to say thank you for your participation. Any personal contact information about you will be stored separately from research data, in a locked filing cabinet in a separate office or on a separate password encrypted electronic file. This information will be be securely stored at [local NHS Trust] or at the University of Oxford and will only be accessed by members of the research team. Your contact details will be deleted as soon as they are no longer required to manage your participation in the research and for a maximum period of 3 years after the study has ended.

Information collected during the study (the research data) will all be de-identified and you will be given a participant study number. Study numbers and the corresponding names will be kept in a separate file location to the study data, in a password-protected file. This information and all data will be stored on the University of Oxford servers and will not be accessed by anyone outside of the research team. The audio-recordings from your consultations, interviews and/or focus groups will be de-identified before being transcribed into a written text by a secure transcription service. The transcribed text will be analysed by members of the research team only.

You will not be identified in any report or publication about the study. We may use quotes from things that you have said during the interview but we will not identify you personally in any way.

Responsible members of the University of Oxford [and the relevant NHS Trust(s)] may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

Will I be reimbursed for taking part?

If you take part in any part of the study you will be reimbursed for any personal expenses that you incur because of taking part, such as travel or childcare. Reasonable travel expenses for any visits additional to normal care will be reimbursed on production of receipts, or a mileage allowance provided as appropriate. Travel on public transport should be by standard/economy class and taxis or mini cabs may be permitted for short and infrequent journeys. Reasonable parking charges, road tolls and congestion charges will be reimbursed. Payments will be made via bank transfer.

For Part One of the study, we do not anticipate that you will need to make any additional visits to the hospital that you would not be making anyway.

For Part Two of the study if you take part in either a longer interview or a focus group we will thank you for your time at a rate of £20/hour (typical length of participation anticipated to be 2 hours). This will be in the form of vouchers which can be redeemed in a wide range of high street shops. This will be in addition to travel or childcare expenses.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the sponsor for this study. It is the data controller and is responsible for looking after your information and using it properly.

We will be using information from you and your medical records in order to undertake this study and will use the minimum personally-identifiable information possible.

We will store any research documents with personal information, such as consent forms, securely at the University of Oxford for 10 years after the end of the study, for 3 years as part of the research record.
Your name and address will be stored in order to send out vouchers after your participation has ended. Your bank details will be stored for 7 years in accordance with University of Oxford financial policy.
We will keep any other identifiable information about you for a maximum of 3 years after the study has finished.

The [local NHS Trust] will use your name and contact details in order to contact you about the research study and to oversee the quality of the study. They will keep identifiable information about you from this study for a maximum of 3 years after the study has finished.

If you agree to your details being held to be contacted regarding future research, we will retain a copy of your consent form securely until such time as your details are removed from our database. We will keep the consent form and your details separate from one another and any research data.

An independent transcription service will be used to transcribe the audio recordings from the research into text. The transcription company will be sent audio recordings with no personal identifier attached. The transcription company will not have access to any of your personal data. To ensure the confidentiality and anonymity of participation, there will be a non-disclosure agreement in place with the transcription company in line with the University of Oxford guidelines. Transfer of electronic files (audio, text) between the research team and transcription service takes place via a secure electronic drop-off service. The transcription service will destroy their copy of the audio recording as soon as transcription has been completed.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at:

https://compliance.web.ox.ac.uk/individual-rights

You can find out more about how we use your information by contacting Dr Sophie Bertaud (email sophie.bertaud@ethox.ox.ac.uk).

What will happen if I don't want to carry on with the study?

You do not have to take part in this study, and this will not affect any care you or your family receive currently or in the future.
Participation is voluntary and you may change your mind at any stage. You are free to withdraw from the study at any time and do not have to give a reason for withdrawing. Withdrawing from the study will not affect any care that you or your family receive.

If you decide you no longer wish to be involved the research team will discuss the following options with you and you may choose to:

- Stop active involvement and all follow up: in which case no further data would be collected after withdrawal but you would allow us to use any research data collected up until that point in the study analysis.
- Withdraw your consent and withdraw from the study completely: in which case any research data (such as consultations and interview recordings) will be withdrawn and, where possible, will not be used in the final study analysis.

If withdrawal of consent occurs late in the study at a point where the thematic analysis has already taken place it may not be possible to fully remove all of your data from the analysis. However, in this scenario, any quotes from you will be removed from study reports and publications.

If you contribute to a focus group and later withdraw your consent, then the audio-recordings from the focus group where you were present may still be used. However, in this scenario, any quotes from you will be removed from study reports and publications.

What will happen to the results of this study?

The data from the study recordings, interviews and focus groups will be analysed together and the results will be published in a respected medical journal. We may also present the results at a medical conference and share our findings with relevant charities and support

organisations. Some of the research being undertaken will also contribute to the fulfilment of a doctoral thesis at the University of Oxford.

You will not be identified in any report or publication about the study. We may use quotes from things that you have said during the interview but we will not identify you personally in any way.

If you are interested in the results of the study, and you consent to us contacting you, we will make sure that a summary of the findings and any publications that arise from the study are sent to you via email.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated, or how your information is handled during the course of this study, you should contact Dr Sophie Bertaud (email sophie.bertaud@ethox.ox.ac.uk) or you may contact the University of Oxford Research Governance, Ethics & Assurance(RGEA) office on 01865 616480, or the Director of RGEA, email rgea.complaints@admin.ox.ac.uk.

How have patients and the public been involved in this study?

Parents who have been through the experience of receiving a serious diagnosis in their baby during pregnancy have been involved in the design of this study from the beginning and helped to develop the research topic and what research questions should be asked. We have also had involvement from two charities: ARC (Antenatal Results & Choices) and SOFT UK (Support Organisation for Trisomy 13/18). They have reviewed the consent forms, information sheets and interview topic guides and will continue to be involved in the study.

Who is organising and funding the study?

The research has been organised by a group of researchers at the University of Oxford in collaboration with doctors at the four hospitals who are taking part in the study. The project is being undertaken as part of a PhD. The University of Oxford is the sponsor for this study. The study is funded by the Wellcome Trust as part of a Research Fellowship for Health Professionals. The research team will not receive any personal financial rewards for including you in this study.

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 participants' interests. This study has been reviewed and approved by the London - Camden & Kings Cross Research Ethics Committee (reference 23/LO/1008).

Participation in future research:

In the consent form for this study, we will ask you whether you are happy to be approached in the future about further research projects related to this one. If you agree, all contact will come from the research team of this study in the first instance and agreeing to be contacted does not oblige you to take part in future research. You can request to be removed from this register at any time you wish.

Your contact details would be held securely, separately from this study, at the University of Oxford and would only be accessible by authorised individuals from the research team.

Further information and contact details:

The research team will be happy to answer any questions you have about this study. You can contact them on the email addresses below (and arrange a telephone call if desired) or speak to them again when you come to the hospital.

Please contact:

Dr Sophie Bertaud, lead researcher	Email: sophie.bertaud@ethox.ox.ac.uk
Professor Dominic Wilkinson, research supervisor	Email: dominic.wilkinson@philosophy.ox.ac.uk

Thank you for taking the time to read this information sheet and for considering participating in this research study.