

## Transparency Statement

IRAS number 209448

Queen's University Belfast is the sponsor for this study based in the United Kingdom. We will be using information from your medical records in order to undertake this study and will act as joint data controller, with Belfast Health and Social Care Trust (BHSCT), for this study. This means that we are responsible for looking after your information and using it properly. Queen's University Belfast and BHSCT 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/>

[Site name] will collect information from your medical records for this research study in accordance with our instructions.

[Site name] will keep your name, NHS/HSC number and contact details confidential and will not pass this information to Queen's University Belfast or BHSCT. [Site name] will use this information as needed, to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Certain individuals from Queen's University Belfast, BHSCT and regulatory organisations may look at your medical and research records to check the accuracy of the research study. Queen's University Belfast and BHSCT will only receive information without any identifying information. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS/HSC number or contact details.

[Site name] will keep identifiable information about you from this study for 5 years after the study has finished.

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.

# We are involved in the SANDWICH trial



## *Study information Leaflet for families and carers of children admitted to paediatric intensive care*

If you would like to know more about SANDWICH you can:

Talk to the Doctors and Nurses caring for your child

or

Call the local research nurse on <XXXX XXX XXXX>

Visit our website at <http://www.nictu.hscni.net/sandwich-trial/>

### Chief Investigator

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## What is the SANDWICH trial?

SANDWICH is a study into the advantages and disadvantages of introducing a new coordinated approach between nurses and doctors (with greater involvement of nurses) for getting children in paediatric intensive care units (PICUs) off the ventilator (known as weaning) as soon as they no longer need it.

## Why is SANDWICH important?

Mechanical ventilation is often necessary to save lives, but is associated with increased risk the longer they remain on the ventilator. Therefore getting children off the ventilator as soon as they are able to breathe for themselves is important. This study is being done to find out if the new approach:

- reduces the length of time children spend on a ventilator without causing any increased risk
- reduces the time children spend in a PICU and the hospital
- is cost effective in the NHS; and
- can easily be adopted by staff delivering care

## What will happen?

This study involves approximately 15 PICUs in the UK. All units will start the study using their current usual care practices. Each month, the staff at one PICU will be trained in the new approach and will continue to use the new approach until the end of the study. By the end of the study, all staff in all PICUs will be using the new approach.

## What information will be collected?

In each PICU, we will collect information on a child's medical condition, the steps that are taken to assess when they are ready to come off the ventilator, their length of time on the ventilator, their length of stay in the PICU, and the costs and issues associated with whatever approach is adopted.

PICANet is a system that routinely collects information on all children admitted to a PICU. SANDWICH will use some of this information. Any identifying information will be removed before the PICU sends the information to the centre helping to coordinate the study.

Some data recorded in your child's medical notes will also be entered into a database held by the centre helping to coordinate the study. All information we collect about

your child will be anonymized and their name or other personal details will *not* be used.

All information we collect will be kept strictly confidential.

## Will the information be safe?

All data will be securely transmitted and stored in a safe way. The data will *not* contain any identifiable information and no-one can see the information, unless it is their job to do so. There is no way at all that your child can be identified in any of our reports.

## How will the information be used?

We will compare the information collected during the usual-care period with the new-approach period. If the latter is found to be easier for staff, and more importantly, better for children, we intend to develop guidelines that will help other PICUs adopt the new approach when they need to wean children off mechanical ventilators.

## Does my child have to be included?

No, you do not have to agree to us collecting your child's information for the study. You can tell the nurse or doctor that you want us to stop collecting information at any time: this will be recorded in your child's medical notes.

If study information has already been collected, it will be removed from the study database and no information about your child will be included in this research.

This will not affect the care your child receives in this or any other hospital.

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