NICE National Institute for Health and Care Excellence

Evidence generation plan for robot-assisted surgery for orthopaedic procedures

Implementation support

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1 Purpose of this document

NICE's early value assessment of robot-assisted surgery for orthopaedic procedures recommends that 6 technologies can be used in the NHS during the evidence generation period. The technologies are:

- ApolloKnee System
- CORI Surgical System
- Mako SmartRobotics
- ROSA Knee Solution
- SkyWalker Robotic-assisted technology
- VELYS Robotic-Assisted Solution.

This plan outlines the evidence gaps and what real-world data needs to be collected for a NICE review of the technologies 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.

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

NICE will revise or 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 format 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.

Once the evidence generation period has concluded, further data about the effectiveness of robot-assisted surgery systems should continue to be collected to support planning and decision making. This could be accomplished through the National Joint Registry.

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 company 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 benefits of the technologies.

2.1 Essential evidence for future committee decision making

Impact on patient quality of life

The impact of robot-assisted surgery (RAS) on people's daily lives in comparison with conventional surgery is uncertain. Information about the impact that RAS has on people's symptoms and quality of life should be recorded using appropriate patient-reported outcome measures, for example, those outlined in section 3.4.

Resource use

More information on how RAS would affect resource use during and after implementation is needed to help the committee understand RAS's clinical and cost effectiveness. For example, the technologies could reduce the number of follow-up physiotherapy appointments, length of hospital stays and readmission rates.

Resource estimates should include:

- the immediate impact of RAS on surgical theatres, for example, the number of procedures per day, staffing (number and grade) and total surgery and theatre time, and the cost of any associated consumables
- the use of post-surgery NHS services, for example, the number of revisions, hospital

readmissions and physiotherapy sessions (see section 3.4).

Further evidence about this will support future economic evaluations in estimating the impact of RAS on consumables, surgical capacity and use of other post-surgery NHS services.

2.2 Evidence that further supports committee decision making

Clinical impact in different subgroups

There is limited evidence on the clinical impact of RAS in different subgroups. Most of the evidence for RAS is in young people with normal body mass indexes. There may be more complications during surgery in older people and people who are overweight or have obesity. So, further evidence is needed to assess the clinical impact of RAS in these subgroups. The committee heard that people from a Southeast Asian background may benefit more from RAS for knee replacements because of anatomical differences that can cause poor alignment with conventional surgery.

The impact of RAS in people with more complex surgical requirements is uncertain. The committee heard that evidence showing the benefits of using RAS in these subgroups would support future clinical- and cost-effectiveness modelling.

3 Approach to evidence generation

3.1 Evidence gaps and ongoing studies

Table 1 summarises the evidence gaps and the evidence available to the committee when the guidance was published. Information about evidence status is derived from the external assessment report. Evidence that did not meet the scope and inclusion criteria is not included.

REINFORCE trial

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

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

The study aims to recruit 2,560 participants and has an estimated completion date of April 2025.

RACER-Knee and RACER-Hip

The RACER-Knee and the RACER-Hip trials are investigating the clinical and cost effectiveness of knee and hip replacement surgery (respectively) of RAS using the Mako SmartRobotics platform, compared with conventional surgery. The studies are likely to collect data on many of the evidence gaps, but they include a 10-year follow up and are anticipated to end in 2032 (RACER-Knee) and 2033 (RACER-Hip). Interim data may be available before then (12-month follow up completes in 2024).

Table 1 Evidence gaps and ongoing studies

Technology (procedure)	Impact on people's quality of life	Resource use	Clinical impact in different subgroups
ApolloKnee System (total knee arthroplasty)	No evidence	Limited evidence	No evidence
CORI Surgical System (total knee arthroplasty)	Limited evidence	Limited evidence	No evidence
Mako SmartRobotics (total knee arthroplasty)	Good evidence Ongoing study	Limited evidence Ongoing study	No evidence Ongoing study
ROSA Knee Solution (total knee arthroplasty)	Limited evidence	Limited evidence	No evidence
SkyWalker Robotic-assisted technology (total knee arthroplasty)	Limited evidence	Limited evidence	No evidence
VELYS Robotic-Assisted Solution (total knee arthroplasty)	Limited evidence	Limited evidence	No evidence
Mako SmartRobotics (partial knee arthroplasty)	Good evidence	Limited evidence	No evidence
CORI Surgical System (partial knee arthroplasty)	No evidence	Limited evidence	No evidence
Mako SmartRobotics (total hip arthroplasty)	Limited evidence	Limited evidence	Ongoing
CORI SmartRobotics (total hip arthroplasty)	No evidence	No evidence	No evidence

ROSAKnee, ApolloKnee, SkyWalker Robotic-assisted technology and VELYS are not indicated for use in partial knee arthroplasty or total hip arthroplasty.

