**Participant Information Sheet**

**COSTrans-MDRGNB: Core Outcome Set in infection prevention and control trials for prevention of Transmission of MDRGNB study**

**IRAS number: 305160**

We would like to invite you to take part in a research study to develop a Core Outcome Set in infection prevention and control. You have been invited because you or someone you know has had an encounter in hospital with infection prevention or you may have an interest in research in general. The research team is based in Leeds Teaching Hospitals Trust (LTHT) and University of Leeds. This study is funded by Healthcare Infection Society and part of a research degree at the University of Leeds.This research has also been reviewed by an NHS Research Ethics Committee. Before you decide whether to take part, please read this information sheet to find out why the research is being done and what it involves.

# Background of the study

Superbugs called multi drug resistant gram-negative bacteria (MDRGNB) are increasingly reported worldwide with increasing rates of hospital outbreaks. As a result, there is a great need to prevent the spread of MDRGNB in hospital using infection prevention (IP) procedures, like handwashing and single room isolation.

To help patients and doctors make decisions about IP procedures, we need evidence about what works best. Researchers look at the evidence and effects different IP procedures have on patients, by measuring an ‘outcome’. Unfortunately, when studies of IP are finished, we cannot compare or combine their results because they have used different outcomes. We would not be comparing like with like.

If all studies in IP for these superbugs used the same outcomes, they could all be compared and combined. When a set of outcomes has been agreed for a health condition, it’s called a ‘core outcome set’.

A core outcome set (COS) is an agreed standardised set of outcomes that should be measured and reported, as a minimum, in all clinical studies in specific areas of health or health care.

# Purpose of the study

The aim of our project is to develop a ‘core outcome set’ for IP studies for prevention of transmission of MDRGNB or superbugs.

Generating a list of core outcomes relevant to patients, carers and health professionals requires the use of a ‘consensus method’ involving these people. Consensus methods are surveys, meetings and discussions where the opinions of relevant experts are drawn together.

**Who is taking part?**

# Deciding which outcomes should be core requires a great deal of discussion. Core outcomes have to be relevant to patients, carers and health professionals. We would like our study to include:

* Patients, carers and healthy volunteers from the public
* Researchers
* Healthcare professionals

# What is involved?

Following reading this participant information leaflet we will wait to hear from you via the contact details below and answer any questions you may have. If you would like to participate, you will be consented to take part in the study (this can be done via telephone or face to face). We will then arrange at a time most convenient to you to an interview (online or via telephone or face-to-face). We will also ask you for an email or postal address and telephone number so that we can contact you with a link to complete the surveys.

Following the interview, we will then be inviting you to complete 3 surveys over a period of 3-4 months. These surveys involve you ranking the importance of a number of outcomes presented to you and will take about 15-20 minutes to complete.

We may also contact you to invite you to take part in the final discussion meeting and we will email/ post you a summary of the study findings at the end of the study. The final discussion meeting will involve all types of participants and will be where the final set of outcomes is decided upon. It will be held on Microsoft Teams. We will not keep your contact details after the end of the study and will not share them with anyone else.

# What would the interview involve?

The interview will be conducted over the telephone or a virtual platform like Microsoft teams or face to face (if in hospital) and will be arranged for a time convenient to you. We do not anticipate the interviews will take longer than 60 minutes, but this will depend on how much you have to tell us. We will ask you if we can audio record the interview so that we can listen without having to take notes. During the interview, we will talk about what outcomes are important to you, what your experiences of IPC are and what study type would be acceptable to you for interventions like single room isolation.

# What are the possible benefits of taking part?

We cannot guarantee you will directly benefit from this research yourself. However, we hope taking part in this project will result in useful conversations about infection prevention and control especially in the era of COVID-19. What we learn from this study will inform IP policy, and may benefit healthcare staff and their patients.

# What are the possible risks of taking part?

We do not anticipate there to be any significant risks in taking part in this study. The study is designed to not be too burdensome on your time. Your decision whether to take part, and any answers that you give, will be kept confidential. The interviewer is a medical doctor and is trained to respond appropriately to signs of distress in participants – appropriate actions will include pausing or if necessary ending the interview, and directing the participant to appropriate support.

# Do I have to take part?

You are free to choose whether to take part. You can take part in just some parts of the study if you prefer. If you do take part you are free to withdraw from the study at any time. If you do withdraw from the study, the COSTrans-MDRGNB study team will keep recordings of interviews, and surveys completed at that point.

# What next?

Please take some time to decide whether to take part and ask us any questions you have. We will be happy to discuss this further with you via email or telephone call. If you think you would like to take part then please read the additional information on the next pages about how we store and use your data.

**For any questions/ complaints about the study, interviews or survey please contact:**

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| --- | --- |
| Dr Razan Saman Leeds Teaching Hospitals NHS trustBeckett StreetLeeds LS7 9TFE: umrsa@leeds.ac.uk  | Dr Andrew KirbyMicrobiology department Old Medical School, Leeds General Infirmary LS1 3EXE: a.kirby@leeds.ac.uk |

If you wish to raise a concern, please contact the PALS team for advice in one of the following ways:

* Tel: 0113 2066261
* E-mail: patientexperience.leedsth@nhs.net

**Additional Information**

**Will my taking part in the study be kept confidential and how will my data be managed?**

Your participation in this project will be kept strictly confidential. We will store your consent forms and identifiable personal data securely and separate from other study documents. A study number will be allocated to you and any identifiable information will not be attached to any data collected in this study (surveys and interviews). If you take part in an interview the recording will be stored on university protected servers. We keep these recordings until the end of the study and then they are deleted (they will not be transcribed verbatim and the interviewer will make some notes following the interview). Anonymized data collected from your interviews may also be used in future research projects.

The University of Leeds 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. The University of Leeds will keep identifiable information about you until the end of the study period. 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.

Individuals from the University of Leeds and regulatory organisations may look at your research records to check the accuracy of the research study. The only people in the University of Leeds who will have access to information that identifies you will be the research team running the study or those auditing the data collection process. The people who analyze the information will not be able to identify you and will not be able to find out your name or contact details.

When you agree to take part in a research study, your data 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](https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-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.

You can find out more about how we use your information: <https://dataprotection.leeds.ac.uk/wp-content/uploads/sites/48/2019/02/Research-Privacy-Notice.pdf>. or Email: umrsa@leeds.ac.uk Tel: 07460850117

University data protection Officer can be contacted at: dpo@leeds.ac.uk