Process Evaluation Participant Information Sheet

Study Title

Process evaluation (PE) of the implementation and delivery of the SANDWICH trial (Sedation AND Weaning in CHildren)

Dear Colleague,

You are being invited to take part in the Process Evaluation (PE) of the SANDWICH trial. The PE will evaluate the process of implementing and delivering the SANDWICH intervention into the paediatric intensive care unit (PICU) setting. Please take time to read the following information before deciding to participate and ask if you would like more information.

What is the purpose of the PE?

The SANDWICH intervention includes a number of component activities. These include, for example, the collaborative ward rounds utilising information about COMFORT scores, sedation and ventilation, and the daily screen for readiness to undertake a spontaneous breathing trial. It is possible that these activities may be understood and delivered differently in the multiple PICUs taking part in the trial.

The purpose of the PE is to explore the process of delivering the intervention across all participating PICU sites to answer the questions 'Does it work?', 'How does it work?' and 'Are all the components necessary?' Additionally, the PE will deliver important information about barriers and facilitators to implementing and delivering this type of intervention. This may help to explain trial outcomes, and will also signpost factors that require attention if, post-trial, the intervention is to be disseminated to other PICUs and sustained in practice.

Why have I been chosen?

You are invited to participate because you work as part of a team involved in the SANDWICH trial. This means you have important knowledge and experiences relating to the process of sedation and weaning in the PICU that will help us understand the impact of the SANDWICH intervention.

What does taking part involve?

Taking part will involve participating in either an individual or focus group interview facilitated by the PE researcher (Joanne Jordan). Individual interviews will last between 30-45 minutes and focus group interviews (usually involving 5-8 participants) will last between 60-90 minutes. Interviews will be audio-recorded.

Do I have to take part?

Participation is entirely voluntary and is completely separate from your employment. If you participate, you can withdraw at any time without providing a reason. If you withdraw, we will not use data collected from you without your consent. If we collected data during a group interview, we will ask your permission to use the data. However, if you request, we will delete and not use your data from the transcript, although we cannot delete it from the recording of a group interview.

What happens next?

If you are willing to take part in the PE, your contact details will be passed to the PE researcher who will organize the individual or focus group interview for a mutually agreed date and time.

What are the potential benefits and risks of taking part?

Information you provide will make a positive contribution to help us more fully understand the issues that have contributed to the effectiveness of the SANDWICH intervention. If the trial results show benefit, information gathered from the PE will inform how best to disseminate, adopt and sustain these beneficial results in clinical practice. There are no anticipated risks to participating in the PE.

Will my information be kept confidential?

If you consent to participate, information collected from you will be handled and stored in strict confidence in accordance with the Data Protection Act (2018), and no traceable personal information will be published. Audio-recorded interviews may be transcribed by an external third party and will be stored securely and confidentially. Audio files on the Dictaphone will be erased. Audio files will be transcribed in full, anonymised and saved to a password-protected computer. Each participant will have a unique identification number. Only the research team will have access to this data.

What will happen to the results of the PE?

We will disseminate findings from the PE and the trial in reports, journal articles and conferences to help explain 'Does it work?', 'How does it work?' and 'Are all the components necessary?'

Who is organising this study?

The SANDWICH study, including the PE, is funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) Programme. The study has been ethically approved by East Midlands – Nottingham 1 Research Ethics Committee.

Complaints Procedure

If you have a concern about any aspect of this study, you can speak with the Chief Investigator (details below). If you remain unhappy and wish to make a formal complaint you may do so by contacting the Research Governance Team at Queen's University Belfast (Telephone: 028 9097 2529; Email: researchgovernance@qub.ac.uk).

Further information and contact details

Thank you for taking the time to read this information sheet. We hope it has provided you with all the information you need in order to decide whether or not to participate. Should you require any further information or have any queries please do not hesitate to contact:

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QUEEN'S UNIVERSITY BELFAST

NHS
National Institute for Health Research

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Transparency Statement

Queen's University Belfast is the sponsor for this study based in the United Kingdom. We will be using information from you in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. Queen's University Belfast will keep identifiable information about you for 5 years after the study has finished.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at:

http://www.qub.ac.uk/privacynotice/

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

This information will not identify you and will not be combined with other information in a way that could identify you. The information will only be used for the purpose of health and care research, and cannot be used to contact you or to affect your care. It will not be used to make decisions about future services available to you, such as insurance.