Participant Information Sheet for Patients

Research study title: A qualitative study exploring service users' and healthcare professionals' opinions of electronic maternity notes

Introduction

We would like to invite you to take part in our research study. Before you decide, we would like you to understand why the research is being done and what it would involve for you. The purpose of this information sheet is to explain to you exactly what is involved in taking part in the research study and to give you the opportunity to consider whether you would like to take part or not. Please take the time to read it carefully, and contact us if there is anything that is not clear or if you would like more information.

Please keep your copy of this Participant Information Sheet for your own reference.

What is the purpose of this research study?

This research study aims to understand what healthcare professionals (midwives and doctors specialising in pregnancy) and patients think about electronic maternity notes and how they are used. Some maternity notes have prompts to help clinicians deliver care (Clinical decision support)

Your insights will help improve electronic maternity notes design and implementation, potentially improving patient care and safety in pregnancy and childbirth.

Why have I been invited to take part?

You have been invited because:

- because you are having your baby in a hospital which uses electronic maternity notes

- because you have recently had a baby in a hospital which uses electronic maternity notes

Your experience and opinions are valuable to our research.

What does taking part in involve?

If you agree to participate, you will be asked to:

- Complete a consent form (this gives us permission to interview you and you will have the option of doing this on paper, electronically or to record an audio confirming consent)
- Complete a brief online survey about yourself (5 minutes) via an online link. This is to allow us to understand the type of experience shared between groups of people (example, experiences of first time mums compared with women who have had a pregnancy before)
- Participate in a 40-60 minute online or phone interview to discuss what you think about electronic maternity notes and decision support algorithms in more detail.
- This will be recorded and transcribed (make a written copy of the spoken words) so that the interviewer can refresh their memory about items discussed.
- Optionally, receive feedback about the results we have collated from interviews with other healthcare professionals, people who are currently pregnant or recently given birth to

If you agree to take part, we will then ask you to sign a consent form. You are free to withdraw within two weeks of the interview taking place without giving a reason and your data will be deleted. After this time, we will have started analysing the data and will not be able to separate and remove your information.

We will not access your electronic maternity notes at any point in this study.

What happens to the audio recordings

The recordings will be transcribed by a professional transcribing company. After this, the recording itself will be deleted. All audio recordings will be anonymised with a unique research identification number so that you cannot be identified from it. If you do not wish for your interview to be audio recorded the researcher will take notes during the interview.

What happens to my data?

Consenting to this work also means that pseudo-anonymised data can be shared. This means that the researchers will be able to hold and share detail about your background (for example your ethnicity) that are linked to the interviews for example, but no one will be able to identify you from the interview specifically. If you consent to take part in this research, you are also saying that you are happy for pseudoanonymised data to be shared with other researchers.

Do I have to take part?

Participation in this research study is entirely voluntary. It is up to you to decide whether to take part and whether you would like to be interviewed.

If you decide to take part, you can still drop out at any time without giving a reason by contacting one of the research team. If you choose not to take part, your health and social care will not be affected in anyway.

What are the possible benefits of taking part?

The information that you provide will help us to decide what makes a good electronic maternity notes system with decision support. This will be used to help health care professionals and patients to improve safety in maternity, but is unlikely to benefit you directly.

What are the possible disadvantages involved in taking part in the research study?

This research study is an interview that will take up some of your time. If some questions make you feel uncomfortable, you do not need to answer it. You can pause or stop the interview completely at any point if you wish to do so. If you were to become upset when talking about your personal experiences in maternity, we will direct you to local support services and if appropriate, suggest that you contact your healthcare provider. Your midwives and doctors will treat you just the same if you do or don't take part.

Expenses and payments

You will receive a £25 voucher as a thank you for your time and taking part in the research study.

Will my taking part be kept confidential?

All the information you provide will be kept confidential to ensure your privacy.

We will need to use information from you for this research project. This information will include your name and contact details. People will use this information to do the research or to check your records to make sure that the research is being carried out correctly. Only people who need to know who you are will be able to see your name and contact details. Your data will be given a unique study identification number instead.

We will keep all information about you safe and secure. We will write our reports in a way that no-one can work out that you took part in the research study. Quotes from your interview may be used in publications but no names or identifiable information will be used alongside them. You can, if you wish, specify if certain quotes cannot be mentioned.

All data will be securely stored on University servers and only accessible to the research team, on password-protected computers. At the end of the research study, research data including paper consent forms and verbal consent audio recordings will be held in line with the University data management policy for 10 years.

If you disclose something during the interview that has implications for the safety or wellbeing of yourself or others, the researcher would inform you of the need for them to discuss this with the lead investigator of the research study, Dr Patricia Apenteng. Information would only be passed to relevant agencies if there is a legal requirement to do so.

What are my choices about how my information is used?

You can stop being part of the research study at any time without giving a reason. Your data will be deleted if you withdraw before the data is analysed. All the data is anonymised before it is analysed, therefore it will not be possible to destroy your data once the analysis has commenced.

Who is organising/funding and reviewing the research study?

The research study is being conducted by the University of Birmingham, and is sponsored and insured by the University of Birmingham. It is funded by the NIHR Knowledge Transfer Programme. The lead researcher is Dr Patricia Apenteng.

This research study has been reviewed and given favourable opinion by the University of Birmingham Research Ethics Service, ref number ERN_4225.

What will happen to the findings from the study?

The findings of the research study will be used to inform healthcare delivery. The findings will also be published in academic papers and presented at conferences. A summary of the findings will be distributed to those who participate in the research study if they wish.

I would like to take part. What should I do?

If you would like to take part, please contact the research team (details on next page).

Where can I find out more about how my information is used?

You can find out more about how we use your information

- by asking one of the research team
- by sending an email to dataprotection@contacts.bham.ac.uk

Who should I contact if I want further information?

If you have any concerns or questions about any aspect of the research study, please contact the lead researcher:

Dr Patricia Apenteng
Department of Applied Health Sciences
University of Birmingham, B15 2TT
Email: p.n.k.apenteng@bham.ac.uk
Tel: 0121 4148 666
Mobile 07771736268

Who should I contact if there is a problem or I have a complaint?

We think that it is unlikely that anything could go wrong in this research study. However, any complaint about the way you have been dealt with during the research study or any possible harm you might have suffered will be addressed. Please address your complaint to the sponsor below:

Email: researchgovernance@contacts.bham.ac.uk Tel. 0121 414 7618

Source of support

If you are struggling to cope emotionally with pregnancy or a new baby, please contact MumsAid, a charity providing pregnant women and new mums with specialist counselling and therapeutic support.

Telephone 07758 763908

Email info@mums-aid.org

Thank you for taking the time to read this Participant Information Sheet.