NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Evidence generation plan

Robot-assisted surgery for soft tissue procedures

31 March 2025

1 Purpose of this document

NICE's assessment of robot-assisted surgery for soft tissue procedures recommends that Da Vinci SP, Da Vinci X and Xi, Hugo robotic-assisted surgical system, Senhance Surgical System and Versius Surgical System can be used in the NHS while more evidence is generated.

This plan outlines the evidence gaps and what real-world data needs to be collected for a NICE review of the technology again in the future. It is not a study protocol but suggests an approach to generating the information needed to address the evidence gaps. For assessing comparative treatment effects, well-conducted randomised controlled trials are the preferred source of evidence if these are able to address the research gap.

The companies are responsible for ensuring that data collection and analysis takes place. Support for evidence generation may be available through schemes such as the National Institute for Health and Care Research (NIHR) funded HealthTech Research Centres.

Guidance on commissioning and procurement of the technologies will be provided by NHS England.

NICE will withdraw the guidance if the companies do not meet the conditions in section 4 on monitoring.

After the end of the evidence generation period (3 years), the companies should submit the evidence to NICE in a form that can be used for decision making. NICE

will review all the evidence and assess whether the technologies can be routinely adopted in the NHS.

2 Evidence gaps

This section describes the evidence gaps, why they need to be addressed and their relative importance for future committee decision making.

The committee will not be able to make a positive recommendation without the essential evidence gaps (see section 2.1) being addressed. The companies can strengthen the evidence base by also addressing as many other evidence gaps (see section 2.2) as possible. This will help the committee to make a recommendation by ensuring it has a better understanding of the patient or healthcare system impact of the technologies.

2.1 Essential evidence for future committee decision making

Understanding the learning curve associated with robot-assisted surgery (RAS) introduction

Evidence considered by the committee indicates that there is a substantial learning curve when RAS technologies are implemented. Further information characterising the learning curve is necessary to help the committee to understand the short- and long-term clinical effectiveness of the technologies.

Resource use

More information on how using the technology would affect resource use during and after implementation is needed to help the committee understand long-term cost effectiveness of the technologies. Key areas that will help to address this evidence gap are:

- technology acquisition and payment model used, and set up costs
- implementation costs, for example, training costs and staff time needed to support the service, as well as any training costs after completion of initial training
- technology maintenance and component (for example, surgical blades) costs

- the short- and long-term impact of RAS on surgical theatres, for example, length of surgery, the number of procedures done and any change in capacity
- the downstream use of NHS services, for example, number of hospital readmissions.

Clinical impact of RAS

The committee noted that the current evidence comparing clinical effectiveness outcomes against standard care in the NHS is limited. The current evidence was also not available for a sufficient time horizon of at least 12 months. This information will be needed to recommend RAS implementation in the NHS. For example, further information is needed on:

- rates of conversion from minimally invasive surgery to open surgery with and without RAS
- adverse events and complications
- patient outcomes such as length of hospital stay, and long-term outcomes including return to normal activities, survival, need for follow-up surgery, and health-related quality of life.

2.2 Evidence that further supports committee decision making

Surgeon opinion of RAS

Evidence on surgeon preference, opinion and uptake rates will help the committee understand how the technologies are viewed by surgeons and assess the real-world uptake of the technologies.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

Table 1 summarises the evidence gaps and ongoing studies that might address them. Information about evidence status is derived from the external assessment group's report. More information on the studies in the table can be found in the supporting documents.

The REINFORCE trial and MASTERY cohort study are collecting data that may address many of the evidence gaps (see section 3.3).

Table 1 Evidence gaps and ongoing studies

Evidence gap	Da Vinci SP	Da Vinci X and Xi	Hugo RAS system	Senhance Surgical System	Versius
Understanding the learning curve associated with RAS introduction	Limited evidence Ongoing study	No evidence Ongoing study	No evidence	Limited evidence	Limited evidence
Resource use	Limited evidence Ongoing study	No evidence Ongoing study	Limited evidence	No evidence	Limited evidence Ongoing study
Clinical impact of RAS	Limited evidence Ongoing study	Limited evidence Ongoing study	Limited evidence	Limited evidence	Limited evidence Ongoing study
Surgeon opinion of RAS	Limited evidence	No evidence	No evidence	No evidence	Limited evidence

3.2 Data sources

There are several data collections that could potentially support evidence generation. NICE's real-world evidence framework provides detailed guidance on assessing the suitability of a real-world data source to answer a specific research question.

