Participant Information
Leaflet- Focus groups

Co-designing and piloting educational materials with patients and healthcare providers following a post partum haemorrhage

INTRODUCTION

You are being invited to take part in a research study. Before you decide whether to take part it is important for you to understand why we are doing this research and what is involved. Please take time to read this leaflet, and if you want to, discuss it with your colleagues, family, or friends. Please feel free to ask us if anything is not clear, or if you would like more information. Thank you for taking the time to read this.

ABOUT THE STUDY

We invite you to participate in this project that aims to co-design and pilot educational materials with patients and healthcare providers following a postpartum haemorrhage (PPH) for a patient. This study is part of a larger project, which has the overall aim of standardising the management of PPH in maternity units in Ireland. As part of this process, we are interested in ensuring women are informed about PPH before, during and after the event.

DO I HAVE TO TAKE PART?

No, participation is completely voluntary. You are free to refrain from participation in this study or to withdraw from the study at any time.

WHAT WILL HAPPEN TO ME IF I TAKE PART?

Participation involves participating in focus groups and feedback/design sessions with the project manager. The focus group will address the area of how best to communicate this information. You will be asked to participate in one focus group. The focus groups will take place online on Microsoft Teams there will be – 10 participants and will be recorded. The focus group will include members of the PPHQII steering committee and local champions. The PPHQII steering committee is a group of obstetrician, midwives, anaesthetist, haematologist, trainers, and risk managers. Local champions are based in each maternity unit and a midwives, nurses, and obstetricians. The focus group may involve sketching, storyboarding and discussion.

The areas below will be examined

- Postpartum haemorrhage (PPH) is defined as excessive bleeding after childbirth. – do we need to define excessive bleeding.
- How do we convey how serious a PPH is?
- How do we describe the Describe the common causes of PPH, such as uterine atony (lack of uterine muscle contraction), retained placenta, or trauma during childbirth.
- Discuss risk factors that may increase the chances of PPH, including previous PPH, multiple pregnancies, prolonged labor, and certain medical conditions.
- List the signs and symptoms of PPH, such as heavy or continuous bleeding, passing large blood clots, feeling lightheaded or dizzy, rapid heart rate, and pale skin.
- What happens during a PPH do we need to explain the diagnostic process, which may include physical examination, blood tests, and ultrasound.
- What are the treatments options and how will they be explained? Describe the various treatment options for PPH, including medication to stimulate uterine contractions, manual removal of placenta, blood transfusion, and, in severe cases, surgery (such as a hysterectomy).
- Discuss preventive measures that can help reduce the risk of PPH, such as attending regular check-ups, receiving antenatal care, and discussing any concerns with healthcare providers.
- When to Seek Medical Help: provide clear instructions on when to seek immediate medical assistance, such as heavy or uncontrollable bleeding, feeling faint or weak, or if the patient is unable to manage the bleeding.
- Recovery and Follow-up Care: Briefly outline the recovery process after experiencing PPH and the importance of rest and proper nutrition.

You will not be asked to give any personal information. We do ask you to consent to participation and sign a consent form. The data from this study will be stored on a password-encrypted computer connected to the UCC server. The responses from the focus groups will be analysed by the study investigators.

BENEFITS, RISKS and SAFETY

The findings from this study will inform the development and implementation of standardised patient information. This is in line with recommendations from the National Perinatal Epidemiology Centre (NPEC) in recent years.

If any of the questions or any of your answers cause you concern or worry please don't hesitate to contact the research team either Joye McKernan or Professor Richard Greene at 021 420 5053 or email joye.mckernan@ucc.ie and r.greene@ucc.ie in confidence. Also please don't hesitate to view supports on https://www.patientadvocacyservice.ie/

WHAT HAPPENS TO THE INFORMATION COLLECTED?

