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Participant Information Leaflet for
Patients, the public, healthcare providers, researchers, academics

Study title
The development of a core outcome set for trials in surgical handover (SH-CORE)

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Introduction

You are being invited to take part in an online research study being carried out by the above investigators (researchers) from the Royal College of Surgeons in Ireland (RCSI), which is a medicine and health sciences university based in Dublin, Ireland.

Informed consent

Informed consent means that before you agree to participate in the study, the investigators (researchers) need to explain everything to you in way that you understand, which includes the potential risks, benefits, and what you can expect. You (the participant) must have adequate information to make a choice to participate, to have the capacity to understand the information provided, and to make a decision. You (the participant) must be able to give your consent freely and without coercion. This information is available for you below in this document.

Before you decide whether you wish to take part, you should read the information provided below carefully and, if you wish, discuss it with your family, friends and/or your healthcare provider. Take time to ask questions – don't feel rushed and don't feel under pressure to make a quick decision. If you have any questions, please feel free to contact us by emailing surgicalhandover@rcsi.com.

You should clearly understand the risks and benefits of taking part in this study so that you can make a decision that is right for you. You don't have to take part in this study. If you decide not to take part, it won't affect your future medical care. You can change your mind about taking part in this study any time that you like. Even if the study has started, you can still opt out. You do not have to provide a reason. If you do opt out, rest assured it will not affect your future medical care.

Study information

What is the goal of this research?

The goal of this study is to create a list of important **outcomes**, called a **"Core Outcome Set" (COS),** that researchers should use in future studies to improve handover between doctors working in surgery (surgical handover).

What is "Surgical Handover" and why does it matter?

Surgical handover is when doctors who work in surgery share important information about a patient's care with another doctor or team of doctors, usually when their work shift ends. For example, when Doctor A finishes their shift, they need to tell Doctor B everything important about the patients they have been taking care of. This sharing of information is called a **"handover".** During a hospital stay for surgery, these handovers happen a lot. They are very important because if the information is not shared correctly, mistakes can happen, and this can harm patients. For example, if the wrong information is given, or important details are left out, doctors may not know the right thing to do.

Many research studies have tried to find ways to make handovers better, but each study uses different methods and measures different **outcomes**. This makes it hard to compare the results and use them to make real changes in hospitals.

What is an "Outcome"?
When researchers do studies to improve something (like handover), they look at something called an **outcome** to see if the change worked. An **outcome** is the effect of a treatment, surgery, or other healthcare change. For example, if a study is looking at a new pain medicine, the outcome could be how much the patient's pain improved after taking the medicine. In the current study, we are focusing on outcomes related to making handovers better. For example, if handover communication improves, it might mean patients stay in the hospital for less time. In this case, the outcome being measured is how long a patient stayed in the hospital. Another example could be that fewer mistakes are made by doctors. In this case, the outcome being measured would be the number of mistakes made. These are just a couple of examples—there are many possible outcomes.

What is a "Core Outcome Set" (COS)?
A **COS** is a group of important outcomes that should always be measured and reported in research for a specific area of healthcare. At the end of this study, we will have a list of the most important outcomes that should be used in any research about improving handover between doctors working in surgery. This will help make sure future studies are measuring the right things and can actually show if new methods are working.

To create this list, we are asking different groups of people—patients, doctors, nurses, researchers, and the public—for their opinions. We will gather these opinions using a special kind of online survey called a **Delphi survey**.

Here is a video and additional information leaflet explaining what a **COS** is in further detail, developed by the COMET (Core Outcome Measures in Effectiveness Trials) initiative:

- https://www.youtube.com/watch?v=g1MZi2mzK1U
- http://www.comet-initiative.org/assets/downloads/COMET%20Plain%20Language%20Summary%20v4.pdf

What is a "Delphi Survey"?
A **Delphi survey** is a way to gather opinions from a group of people to reach an agreement on a topic. In this study, the Delphi survey will help figure out the most important outcomes to look at in studies which aim to improve surgical handover between doctors. You will be presented with different outcomes and asked to rate how important (or not important) you feel each one is. Below is an information leaflet with further general information on Delphi surveys, also developed by the COMET (Core Outcome Measures in Effectiveness Trials) initiative:
http://www.comet-initiative.org/assets/downloads/Delphi%20plain%20language%20summary%20for%20COMET%20website.pdf

Who is organising and funding this study?

This research is being carried out by Dr. Jessica Ryan MRCSI, and the other above-mentioned investigators (researchers) on behalf of RCSI. This research will form part of a higher degree (J Ryan, PhD). The research is grant-funded by the Bon Secours Hospital in Dublin via the RCSI's Strategic Academic Recruitment (StAR PhD) program and by the Medical Protection Society Foundation. The investigators (researchers) are not being paid to recruit people to this study.

Why am I being asked to take part?

You are being asked to take part in this study because your opinions are important to help us make sure that this Core Outcome Set includes a wide range of perspectives.

We are inviting the following people (i.e., stakeholders/participants) to take part in this study:

1. People who have previously been admitted to hospital under the care of a surgical team with at least one overnight stay, their caregivers, spouses/partners, or other family members
2. Health professionals who specialise in the area of surgery (for example, doctors, nurses, physiotherapists, etc)
3. People with an interest in carrying out research or teaching in the area of surgery or handover

How will this study be carried out?