3.2 Data sources

Data could be collected using a combination of suitable real-world data sources and primary data collection. 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.

The National Joint Registry (NJR) is the data source that is most likely to be able to collect the real-world data necessary to address the essential evidence gaps. The registry includes everyone having joint replacement surgery (conventional or robot-assisted) across private healthcare settings and in the NHS. The registry also records the specific robotic systems used, and links to the NHS Personal Demographics Service to get data for revision surgery and mortality outcomes.

NHS England's national patient-reported outcome measures (PROMs) programme records PROMs before and 6 months after surgery. The relevant PROMs measured for joint replacement include the EuroQol 5D (EQ-5D) 3L index score, Oxford Hip Score and Oxford Knee Score. Patient-level data from the NJR can be linked to other datasets such as NHS Digital's Hospital Episode Statistics. This could support the evaluation of outcomes such as adverse events, further hospital appointments and referral for physiotherapy.

Combining these real-world evidence data sources will address most of the evidence gaps around resource use and the impact on people's quality of life. The high-quality data and broad coverage within the NJR should enable relevant subgroup analyses to assess who the technologies might benefit.

The addition of outcomes to the registry is also unlikely within the timeframe of an early value assessment. Outcomes not already collected will need to be collected separately, for example, in a prospective audit.

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 for ensuring good-quality data with broad coverage.

3.3 Evidence collection plan

Most of the evidence gaps can be addressed through a real-world historical control study. For evidence gaps not addressed by the real-world evidence datasets, a prospective audit is proposed to collect data on the impact of RAS on surgical capacity.

Real-world historical control study with propensity score methods

A historical control study could compare outcomes before and after the implementation of RAS. This could assess the clinical impact of RAS as well as resource use associated with RAS, such as:

- volume of procedures and RAS uptake
- hospital stays
- readmission
- revision rates and
- use of other associated services.

The NJR has data on RAS from March 2020 onwards, but this could enable collection of longer-term data such as revision rates (ideally up to 5 years). Hospital location data could inform evidence gaps around geographical access to RAS. Data on the location of RAS systems may be available through the National Equipment Tracking and Inventory System, which aims to provide visibility around equipment assets. Collection of other baseline patient characteristics such as sex, age, gender, body mass index (BMI) and ethnicity will enable relevant subgroup analyses. These baseline cohort differences may affect clinical outcomes and should be corrected for in future analyses.

Despite consistent eligibility criteria, non-random assignment to interventions can lead to confounding bias, complicating interpretation of the intervention effect. To minimise bias and identify a suitable control group, appropriate statistical approaches that balance confounding factors across comparison groups should be used, for example, using propensity score matching. The comparator group of primary interest is conventional surgery using manual techniques. NICE's real-world evidence framework provides further detailed guidance on the planning, conduct and reporting of real-world evidence studies

assessing comparative effects.

Prospective audit

Some of the evidence gaps around resource use will not be captured by the historical control study. For example, surgical time and total theatre time, or volume and cost of surgical consumables. An audit to collect data on the impact of RAS on surgical capacity is proposed to address these gaps. Technical failure rates should also be reported.

3.4 Data to be collected

Technologies

- A detailed description of the RAS technologies and the specific versions.

Patient characteristics and outcomes

- Information about individual characteristics at baseline, for example, age, sex, gender, BMI, ethnicity, surgery indication, and where in the country the operation was done. Characteristics should include those needed for adjustment to address confounding, and for subgroup analysis.
- Patient pain, mobility and functioning PROMs at baseline and post-surgery. Currently PROMs linked to the NJR are collected before surgery and 6 months after. Ideally, this information would also be collected at 12 and 18 months. PROMs should include Oxford Knee scores, Oxford Hip scores and EuroQol 5D (EQ-5D) 3L index scores (outcomes already collected and linked to the NJR).

