Participant Information Sheet

Multispecialty Robotic Outpatient Surgery Program for Improved Length of Stay and Recovery (MAYFLY)

As you are booked to have an outpatient procedure using one of our robotic platforms, we would like to invite you to take part in our research study. Your participation is entirely voluntary, but before you decide whether or not you want to participate, we would like you to understand why the research is being done and what it will involve. Please take this information sheet home, take your time to read through it, and make sure to ask any questions that you may have. You do not have to make an immediate decision.

What is the purpose of the study?

This study is part of a research project to investigate the role of a robotic outpatient surgery program in the NHS (National Healthcare Service). Outpatient surgery means that we expect the patient to be able to go home within 24 hours after the surgery, usually without the need to stay in hospital overnight. Robotic surgery means that the operation is done by a human surgeon using an advanced tool (the robotic platform) to perform the surgery through small cuts in the body. This robot is not autonomous, meaning that at no point is a robot performing the operation itself, a human surgeon will be controlling the robot during the entire operation.

Robotic surgery has been around since the early 2000s and is already being used successfully for these types of operations across the world. However, the benefits and costs of robotic surgery have not yet been fully examined. That is why we have set up this study to find out the impact that the robotic platform has to outpatient surgery within the NHS. We want to study clinical outcomes, such as how quickly you are able to leave the hospital after surgery, economic outcomes, such as how much robotic outpatient surgery costs to the NHS, and efficiency outcomes, such as whether patients are able to be operated on sooner.

We want to invite all patients undergoing an outpatient procedure using one of our robotic platforms to participate in this trial, so that we can hopefully fill this current gap in knowledge.

Why have I been invited?

You are being asked to participate in this research as you have been offered an operation using the robotic platform as an outpatient at Portsmouth Hospitals University NHS Trust. If you choose to participate, our research team will assess your situation once more to check if your treatment fits our research goals and include you into our study.

Figure 1: An example of a robotic platform (the Da Vinci Xi). From left to right, the devices shown are the surgeon console (where the surgeon sits to control the robot), the vision cart (the computer and brain of the platform), and the patient cart (the robot arms that hold and move the surgical instruments).
Pictures taken from https://www.intuitive.com/en-us/about-us/newsroom/press-resources#, accessed on 19/03/2023.

What will happen if I take part?

If you agree to participate in this study, your procedure will go ahead just as your surgeon had planned. Participating in this study does not alter the treatment that you receive in any way. The surgeon remains free to perform the steps of your operation as they usually would.

You will be asked to sign a consent form before you have your operation as confirmation that you agree to take part. You will be given a copy of the consent form to keep, and you can also keep this information sheet. Consent can also be taken remotely, for example over the telephone, where we read each line of the consent form out loud for you and ask you to confirm you verbally agree to take part in the study. If you agree to the line, we will sign the consent form on your behalf, and give you a copy of the final consent form via email or in person.

After you have your operation, the clinical team (including the research team) will gather further information about the procedure you have had and your recovery by reviewing your medical notes. You will receive questionnaires before your surgery, and at 2, 7, 30, and 365 days after your surgery. Before surgery and at 2 and 30 days after surgery you will receive two questionnaires, and at 7 and 365 days after surgery you will only receive one questionnaire. You will be able to access these questionnaires on your smart mobile phone, tablet, or personal computer. You will have the option of using either your email address or your phone number to create a secure login to the website, where you can complete these questionnaires. We will provide you with instructions and support on how to login and complete the questionnaires. We will also be able to provide you with paper versions of the same questionnaires if you do not want or are unable to complete the questionnaires electronically. The questionnaires take approximately 5-10 minutes to complete (times may vary between participants).

We will contact you for a short telephone visit at 30 days after your surgery, which will take approximately 5 minutes to complete (times may vary between participants). We will ask you how your recovery has been following your surgery, including if you are still taking any painkillers after your surgery, whether you have sought any medical care since leaving the hospital, and how quick you have been able to return to work or normal activity. We will also collect information from your medical records on any hospital visits you may have had within 30 days after your surgery. There will be no telephone call at 90 days after your surgery, but we will collect information on any hospital visits you may have had from your medical records.

You will also be given the option to receive a summary of the study results when these become available, which you can select on the consent form. If you want to receive these study results, we will keep your contact details on only the Trust servers and these will only be accessible by the direct research team. We will only use this information to contact you for study related communications.

We would also like to use the anonymized data captured in this study for potential future research projects. This includes data from your medical records about your medical history, procedure, and recovery after surgery, as well as long-term follow-up. It may also include data that is automatically captured by the robotic platforms (including instrument movements and timings), but is normally not linked to your person. This does not mean that any third parties will have access to your personal data, as this strictly remains on our own Trust servers. Consent for this is optional and you can opt out of this on the consent form. If you do agree to this, we would make sure that you will not be able to be identified from any of the data we use.

If your situation changes and you are deemed unable to make informed decisions after consenting, you will be withdrawn from the study. Identifiable data already collected with consent will be retained and used in the study, but we would not collect any further data nor carry out any other research procedures in relation to the you. We do not offer participants any financial compensation for taking part in the study.

Do I have to take part?

No, participation is entirely voluntary. You will be given time to consider taking part. You are free to refuse to take part or to withdraw from the study at any time without having to give a reason. This will not affect your medical care or your relationship with anyone looking after you.