This study will run from October 2024 to July 2025. If you agree to participate, you will need to sign a digital consent form on the website you used to access this information leaflet. After that, you can start the Delphi survey. You will get instructions on how to complete the survey when you access it. The survey will ask you to rate how important you feel different outcomes are for research in surgical handover.

We will try to make all the terms easy to understand, but if you still have questions, you can email us at surgicalhandover@rcsi.com for help. Your answers will be combined with the answers from others in your group. You will also have the chance to suggest any outcomes you think we missed. The survey will stay open until December 2024. During this time, you will be invited to return to the survey to see the combined anonymous results (ratings) from each group of people taking part. You can then choose to change your answers if you want.

We will use all the group ratings to create a smaller set of outcomes. We will then invite those who took part in the survey to attend an **optional** online meeting. During the meeting, we will review the outcomes and ask you to rate them again. This process will help us create a final set of outcomes, which we will publish for researchers to use.

Your information will be stored securely during the study so we can contact you, if needed, during the study time. Once the study ends (expected in July 2025), your information will be deleted to protect your privacy.

What will happen to me if I agree to participate?

We will ask you to complete the survey, as described above. If you choose to take part, you will need to sign an online consent form. After that, you can start the survey. If you have any questions before deciding, please email us at surgicalhandover@rcsi.com.

You will also get emails about the progress of the study and be invited to see new ratings and results. In January 2025, you may be invited to join an optional online meeting, as mentioned earlier. The survey itself should take around 10-15 minutes to complete in total. The online meeting, should you choose to take part, will take a few hours.

Your personal information will be kept safe, and only the research team at RCSI will be able to see it (further information below).

What are the benefits?

Research studies on improving handover between surgical doctors have not always been done in the same way. Because of this, it's hard to use what we've learned to make handovers better and reduce risks for patients. We hope that by creating this core outcome set, we can improve future research. This way, these handovers can be done better, and future patients will have safer care.

What are the risks?

There is a potential risk of breach of confidentiality as we will be storing your personal contact information while the study is being carried out, however, all reasonable steps will be taken to protect your details and minimise the risk of a breach. If we become aware of any such breach, we will let you know and try to correct it. Your personal details/information will only be retained for the study period. After this, as mentioned above, stored personal details (data) will be destroyed.

It will also take time to complete the survey and online meeting, as mentioned above.

Will it cost me anything to participate?

There are no financial costs associated with this study, however, it will cost some of your time.

Is the study confidential?

We will not be able to identify you from the answers you give in the survey. If you join the optional online meetings, other people will be able to hear and read what you share. However, we will not share anything from the meetings in a way that could identify you. We will keep your contact information (name and email address) safe on a password-protected online drive at RCSI (OneDrive).

We plan to use the information we gather during the study to write academic papers and present at conferences. You will not be identified in any of these papers or presentations. We will share updates, news, and publications on our Twitter page (https://x.com/SH_COREstudy) so that you can find them when they are ready.

Data Protection Information:

The research team are contactable via the email address surgicalhandover@rcsi.com

1. We will be using your personal information (data) in our research to help us create a core outcome set which will improve the standard of future research to improve surgical handover.
2. Your data is being processed under the legal basis of 'legitimate interest and for scientific research purposes' – see Article 6 of the General Data Protection Regulation 2016, available at: https://www.dataprotection.ie/sites/default/files/uploads/2020-04/Guidance%20on%20Legal%20Bases.pdf
3. The Principal and co-investigators (co-researchers) (D McNamara, W Eppich, D Kavanagh, J Ryan, D Devane, A Simiceva) will have access to your pseudo-anonymised data. 'Pseudo-anonymised data' means that your personal information (e.g., name, email address) is disguised so that it is not directly linked to your replies. Only J Ryan, A Simiceva, and D McNamara will have access to your identifiable data.
4. Your data will be stored for the duration of the study, which will end in July 2025.
5. There is a risk of data breach, but every effort will be taken to ensure that your data remains secure
6. You have a right to withdraw consent by contacting the research team.
7. You have the right to lodge a complaint with the General Data Protection Commissioner, who can be contacted by phone (01) 765 01 00 or 1800 437 737 or online through the following link https://forms.dataprotection.ie/contact
8. You have a right to request access to your data and a copy of it by contacting the research team, unless your request would make it impossible or make it very difficult to conduct the research.
9. You have a right to restrict or object to processing of your personal information (data), unless your request would make it impossible or make it very difficult to conduct the research. This can be done by contacting the research team.
10. You have a right to have any inaccurate information about you corrected or deleted, unless your request would make it impossible or make it very difficult to conduct the research. This can be done by contacting the research team.
11. You have a right to have your personal data deleted, unless your request would make it impossible or make it very difficult to conduct the research. This can be done by contacting the research team.
12. You have a right to data portability, meaning you have a right to move your personal information (data) from one controller to another in a readable format. If you would like more information on this, please contact the research team.
13. There will be no profiling of your data. Profiling is any form of automated processing of personal data consisting of the use of personal data to evaluate certain personal aspects relating to a person, in particular to analyse or predict aspects of their performance at work, health or behaviour.
14. We must inform you if we intend to further process your personal data and provide you with information on that other purpose.
15. We must inform you if we wish to transfer your data to a country outside of the EU or an international organisation.

Where can I get further information?

If you have any further questions about the study or if you want to opt out of the study, you can rest assured it won't affect your future medical treatment. If you need any further information about this study now or at any time in the future, please contact:

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