

# Real-world evaluation of robot-assisted surgical services

<b>Submission date</b> 07/07/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 10/10/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/08/2025	<b>Condition category</b> Surgery	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

This study aims to work out if robot-assisted surgery (RAS), a relatively new development, should be routinely available in the NHS and also assess any barriers to its implementation. Over the next 20 years, surgery performed with the help of a robot is expected to increase rapidly around the world, especially for cancer conditions. Previous research shows that when RAS 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 RAS may also speed up training for surgeons to enable them to become experts more quickly. However, RAS has not been tested in all clinical areas and is very expensive with each robot costing over £ 1 million). Also, when RAS is introduced into hospitals it requires special consideration as the set-up can be disruptive. 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. This study aims to answer that question and provide guidelines for the best way of doing it if robotic surgery is shown to be useful.

We have designed the research to be able to measure the impact of RAS 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 RAS as it is rolled out at 16 different sites in a planned way. We will measure what happens to patients who get RAS as part of the service and compare their outcomes (e.g., complications, recovery time) to conventional surgery. We will also track how introducing RAS impacts on the staff and the surgeons, and how it affects wider care in hospitals across the country.

This study aims to undertake a real-world, large-scale evaluation of the introduction and scale-up of RAS services evaluating its impact on NHS service delivery, clinical effectiveness, budget and cost-effectiveness.

### Who can participate?

Any patient undergoing the specified surgical procedure at a participating hospital site

### What does the study involve?

The study involves patients completing a questionnaire before and after surgery to evaluate

their experience of the procedure. We will also interview and survey staff involved with REINFORCE at sites, and calculate the total cost to the NHS (e.g., labour, consumables and other items of surgical equipment).

What are the possible benefits and risks of participating?

There is no direct benefit to participants, but the results of the study are likely to benefit future NHS patients undergoing surgery. Outside of the usual risks associated with surgery and anaesthetic, there are no anticipated risks or disadvantages to participating in the REINFORCE study.

Where is the study run from?

Surgical Intervention Trials Unit (SITU), University of Oxford and Centre for Healthcare Randomised Trials (CHaRT), University of Aberdeen (United Kingdom)

When is the study starting and how long is it expected to run for?

January 2022 to August 2025

Who is funding the study?

NIHR Health and Social Care Delivery Research (NIHR HSDR) (United Kingdom)

Who is the main contact?

REINFORCE@ndorms.ox.ac.uk

## Contact information

### Type(s)

Public

### Contact name

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### Contact name

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### **Type(s)**

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### **Contact name**

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## **Additional identifiers**

### **Clinical Trials Information System (CTIS)**

Nil known

### **Integrated Research Application System (IRAS)**

311223

### **ClinicalTrials.gov (NCT)**

Nil known

### **Protocol serial number**

CPMS 53026, IRAS 311223

## **Study information**

**Scientific 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 (the REINFORCE study)

## **Acronym**

REINFORCE

## **Study objectives**

This study aims to undertake a real-world, large-scale evaluation of the introduction and scale-up of Robot-Assisted Surgery (RAS) services evaluating its impact on NHS service delivery, clinical effectiveness, budget and cost-effectiveness.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

This is an observational study of healthcare professionals. The Sponsor, University of Oxford, reviewed the study as a Service Evaluation project and indicated the project does not need to be submitted for REC review.

## **Study design**

Observational cohort study

## **Primary study design**

Observational

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Evaluation of robot-assisted surgery

## **Interventions**

1. Study design: A stepped-wedge evaluation with integrated process evaluation and economic assessment.
2. Study sites: NHS hospitals planning to introduce/expand robot-assisted surgery (RAS) services. Sites will be switched over from non-RAS to RAS-augmented services (or switch up from one level of provision to another) in random order
3. Study participants (stepped-wedge evaluation): All patients undergoing the index procedure (RAS or otherwise) at each site across all time periods of the study  
The project is embedded in normal NHS care and it is intended to be non-selective (all patients undergoing surgery for the index procedure are candidates).
4. Participants (process evaluation): Three key personnel including surgeons, theatre staff and service managers will be sampled from 6 REINFORCE sites and invited to interview. Additionally, 3-4 commissioners will also be interviewed and sampled from across the suite of trial sites. The sample size overall will be approximately 40 interviews.  
Sample Size: 2,560 procedures
5. Objectives:
  - 5.1. Impact of RAS system transformation on clinical and service delivery
  - 5.2. Budget impact and cost-effectiveness to the NHS of the introduction of RAS at scale

