Patient Information Sheet
QUIDS - Quantitative Fibronectin to help Decision-making in women with Symptoms of Preterm Labour. Determining decisional requirements focus group

We are researchers from the University of Manchester, collaborating with Birmingham Women's Hospital, Liverpool Women's Hospital and the University of Edinburgh who are interested in women's views on care when labour starts early. We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Talk to others about the study if you wish. Ask us if there is anything that is not clear

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project 14/32/01). The views and opinions are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR or the Department of Health.

or if you would like more information. Take time to decide whether or not you wish to take part.

CONTENTS

What is QUIDS qualitative research?

Preterm labour is when labour starts before 37 weeks of pregnancy. Diagnosing preterm labour is difficult. Most women who have signs of preterm labour are still pregnant a week later. This means that some women may receive treatment or care that is not helpful to them if they do not give birth following signs of preterm labour. A test called quantitative fetal Fibronectin may help to improve the diagnosis of preterm labour.

We are running focus groups where people will discuss what they think are important questions for doctors, midwives and baby doctors to answer for women who have the symptoms of preterm labour.

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project 14/32/01). The views and opinions are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR or the Department of Health.

This information will be used to develop a tool that will help doctors interpret tests such as quantitative fetal Fibronectin and ultrasound scans. The tool will be used by doctors who are caring for women with signs of preterm labour to aid them in making decisions and recommendations about care.

Why have I been invited?
You have been asked to take part either because you have personal experience of preterm birth, you have experienced going into labour early, or you are currently pregnant and at risk of preterm birth.

Do I have to take part?
It is entirely your choice if you want to take part in this research or not. If you decide to take part we will then ask you to sign a consent form to show you have agreed. You are free to withdraw at any time, without giving a reason. However, once you have taken part in the focus group it may not be possible to remove your contribution to the discussion from the audio recording and transcript. All other data, including demographic information, can be removed until it is used for the development of the tool. Whether you take part or not will not affect the standard of care you receive now or in the future.

What if there is a problem?
If you are worried about any part of this study or have a minor complaint, you should ask to speak to the researchers who will do their best to answer your questions (Dr Helen White, 0161 306 7844 or helen.white@manchester.ac.uk and then enter the PI for the site).

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project 14/32/01). The views and opinions are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR or the Department of Health.

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:
The research Governance and Integrity Manager
Research Office, Christie Building
University of Manchester
Oxford Road
Manchester M13 9PL
Email: research.complaints@manchester.ac.uk
Telephone: 0161 275 2674 or 275 2046

You can also complain formally through the NHS Complaints Procedure.

The hospital Patient Advice and Liaison Service (PALS) can give you information about how to do this.
PALS are located in [insert local details].
Email: [insert local details]
Patient Services Department – Tel: [insert local details]

What will happen to me if I take part?
If you agree to take part, you will be invited to attend a focus group of 4–8 people. This will take place in a private room in the hospital.

When you attend the focus group the researcher will explain the purpose of the study and how the group discussion will be conducted. The researcher will explain that discussions will be tape recorded with your permission and another member of the research team will make notes so that all the important information is accurately obtained.

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project 14/32/01). The views and opinions are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR or the Department of Health.

You will be given a study number so that all information about you and any comments made by you will not identify you by name and will be kept strictly confidential. It is also important that participants respect the confidentiality of other participants by not disclosing personal information outside of the focus group.

Before the focus group takes place you will be asked to give your informed written consent by signing a consent form. You will be given a copy to keep, a copy will be kept by the researcher and a further copy placed in your medical notes. You will be given the opportunity to ask questions.

You will then be invited to take part in the discussion to explore your views about important questions for doctors to answer for women at risk of preterm delivery in order to provide the most appropriate care for that woman and her baby. The researcher will facilitate the focus group discussion by asking questions that you will talk about with the other participants. The discussion will last about an hour and a half.

If you decide you would like to take part but are unable to attend the focus group, the researchers may ask if you would be happy for them to interview you over the telephone.

Expenses and Reimbursements

Every effort will be made to arrange focus group discussions on a day when you will already be attending clinic to avoid additional travel expense or inconvenience. However, if this is not possible you will be reimbursed for out of pocket expenses.

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project 14/32/01). The views and opinions are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR or the Department of Health.

What are the possible disadvantages and risks of taking part?

There are no disadvantages or risks to your health in taking part, it will, however, take up some of your time. You may find it distressing to talk about preterm birth, even if you don't expect to. If you do become distressed we will ask you whether you would like to leave the focus group with one of the researchers. We have informed the local Supervisors of Midwives team about this study and will provide you with their contact details and also details of local counselling services that you can access.

What are the possible benefits of taking part?

There are no direct benefits for you for taking part in this study, other than an opportunity to voice your views and opinions. However by taking part in this research you will help provide information that will inform the information given to women who may experience preterm labour in the future.

If I take part in this research will it be confidential?

Yes. The research team will treat all information confidentially and all records will be kept secure. The team is very experienced and is bound by the laws and protocols surrounding confidentiality and data protection. The focus group conversation will be audio recorded and then written out in full (transcribed). At this point any information that can be used to identify an individual will be removed. The voice recording will be destroyed once the analysis has taken place. The written document will be stored on a password protected University computer in a locked room.

Recordings from the focus groups will be transferred to one of the University of Manchester's approved suppliers

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project 14/32/01). The views and opinions are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR or the Department of Health.

to be transcribed. The company is bound by the laws and protocols of confidentiality. The recordings and transcripts will be encrypted during transfer to ensure that no unauthorised individuals can access them.

The only time information with your name on it may be seen by people that are not part of the research team is if the study is looked at by the University of Manchester, regulatory authorities or the NHS Trust. The study is checked to make sure it is being carried out as planned, which involves looking at all the data collected. Any of the individuals authorised to carry out the checks have a duty to keep all the information confidential.

Publications from this study will contain direct quotes from the focus groups and brief details of individuals' experience of preterm labour (e.g. experienced preterm birth). Although the quotes will not have your name or any other information that could directly identify you, it is possible that you may be identifiable to people that are already aware of your experience.

The research data will be kept for 15 years and then destroyed, which is good practice for any research related to public health. During this time data will be held securely and only the research investigators, the University of Manchester, regulatory authorities or the NHS Trust may have access. Storage and destruction of the data will follow the strict data protection protocols of the University of Manchester.

Who is organising and funding the research?
The research is being funded by the National Institute of Health Research, Health Technology Assessment

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project 14/32/01). The views and opinions are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR or the Department of Health.

Programme. The research is being sponsored (organised) by the University of Manchester.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people called a Research Ethics Committee. This Committee looks carefully at what participants are being asked to do and whether it is reasonable. They are there to protect your safety, rights, wellbeing and dignity and no research project in the NHS can start without its approval. This study has been reviewed and approved by NRES Committee enter details of ethics committee review here

If you have any questions or concerns about the project please telephone or email the researchers who will do their best to answer your questions.

Details of researchers

Chief Investigator: Dr Helen White, 0161 306 7844, helen.white@manchester.ac.uk

Birmingham Women's Hospital NHS Foundation Trust
Principle Investigator: [insert site specific PI details here]

Thank you for reading this and considering taking part in the study.

This study is being funded by the National Institute for Health Research (NIHR), Health Technology Assessment (HTA) Programme (Project 14/32/01). The views and opinions are those of the authors and do not necessarily reflect those of the HTA Programme, NIHR or the Department of Health.