Resource use

- Immediate consumables and resourcing associated with surgery, including:
  - pre-operative CT imaging requirements
  - training time and costs
  - surgical and theatre accessories

  - staffing (number and NHS band)
  - total theatre time and total surgical time
  - volume of procedures per day and
  - implant costs.
- Post-surgery treatment and service use, including:
  - length of hospital stay
  - readmission rates
  - number of physiotherapy sessions and
  - revision rates (stratified by implant type).
- All costs associated with the immediate consumables and resourcing and with post-surgery treatment and services.

Subgroup analyses

Data could be stratified by:

- patient characteristics including age, sex, gender, BMI and ethnicity
- where in the country the procedure was done
- volume of procedures
- people from Southeast Asian backgrounds
- pre-existing medical conditions
- people having more complex surgeries, such as alternative alignment approaches
- physical status as defined by American Society of Anaesthesiologists risk scores.

Other important covariates should be chosen with input from clinical specialists to support subgroup analysis.

Safety

- Adverse events, including conversion to manual surgery and dislocation.
- Consequences of additional radiation exposure if more imaging is needed.

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 evidence studies.

3.5 Evidence generation period

This will be 3 years to allow for setting up, implementation, data collection, analysis and reporting.

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 technology 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

The committee heard that the robot-assisted surgery (RAS) technologies may improve patient outcomes and improve surgical efficiencies, although evidence for this is uncertain. All the technologies that have been recommended for use in the NHS during the evidence generation period have some implementation experience in the NHS. The companies did not report any safety concerns for using RAS for knee or hip replacements and this was supported by expert opinion and the identified evidence. The committee agreed and concluded that the safety of RAS for orthopaedic procedures should be monitored as per post-market surveillance.

The committee has indicated that it may in the future be able to recommend new technologies in this topic area if there is evidence on both:

- non-inferiority of the RAS technology compared with conventional surgery for orthopaedic procedures (for primary outcomes including length of hospital stay, complications, patient-reported outcome measures, utilities and revisions), and
- cost or time-savings resulting from resource use associated with the technologies.

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.

System considerations

- Different leasing options for each technology may be negotiable based on procedural volume and contract duration.
- The robotic technologies included in the assessment are 'closed' systems, which means they only work with implants made by the same manufacturer. Financial commitment to 1 robotic technology may limit the choice of implants available at that hospital. This should be considered when choosing to adopt specific systems.
- The National Joint Registry (NJR) does not cover all parts of the UK, for example, procedures done in Scotland are not included.

Evidence generation

- The published economic evaluations based on real-world evidence had to adjust for observed differences in patient characteristics between robot-assisted surgery (RAS) and conventional surgery arms (including age and body mass index). So, future analysis should account or adjust for all important differences in population characteristics between RAS and conventional surgery.
- Issues with data quality may impact analysis. Clear reporting about data quality is important and approaches such as multiple imputation could be used to address them.
- The ergonomic benefit to surgeons and their career longevity may be difficult to capture.
- The impact of RAS on the development of the manual skills of trainees is unknown. Competency is reviewed through peer-review and reported in NJR audits, but may not detail if the operation was performed by a trainee.
- The NJR has expressed a willingness to explore opportunities to link intraoperative

metadata from the robotic systems with the NJR. Further information about the effectiveness of RAS systems should be linked to the NJR and continue to be collected after the period of evidence generation.

- Companies may improve their chances of a getting a recommendation in future assessments by also collecting data on other outcomes relevant to other national organisations, for example, data on returning to work and normal activities.

Equalities

- Robotic systems are more widely adopted in the private sector, which could drive health inequalities if they show promise in improving patient outcomes and are not adopted by the NHS.
- Access to RAS may be restricted to people who live near larger specialist centres or high-volume centres that can afford the technology. Experts said that the geographical placement of additional robotic systems, and the availability of training, resources and staff to implement RAS services could worsen these disparities. These concerns were reiterated by patient organisations and patient expert feedback. The NHS England RAS steering group may be influential in moderating this with national strategy going forward. It is actively analysing and mapping current RAS provision in England. A key priority will be equitable provision of RAS based on need rather than current configuration.
- Having limited access to RAS in the NHS may drive health inequalities, worsening the post-code lottery, particularly for people living in deprived areas, or if the technology is more widely adopted in private healthcare systems.
- RAS is not suitable for several subgroups, but people in these groups would still have access to conventional surgery. Manual skills will be maintained for these people and for conversion surgery.

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