



INFORMATION ABOUT AN INTERVIEW & OBSERVATIONAL RESEARCH STUDY

Partnership between families and professionals: Managing risks of infection in children with invasive devices

WHAT IS THE STUDY ABOUT?

Children with invasive devices are at risk of getting device-related infections. This includes devices like central lines, portacaths, gastrostomies, tracheostomies, & dialysis catheters. Families and community services work together to look after the device. A team at the University of Leicester are doing an interview study of children with devices and their parents to find out how they look after the device, and what challenges there are to keeping a device free from infection.

To go with the interviews, we are observing what everyday life is like with a device, and seeing what challenges come up. We are also interviewing staff who are involved in looking after children with invasive devices to find out what they think.

Before you decide whether you would like to take part in the study, it is important that you understand why this research is being done, and what it would mean for you and your family.

Please read this information sheet carefully, and discuss it with others if you wish to do so. If anything is unclear, or you would like more information, then please ask us. Take your time to think about the information, and to decide whether you wish to take part.

WHY AM I BEING ASKED TO TAKE PART?

You have been asked to take part because you have a child with an invasive device. We want to know about you and your child's experiences:

- What you think about managing the risks of infection?
- How to help families and professionals work together to reduce infections.

DO I HAVE TO TAKE PART?

No, it is entirely up to you whether you choose to take part or not. You do not have to decide now. If after going through the information leaflet you still have questions about the study, then contact Carmen Soto, and she will discuss the study with you.

If you agree for your child to take part in this study, we will check with them that this is OK before we begin. We have included an information leaflet to help them understand the research.

If you decide you take part, you can change your mind about the study at any time, even after we have finished the interviews. If you decide not to take part in this study, this will not affect the care that your child receives.

WHAT WILL HAPPEN TO THE RESULTS OF THE STUDY?

The results of this study will be fed back to support groups for families, and to organisations which work with children and families in the community.

The findings from this study will be published as part of Carmen's PhD thesis. The study will also be published in scientific journals.



Carmen Soto is a children's doctor.
She will be doing the interviews

WILL MY TAKING PART IN THE STUDY BE KEPT CONFIDENTIAL?

It is very important to us that the information you give during the interviews is kept confidential, and that you (or your child) cannot be linked with what is said. You or your child's name will not appear in the PhD, published medical papers, or the internet.

With your permission, the interviews will be recorded and typed out. Recordings will be labelled with a number only, and any personal details (like names) will be taken out. This makes sure that nobody can identify you or your child from what you say. We may use some quotations from your interview – if we do this, then we will change any details to make sure that you or your child cannot be identified.

In the observation part of the study, Carmen Soto will make notes about what she has seen. These won't have any personal details like names of people or places in them.

The only times when we cannot keep information confidential is if we think there is an immediate risk to someone, for example if there are concerns about child protection. We will also break confidentiality if there is a serious risk to the child's health because of something we find out during the study.

Sometimes, the study information might be looked at by inspectors to make sure that the study is being carried out properly, and these inspectors would have access to your information.

WHAT ARE THE POSSIBLE RISKS AND BENEFITS OF TAKING PART?

We do not think that there are any major risks to taking part in this study. You or your child may find some of the things we talk about upsetting. You can always refuse to answer any questions, or stop the interview if you wish.

There are no direct benefits to you from taking part in this study. However, the information that we get will help us to understand more about how families live with a device and what more can be done to improve this.

WHAT HAPPENS DURING THE INTERVIEW?

During the interview, Carmen will ask you to talk about how you manage the infection risks of an invasive device. She will come to your home or another convenient place to do the interviews, and these will probably last half an hour for children, and up to an hour for parents. She will ask you to sign a consent form for yourself before the interview starts, and a separate form for your child.

Some of the things she might ask are: your daily routine with the device; anything that the device stops you doing; the other people involved in looking after the device; and how you feel about device-related infections. Don't worry about giving the "right" answer. We want to know what you think, and your experiences are important to find out how families manage in real life.

Interviews with children will ask similar questions, but Carmen will try to make the interview fun. Carmen is a children's doctor and experienced with working with children. She will use toys and drawings to make the experience as enjoyable as possible.

WHAT HAPPENS DURING THE OBSERVATION PERIOD?

Carmen will also visit you to observe how the device is cared for, for example, watching the device being used or in daily care. This is so that we can understand more about daily life with the device. This will happen one or two times, and each time lasting no more than 3 hours. This could be either at your home, or out in the community (for example at school, or at the doctor's). She will arrange when and where this will happen with you in advance. After the visit, Carmen will write up some notes about what she has seen. These won't have any personal details like names or places in them.

WHAT WILL HAPPEN IF I AM INTERESTED IN TAKING PART?

If you are interested in taking part in this study, then please fill in the form in this pack and send it back in the envelope provided. You can contact us by e-mail or telephone if you prefer. You can also give your details to Carmen if you see her on the unit. Carmen will then get in touch with you to discuss the study further, and answer any questions you may have. You can also contact us by email or telephone if you prefer. You can decide after this if you want to go ahead with the study. If you decide to take part, we will then arrange a date and time to suit you when the interview(s) can take place.



**University of
Leicester**

WHAT IF THERE IS A PROBLEM?

If you have any concerns about this study, then please contact Carmen Soto, or Professor Mary Dixon-Woods (the project supervisor) in the first instance. We will do our best to answer any questions that you have. Our contact details are at the bottom of this page.

This study involves interviews therefore it is unlikely that you will be harmed. In the unlikely event that harm does occur that is due to someone's negligence, then you may have grounds for compensation against the University of Leicester. You may still have to pay your legal costs. The normal NHS complaints mechanisms will still be open to you.

WHO IS ORGANISING AND FUNDING THE RESEARCH?

The research is being organised and sponsored by the University of Leicester, and is being funded by the Wellcome Trust.

WHO HAS REVIEWED THE STUDY?

This study has been reviewed by a Research Ethics Committee (an independent group of people who review all studies in the NHS).

WHO ELSE IS INVOLVED IN THE STUDY?

The project is being supervised by Professor Mary Dixon-Woods, and Dr Carolyn Tarrant, from the Department of Health Sciences at the University of Leicester. It is funded by the Wellcome Trust.

WHO CAN I CONTACT FOR MORE INFORMATION?

Carmen Soto, PhD Student, Department of Health Sciences, University of Leicester, 22-28 Princess Road West, Leicester, LE1 6TP. Tel: 0116 252 5431. E-mail: ces39@le.ac.uk

Mary Dixon-Woods, Professor of Medical Sociology, Department of Health Sciences, University of Leicester, 22-28 Princess Road West, Leicester, LE1 6TP. Tel: 0116 252 7262. E-mail: md11@le.ac.uk

Carolyn Tarrant, Research Fellow and Senior Lecturer, Department of Health Sciences, University of Leicester, 22-28 Princess Road West, Leicester, LE1 6TP. Tel: 0116 252 3217. E-mail: ccp3@le.ac.uk