For uses of RAS on tumours, the National Disease Registration Service (NDRS) provides the Cancer Outcomes and Services Dataset (COSD) as part of the National Cancer Registration and Analysis Service. COSD is a complied dataset that includes all patients diagnosed with or having cancer treatment in or funded by the NHS in England. It includes much of the data needed to address the evidence gaps, such as individual patient outcome data items, length of hospital stay, and the surgery type done for each surgical procedure (for example, conventional minimally invasive or open surgery).

COSD can be linked to other datasets such as NHS Digital's Hospital Episode Statistics (HES) dataset which contains details about admissions, outpatient appointments and historical A&E attendances at NHS hospitals in England. This combined dataset can be used to estimate resource use.

The quality and coverage of real-world data collections are of key importance when used in generating evidence. Active monitoring and follow up through a central coordinating point is an effective and viable approach of ensuring good-quality data with broad coverage.

3.3 Evidence collection plan

The REINFORCE and MASTERY studies may deliver comparative evidence addressing the evidence gaps for resource use, clinical impact of RAS technologies and the learning curve associated with implementation of RAS technologies.

Technologies that are not involved in these studies may need to generate equivalent comparative evidence. Approaches to delivering this are described in the NICE's real-world evidence framework.

REINFORCE trial

The REINFORCE trial is investigating the impact of robot-assisted surgery as it is introduced to or scaled up across NHS hospitals. The primary outcome measures include outcomes at:

- patient level (quality of life and complications)
- surgeon or team level (covering precision or accuracy, and surgery-specific workload)
- organisation level (equipment failure, standardisation of operative quality, overall economic or cost effectiveness)
- population level (equity of access).

The trial has recruited patients across urology, colorectal, gynaecology and upper gastrointestinal soft tissue specialties from 16 NHS trusts in England and Wales. This study recruited sites that were procuring new RAS equipment and sites that were already using RAS but were considering a change in specialty or procedure using RAS methods. The study aims to recruit 2,560 participants and has an estimated completion date of December 2025.

MASTERY study

The MASTERY cohort study is using robotic systems to measure progress in surgical training and quality of surgeries. The primary outcomes measure is surgical complication rate at day 30 and other outcome measures are total operating time per surgery, time taken by surgeon to complete each surgery 'cardinal step', number of robotic-assisted surgeries carried out by surgeon before enrolment in study, number of patients with complete or incomplete surgical resection, number of patients with readmission at day 30, and number of patients with adverse events reported at day 30. The study has recruited patients who have agreed to RAS for colorectal tumours, lung tumours, gynaecological tumours, ear, nose and throat tumours, hepatobiliary tumours and prostate tumours. The study has recruited 500 participants across 15 NHS trusts in England and Scotland.

Real-world observational study

Additional evidence generation is necessary to supplement the studies and collect information that shows the evidence from them is generalisable to other implementations of the technologies.

An approach to delivering this is through a real-world observational study in which applicable outcomes are collected for patients having RAS. For example, post-surgical complications and length of stay. This data could be used to strengthen evidence for the learning curve, resource use and clinical impact evidence gaps. This study could be done both in centres that are already using RAS and those that are making new implementations.

Where RAS is being used in people with cancer, the Cancer Outcomes and Services Dataset (COSD) could be a suitable data source to support this study. Retrospective data from COSD could also be used to deliver long-term outcome information.

Qualitative survey

A qualitative survey may provide qualitative evidence on healthcare professional preferences. This study should include questions about healthcare professional experience using the technologies, their acceptability, and ideally, the ergonomic impact of these technologies to the surgeons.

Data collection should follow a predefined protocol and quality assurance processes should be put in place to ensure the integrity and consistency of data collection. See NICE's real-world evidence framework, which provides guidance on the planning, conduct and reporting of real-world cohort studies to assess comparative treatment effects.