The study data will solely be accessible to the study research team. All information collected from you will be kept private and confidential and will be stored on the UCC server in a password-encrypted file. You are not asked to submit any identifiable information. The consent forms and data will be stored securely at Cork University Maternity Hospital in a locked filing cabinet in the NPEC offices.

WHAT HAPPENS TO THE INFORMATION FROM THE STUDY?

Data which you provide to us will be treated with the highest standards of security and confidentiality, in accordance with Irish and European Data Protection legislation.

The General Data Protection Regulation allows us to process your data because you have provided your consent. Your personal information will be stored securely at Cork University Maternity Hospital.

INSURANCE

This study is covered by the Clinical Indemnity Scheme, which is operated by the State Claims Agency for staff working in the health services.

WHAT WILL HAPPEN TO THE RESULTS OF THIS RESEARCH?

Results of this research will be used to develop a toolkit for use by maternity unit staff and will inform future projects. The results may be published in medical journals and presented at professional or scientific meetings.

FOR HOW LONG WILL THIS DATA BE KEPT?

As per research procedures we store your anonymous de-identified data for future related research for a period of 25 years. Further research analyses may be performed but this will be

subject to further ethics approval if applicable. If you have any complaints in connection with our processing of data, you can contact UCC's Information Compliance Manager:
Office of Corporate & Legal Affairs
University College Cork
Western Road, Cork

E: foi@ucc.ie Tel: +353 21 4903949

You also have the right to lodge a complaint with the Data Protection Commission. Details of how to lodge a complaint can be found on the Data Protection Commission's website (www.dataprotection.ie), or by telephoning 1890 252 231.

WHO HAS REVIEWED THIS STUDY?

All research in Ireland is carefully reviewed by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing, and dignity. This study has been approved by the Clinical Research Ethics Committee of the Cork Teaching Hospitals (CREC).

WHAT WILL HAPPEN IF I DO NOT WISH TO CARRY ON IN THIS STUDY?

You are free to withdraw at any time, for any reason and without giving a reason. This will not affect your employment.

WHERE CAN I GET MORE INFORMATION?

If you have any further questions regarding this study, please contact the Study Investigator: Dr Joye McKernan, telephone: 021 4920503, email: pphqii@ucc.ie
https://www.ucc.ie/en/npec/researchprojects/postpartumhaemorrhagequalityimprovementinitiative/

Consent Form

Thank you for reading the participant leaflet for the project "Co-designing and piloting educational materials with patients and healthcare providers following a postpartum haemorrhage(PPH)" Your participation in this research project is entirely voluntary, and you have the right to withdraw at any time without penalty.

Title of Research Project: "Co-designing and piloting educational materials with patients and healthcare providers following a PPH."
Principal Investigator: Professor Richard Greene

Purpose of the Study: The purpose of this research project is to co-design, develop and implement educational material following a PPH.

Procedures: If you agree to participate, you will be asked to participate in a focus group and two feedback sessions.

Risks and Benefits: There are no direct benefits to you as a participant, but your participation will contribute to advancing knowledge in the field of postpartum haemorrhage.

Confidentiality: All information collected during this research project will be kept strictly confidential. Your personal information will be anonymized and stored securely. Only authorized researchers will have access to the data, and it will be used solely for the purposes of this study. Any research findings or publications resulting from this study will not contain any personally identifiable information.

Voluntary Participation and Withdrawal: Participation in this research project is entirely voluntary, and you have the right to withdraw your consent at any time without penalty.

Contact Information: If you have any questions or concerns about this research project, please feel free to contact Professor Richard Greene or Dr Joye McKernan at r.greene@ucc.ie or joye.mckernan@ucc.ie 021 4205053.

If you agree to participate in this research project, please sign and date this consent form below. By signing this form, you acknowledge that you have read and understood the information provided in this consent form, and you voluntarily agree to participate in the study.

Participant's Signature: _____
Date: _____

Printed Name: _____

Thank you for considering participation in this research project. Your contribution is greatly appreciated.