STUDY SUMMARY

FULL TITLE

A Real-World, In-Situ, Evaluation Of The Introduction And Scale-Up Of Robot-Assisted Surgical Services In The NHS: Evaluating Its Impact On Clinical And Service Delivery, Effectiveness And Cost

SUMMARY OF RESEARCH

RESEARCH QUESTION

What is the impact of the introduction and scale-up of robotic-assisted surgery (RAS) on NHS service delivery, clinical effectiveness, budget and cost-effectiveness?

BACKGROUND

Over the next 20 years, surgery performed with the help of a robot (called "robot-assisted surgery") is expected to increase rapidly around the world, especially for cancer conditions. Previous research shows that when robot-assisted surgery has been introduced in some clinical areas, like urology, it can help surgeons be more precise and can reduce a patient's hospital stay. Using robot-assisted surgery may also speed up training for surgeons to enable them to become experts more quickly. However, robot assisted surgery has not been tested in all clinical areas and is very expensive with each robot costing over £1million). Also, when robot-assisted surgery is introduced into hospitals it requires special consideration as the set-up can be disruptive. The robot can take up a lot of space requiring physical modifications to operating theatres. The surgeons and the wider surgical team have to change how they operate, and the way patients move through their patient journey also has to change. It is not yet clear whether the benefits to patients or the health system of doing surgery this way is worth the cost and the disruption. The REINFORCE study aims to answer that question and provide guidelines for the best way of doing it if robotic surgery is shown to be useful.

AIMS & OBJECTIVES

To undertake a real-world, large-scale evaluation of impact on the introduction and scale-up of RAS services in the NHS. Specifically, to provide evidence on the:

1. Impact of RAS on clinical and service delivery
2. Budget impact and cost-effectiveness to the NHS of the introduction of RAS at scale
3. Potential benefits and harms of RAS across and within specialty areas
4. Mechanisms underpinning any changes in outcome, including surgeon training

METHODS

We have designed the study to be able to measure the impact of robot-assisted surgery as it is introduced in the UK and scaled up in other hospitals currently performing robotic surgery but planning to expand services. It will study the effects of robot assisted surgery as it is rolled out at different sites in a planned way. It will measure the safety and benefit of the new treatment as it is being rolled out. We will measure what happens to patients who get robot-assisted surgery as part of the service and compare their outcomes (e.g.,

complications, recovery time) to conventional surgery. We will also track how introducing robot-assisted surgery impacts on the staff and the surgeons, and how it affects wider care in hospitals across the country. We will also work out how much robot-assisted surgery really costs and whether the benefits are value for money.

Specific outcomes addressed are based on the RoboCOS outcomes measures.

Outcome Level	Outcome Name
Patient level	Disease-specific quality of life
	Overall quality of life
	Overall measure of treatment effectiveness/benefit
	Overall-measure of complications inc. mortality
Surgeon/Team level	Precision/accuracy
	Visualisation
Organisation level	Equipment failure
	Standardisation of operative quality
	Overall economic/cost-effectiveness
Population level	Equity of access

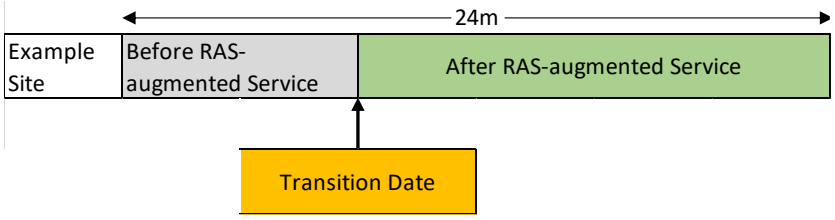
STUDY DESIGN & DELIVERY

The study will be delivered as a multi-centre, pan-specialty Service Evaluation project. It will be Centrally managed by the University of Oxford (SITU), with support from the NIHR CRN portfolio and Associate PI scheme.

Sites will fall into one of three categories:

Site Type	**Description**	**Example Index Procedure**
1. Change in Delivery (RAS naïve)	No previous provision in any specialty	Radical prostatectomy (as first RAS procedure performed at site)
2. Change in Specialty	RAS established in one specialty, commencing service for new specialty	Low anterior resection (new specialty, having previously only performed RAS prostatectomy)
3. Change in Procedure	RAS established, commencing new procedure within specialty	Partial nephrectomy (same specialty, having previously only performed RAS prostatectomy)

Sites will decide an index procedure to be followed throughout the study period, ensuring to capture control data before implementation. Data will be captured continuously, with the date of transition recorded (as shown in the below diagram).



All patients undergoing the index procedure (RAS or otherwise) will be invited to consent for questionnaires pre- and post-surgery. These will contain questions on quality of life (EQ-5D-5L), procedure specific PROMS and patient experience. Clinical staff will be asked to complete a form at the time of surgery and 3-months post-surgery. This will ask about surgical complications, length of stay and surgeon experience.

During the study period, a survey will be sent to all sites pre- and post-implementation to ask about their experience with RAS. Additionally, 6 sites will be chosen to invite staff members for interview as part of the integrated process evaluation study.

We have consulted widely about how best to design the study. Patients, surgeons, nurses, NHS managers, scientists, and industry have been involved and will continue to advise on this study. We will involve patients throughout the study period.

KEY DATES & FIGURES

Number of Sites	16
Sample Size	2,560 procedures (160 per site)
Planned Study Period	01 Jan 2022 – 31 Mar 2025
Planned Recruitment Period	01 Jul 2022 – 01 Jul 2024 (2years)

ANTICIPATED IMPACT & DISSEMINATION

This study will provide the NHS the information needed on the benefits of robot-assisted surgery and how it affects the wider health system. It will help decide whether the benefits of robot-assisted surgery are worth the cost and the disruption to services and whether robot-assisted surgery should be available routinely in the UK. It will also provide important guiding information on how best to provide robotic surgery, if found to be useful.

COLLABORATING ORGANISATIONS

Funder: NIHR Health Services & Delivery Research (HS&DR), Reg: 131537
Sponsor: University of Oxford
Co-CIs: Professor David Beard (University of Oxford), Professor Marion Campbell (University of Aberdeen)
Clinical Trials Unit: Centre for Healthcare and Randomised Trials (CHaRT), University of Aberdeen
Study Management: Surgical Intervention Trials Unit (SITU), University of Oxford

CONTACT US

If you would be interested in finding out more about the proposed study, please contact us by:

Email: REINFORCE@ndorms.ox.ac.uk
Tel: 07721 491938