3.4 Data to be collected

Study criteria

- At recruitment, eligibility criteria for suitability of using RAS technologies and inclusion in the real-world study should be reported, along with a detailed description of the RAS technologies and the specific versions.

Patient information and outcomes

- Conversion rates to open or standard minimally invasive surgery from RAS
- Length of hospital stay
- Clavien–Dindo score as a measure of surgical complications
- Peri- and postoperative complication frequency (ideally up to 12 months)
- Ideally, EQ-5D-3L or EORTC QLQ-C30 at baseline and over follow up (ideally up to 12 months)
- Return to normal activities
- Applicable condition-specific outcomes
- Revision surgery (ideally for a minimum of 12 months follow up).

Surgeon information and outcomes

- Number of RAS surgeries performed
- Any prior experience of using any RAS technology before recruitment into the study.

Organisational information and outcomes

- Rate of minimally invasive surgery compared with open surgery after robot-assisted surgery is introduced
- Number of procedures done at the hospital
- Hospital capacity and surgical waiting lists
- Patient readmission rates, ideally up to 12 months
- Number of RAS surgeries performed at the hospital
- Information on healthcare resource use and hospitalisation costs related to RAS, including:
  - technology acquisition cost and how it has been paid for
  - technology set up costs including staff training and time costs
  - technology maintenance and consumable (for example, surgical blades) costs.

Safety monitoring outcomes

- Any adverse events arising from using RAS technologies.

3.5 Evidence generation period

The evidence generation period should be 3 years (during which a minimum of 12 months of follow-up data will be collected). This will be enough time to implement the evidence generation study, collect the necessary information and analyse the collected data.

4 Monitoring

The companies must contact NICE:

- within 6 months of publication of this plan to confirm agreements are in place to generate the evidence
- annually to confirm that the data is being collected and analysed as planned.

The companies should tell NICE as soon as possible of anything that may affect ongoing evidence generation, including:

- any substantial risk that the evidence will not be collected as planned
- new safety concerns
- the technologies significantly changing in a way that affects the evidence generation process.

If data collection is expected to end later than planned, the companies should contact NICE to arrange an extension to the evidence generation period. NICE reserves the right to withdraw the guidance if data collection is delayed, or if it is unlikely to resolve the evidence gaps.

5 Minimum evidence standards

All the technologies that have been recommended for use in the NHS while more evidence is generated have some clinical evidence suggesting that they are comparable with current standard of care for primary patient-level outcomes and have some resource use costs and implementation experience in the NHS. None of the technologies reported any safety concerns.

In addition to this evidence, the committee has indicated that it may be able to recommend technologies in this topic area in the future that have evidence for:

- the learning curve for healthcare professionals using the technology
- the impact of the technology on resource use in the NHS
- the impact of the technology on clinical outcomes.

Companies can strengthen the evidence base by also having qualitative evidence about healthcare professional opinion, procedure-related discomfort, and ergonomics of the RAS technology for the surgeon.

6 Implementation considerations

The following considerations around implementing the evidence generation process have been identified through working with system partners:

Evidence generation

- The companies could collect and analyse outcome data stratified by age to ensure that the evidence is informative in all clinically important subgroups, including children.
- Accessing COSD has an application process that may take many months. Companies should plan adequate time to apply to use the data.

Equalities

- Distance travelled by patients could be a barrier to access to RAS technologies. This is due to RAS technologies being available in larger trust hospitals doing more complicated surgical procedures. Care should be taken to ensure equitable access to RAS technologies. The NHS England robot-assisted surgery steering group may be influential in moderating this geographical placement of additional robotic systems, and the availability of training, resources and staff to implement robot-assisted surgery services, with national strategy going forward. They are actively analysing and mapping current robot-assisted surgery provision in England. A key priority will be equitable provision of robot-assisted surgery based on need rather than current configuration.

System considerations

- While designing the training curriculum for RAS, care should be taken to ensure comparable surgical skills such as laparoscopic and open surgical skills are not lost.
- The evidence generation process is most likely to succeed with dedicated and incentivised research staff to reduce the burden on NHS staff, and by using suitable real-world data to collect information when possible.

ISBN: [to be added at publication]