5.3. Potential benefits and harms of RAS across and within speciality areas

5.4. Mechanisms of change underpinning any change in outcome, including surgeon training

## **Intervention Type**

Other

## **Primary outcome(s)**

1. Patient level:

1.1. Disease-specific quality of life measured using procedure-specific PROM at baseline and 3 months

1.2. Overall quality of life measured using the EQ-5D questionnaire at baseline and 3 months

1.3. Overall measure of treatment effectiveness/benefit measured using a Patient Questionnaire at baseline and 3 months

1.4. Overall measure of complications inc. mortality measured using Clavien-Dindo score at 3 months

2. Surgeon/Team level:

2.1. Precision/accuracy measured using Surgeon Task Load Index (TLX) on the day of surgery

2.2. Visualisation measured using Surgeon Task Load Index (TLX) on the day of surgery

3. Organisation level:

3.1. Equipment failure measured using a Surgery Form on the day of surgery

3.2. Standardisation of operative quality measured using process evaluation interviews pre/peri/post-robot-assisted surgery (RAS) implementation

3.3. Overall economic/cost-effectiveness measured using Health Economics review throughout the study

4. Population level:

4.1 Equity of access measured using Health Economics review throughout the study

## **Key secondary outcome(s)**

There are no secondary outcome measures

## **Completion date**

30/08/2025

## **Eligibility**

### **Key inclusion criteria**

All patients undergoing the index procedure (robot-assisted surgery or otherwise) at each site across all time periods

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

**Sex**

All

**Total final enrolment**

2836

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

01/07/2022

**Date of final enrolment**

31/05/2025

**Locations****Countries of recruitment**

United Kingdom

England

Wales

**Study participating centre****University Hospital of Wales**

Cardiff Urology

Dept of Urology

Cardiff & Vale University Health Board

Heath Park

Cardiff

United Kingdom

CF144XW

**Study participating centre****University Hospital of Wales**

Cardiff Colorectal

Dept of Gastroenterology

Cardiff & Vale University Health Board, University Hospital of Wales

Heath Park,

Cardiff

United Kingdom

CF144XW

**Study participating centre**

**Ysbyty Gwynedd**

Betsi Cadwaladr Gynaecology  
Dept of Gynaecology  
Penrhosgarnedd  
Bangor  
Gwynedd  
United Kingdom  
LL57 2PW

**Study participating centre****University Hospital of Wales**

Cardiff Gynaecology  
Dept of Gynaecological Oncology  
Cardiff & Vale University Health Board  
Heath Park  
Cardiff  
United Kingdom  
CF144XW

**Study participating centre****Norfolk & Norwich University Hospital**

Colney Lane  
Colney  
Norwich  
United Kingdom  
NR4 7UY

**Study participating centre****North Bristol NHS Trust**

Southmead Hospital  
Southmead Road  
Westbury-on-trym  
Bristol  
United Kingdom  
BS10 5NB

**Study participating centre****South Tees Hospitals NHS Foundation Trust**

James Cook University Hospital  
Marton Road  
Middlesbrough  
United Kingdom  
TS4 3BW

**Study participating centre**  
**Swansea Bay University Local Health Board**  
Tonna Hospital  
Tonna Uchaf  
Tonna  
Neath  
United Kingdom  
SA11 3LX

**Study participating centre**  
**Stockport NHS Foundation Trust**  
Stepping Hill Hospital  
Poplar Grove  
Stockport  
United Kingdom  
SK2 7JE

**Study participating centre**  
**Salford Royal Hospital**  
Stott Lane  
Eccles  
Salford  
United Kingdom  
M6 8HD

**Study participating centre**  
**Salisbury District Hospital**  
Salisbury District Hospital  
Odstock Road  
Salisbury  
United Kingdom  
SP2 8BJ

**Study participating centre**  
**Wrightington Hospital NHS Trust**  
Hall Lane  
Wrightington  
Wigan  
United Kingdom  
WN6 9EP

**Study participating centre**

**Cwm Taf Morgannwg University Local Health Board**  
Dewi Sant Hospital  
Albert Road  
Pontypridd  
United Kingdom  
CF37 1LB

**Study participating centre**

**Oxford University Hospitals NHS Foundation Trust**  
John Radcliffe Hospital  
Headley Way  
Headington  
Oxford  
United Kingdom  
OX3 9DU

**Study participating centre**

**Barts Health NHS Trust**  
The Royal London Hospital  
80 Newark Street  
London  
United Kingdom  
E1 2ES

**Sponsor information****Organisation**

University of Oxford

**ROR**

<https://ror.org/052gg0110>

**Funder(s)****Funder type**

Government

**Funder Name**

National Institute for Health and Care Research Evaluation, Trials and Studies Co-ordinating Centre (NETSCC); Grant Codes: NIHR131537

**Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

**Funding Body Type**

Government organisation

**Funding Body Subtype**

National government

**Location**

United Kingdom

## Results and Publications

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from the Surgical Intervention Trials Unit (SITU) at [situ@ndorms.ox.ac.uk](mailto:situ@ndorms.ox.ac.uk). Further details will be made available at a later date.

**IPD sharing plan summary**

Available on request

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Protocol file</a>	version 3.0	20/03/2025	30/05/2025	No	No
<a href="#">Study website</a>	Study website	11/11/2025	11/11/2025	No	Yes