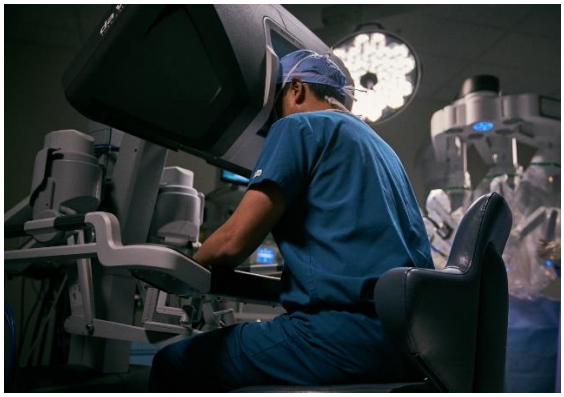

Figure 2: Example of a surgeon sitting at the surgeon console, with the patient cart in the background. The surgeon controls the robotic platform from the surgeon console.
Picture taken from https://www.intuitive.com/en-us/about-us/newsroom/press-resources#, accessed on 19/03/2023.

What are the possible disadvantages or risks of taking part?

Taking part in this study will not add any additional risk to you than you would have as part of your surgery and postoperative recovery. All surgeons taking part in this research are experts in their respective fields and have extensive experience. Our Trust is already performing robotic surgery as a part of standard of care, and all surgeons participating in this trial have been appropriately trained to perform robotic surgery within their specialties. As part of this research project we are also assessing the operational safety of the program, though we do not expect there to be any individual risks as a result of this program.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This will include your initials, NHS number, name, and contact details. People will use this information to do the research or to check your records to make sure that the research is being done properly. Anyone who does not need to know who you are will not be able to see your name or contact details. Your study data will be stored in a secure online database (called Medidata RAVE) and will have a code number assigned, a process we call pseudonymization. This code number will be stored at our Trust and will remain our responsibility to maintain. The online database has been made by Intuitive Surgical Ltd., who will also maintain the database infrastructure during the study. Though they are able to see the data within the database, they will only see your code number and not your name or other personal information, thus protecting your privacy. We will keep all personal information about you safe and secure at our Trust and will respect your privacy rights.

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. The data will be securely stored by our research department for a period of 15

years after the trial is completed. Your coded data may be transferred to other countries for study purposes, such as the United States, and these countries may not provide the same standard of legal protection for information as in the United Kingdom. We will, however, never transfer any personal information or patient identifiable data to these countries, and will take appropriate measures to ensure protection of your privacy. Your rights to access, change, or move your personal information may be limited, as we need to manage your information in specific ways in order for the study to be reliable and accurate. Further information about your rights with respect to your personal information is available at: https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/transparency-wording-for-all-sponsors/.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and your hospital records. If you do not want this to happen, tell us and we will stop. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?

You can find out more about how we use your information at www.hra.nhs.uk/information-about-patients/ or by asking one of the research team by ringing us on 02392286000 ext 5158. If you wish to raise a complaint on how your personal data was handled, you can contact our Data Protection Officer who will investigate the matter:

Contact Person: Ms Emile Armour

Email: emile.armour@porthosp.nhs.uk

Telephone: 02392 286000 ext 1288

Who has reviewed the study?

This study has been reviewed by the [INSERT IRAS BODY] Research Ethics Committee, who has given their favourable opinion for this project (*reference …*).

What will happen to the results of the research study?

Results of the study are likely to be published in scientific medical journals. They may be used for scientific presentations and may be forwarded to health authorities worldwide. You will not be identified in any reports or publications resulting from the study.

To summarize

Firstly, we would like to emphasize that we strongly recommend you read the PIS in its entirety before reading the following bullet points. We have added the following bullet points to highlight some of the most important aspects of this PIS, but these are meant as an addition to the rest of the information provided and cannot replace the rest of the PIS. After you have read the PIS, here are the key points once more:

- You have been invited to take part in our research study as you are booked to have a outpatient procedure using one of our robots.
- Participation is entirely voluntary, and you are free to decline or withdraw from the study at any time. This will not affect your medical care or your legal rights.
- Outpatient surgery using the robot is already being done worldwide for several specialties, but there is limited data on the potential benefits.
- Participation in the trial does not affect your treatment in any way.
- If you agree to participate, you will be asked to sign an informed consent form.
- If you participate in the trial, we will need to collect data from you and your medical records.
- We will ask you to fill in questionnaires at four timepoints, which will take approximately 5-10 minutes to complete. These timepoints will be as follows:
    - Two questionnaires before your surgery
    - Two questionnaires 2 days after your surgery
    - One questionnaire 7 days after your surgery
    - Two questionnaires 30 days after your surgery
    - One questionnaire 365 days after your surgery
- We will contact you for a short telephone follow-up visit at 30 days after your surgery, which will take approximately 5 minutes to complete.
- There are no possible disadvantages or additional risks to you for taking part in this study. Your operation and postoperative care will go ahead as planned.
- Results of the study are likely to be published in scientific medical journals, but you will not be identified in any reports or publications.

What if there is a problem?

If you have a concern about any aspect of this study, you can speak to the team looking after you, who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the Hospital's Patient Advice and Liaison Service (PALS):

Patient Advice and Liaison Service (PALS), A-level Atrium, Queen Alexandra Hospital

Telephone	02392 286309
Email	PHT.PALS@porthosp.nhs.uk

Thank you for taking time to read this information sheet.

If you have any further questions or concerns regarding this project, please contact any member of the research team by email or telephone (**see below**).

MAYFLY Research Team

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