NICE National Institute for Health and Care Excellence

NICE guidance

Robot-assisted surgery for soft tissue procedures: early value assessment

HealthTech guidance
Published: 17 April 2025

www.nice.org.uk/guidance/htg742

Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces HTE21.

1 Recommendations

These recommendations do not include robot-assisted surgery for prostatectomy. Robot-assisted surgery for prostatectomy is established practice in the NHS, so this procedure was excluded from the scope of this early value assessment.

1.1 Five technologies can be used in the NHS during the evidence generation period as options for robot-assisted surgery for soft tissue procedures. The technologies are:

- Da Vinci SP
- Da Vinci X and Xi
- Hugo robotic-assisted surgery system
- Senhance Surgical System
- Versius Surgical System.

These technologies can only be used:

- if the evidence outlined in the evidence generation plan for robot-assisted surgery for soft tissue procedures is being generated
- once they have appropriate regulatory approval including NHS England's Digital Technology Assessment Criteria (DTAC) approval.

1.2 The companies must confirm that agreements are in place to generate the evidence. They should contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may revise or withdraw these guidance if these conditions are not met.

1.3 At 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 the evidence and assess if the technology can be routinely adopted in the NHS.

What evidence generation is needed

More evidence needs to be generated on:

- the learning curve for the surgeon and centre
- resource use for robot-assisted surgery services:
  - set up, including staff training
  - delivery, including staffing, technology maintenance, additional training and consumables
  - number of procedures and robot use
- costing structures to procure and implement a robotic system
- the effect on outcomes including:
  - rates of conversion to open surgery
  - length of hospital stay
  - complications
  - health-related quality of life
  - procedure-related discomfort and ergonomics for the surgeon
  - rates of minimally invasive surgery compared with open surgery after introduction of robot-assisted surgery into a centre
  - hospital capacity and surgical waiting lists
  - readmissions
  - long-term outcomes for people having robot-assisted surgery.

The evidence generation plan gives further information on the prioritised evidence gaps and outcomes, ongoing studies and potential real-world data sources. It includes how the evidence gaps could be resolved through real-world evidence studies.

NHS England and the Getting It Right First Time (GIRFT) programme have produced a guide to support implementation of this guidance.

Potential benefits of use in the NHS with evidence generation

- **Access:** Robot-assisted surgery for soft tissue procedures may increase access to minimally invasive surgery for some procedures and some groups of people.
- **System benefit:** Some features of robotic systems may make it easier for surgeons to train to do minimally invasive surgery. All the technologies allow the surgeon to sit at a console to control surgical tools during the procedure. This may mean that more surgeons can do more physically and ergonomically challenging procedures, and that these procedures are easier to do. Also, it may enable surgeons to work for more years because work is less physically demanding.
- **Clinical benefit:** Evidence suggests that robot-assisted surgery for soft tissue procedures is generally comparable with standard minimally invasive surgery for a range of clinical outcomes. Some evidence shows that length of hospital stay is shorter compared with open surgery and may be shorter than some standard minimally invasive procedures.
- **Resources:** These technologies are likely to reduce length of hospital stay for some procedures and may reduce surgical waiting lists and need for additional treatment after surgery.
- **Equality:** Minimally invasive surgery may not be suitable for some groups of people without using robot-assisted surgery. This can depend on the type of procedure and a mix of factors such as age and comorbidities.

Managing the risk of use in the NHS with evidence generation

- **Training:** All members of the surgical team must be trained on each robotic system that they use. There is a surgeon and centre learning curve associated with robot-assisted surgery. Patient outcomes and service efficiency may not be maximised until the end of the learning curve.
- **Costs:** Early economic modelling shows that robot-assisted surgery for soft tissue procedures could be cost effective in the long term, depending on some assumptions (see sections 3.17 to 3.19). It is more likely to be cost effective when it replaces open surgery. There are substantial budgetary costs to introduce a

robot-assisted surgery service to a centre, like the cost of purchasing and maintaining the technology. There are different costing structures available, which may affect cost effectiveness and feasibility of acquisition. This guidance will be reviewed after the evidence generation period (3 years) and the recommendations may change. Centres should take this into account when negotiating the length of contracts and licence costs.

- **Resource:** There may be resource implications when staff who provide open and standard minimally invasive surgery services train in robot-assisted surgery.
- **Technology selection:** All technologies are systems used to do soft tissue surgical procedures. But the technologies have differences in their indications for use, physical features, capabilities, costs and available costing structures. Each centre should consider the benefits and limitations of each for their intended use case and budget.
- **Equality and access:** Minimally invasive surgery is done less frequently in the most deprived areas of the NHS than the least deprived. Also, there has been a lower uptake of robot-assisted surgery in some parts of England and most high-volume centres are based in and around London. The geographical placement of robotic systems, and the availability of training, resources and staff to implement robot-assisted surgery services for soft tissue procedures, could worsen equalities issues. An NHS England robot-assisted surgery steering group has been assembled to address some of these challenges.

2 The technologies

2.1 Robotic technologies for soft tissue procedures are used in operating theatres. For this assessment, they were defined as a technology that enables robot-assisted surgery for multiple interventional surgical procedures. They have one or more mechanical arms to which a small camera (endoscope) and surgical instruments are attached. The surgical instruments are wristed, meaning they can move like the human hand but with more range. The surgeon controls the apparatus from a remote console during the procedure.

2.2 Five technologies were identified for this early value assessment. The technologies have different features and indications for use, but can all be used to do minimally invasive soft tissue procedures. This includes procedures involving internal organs, the body wall, masses or tumours, and hernias or defects (such as colorectal, general surgery, head and neck, gynaecological and urological procedures). It does not include procedures on bones, or for wider musculoskeletal or neurological conditions. The scope of this assessment does not include robot-assisted surgery for prostatectomy. A table comparing key features and indications for use is included in the external assessment report.

Da Vinci SP (Intuitive Surgical)

2.3 The Da Vinci SP surgical system includes a surgeon console, a patient cart and a vision cart. It is designed to do surgery through 1 point of entry or a natural orifice. Up to 3 instruments and the endoscope are attached to a 1-armed patient cart. There are 4 specially designed surgical instruments that are compatible for use with the system. The surgeon sees inside the body through a closed 3-dimensional high-definition (3DHD) viewer on the surgeon console (only they can see the screen). Other people in the operating theatre can see what the surgeon sees on the vision cart. The vision cart also has functionality to control aspects of the system. The system collects data on usage metrics such as time, date, kinematics and procedure information. The Da Vinci SP surgical system is indicated for breast surgical procedures, endoscopic abdominopelvic, thoracoscopic and transoral otolaryngology in adults, with some exclusions.

Da Vinci X and Xi (Intuitive Surgical)

2.4 The Da Vinci X and Xi surgical systems include a surgeon console, a patient cart and a vision cart. The patient cart has 4 arms that hold the endoscope and up to 3 surgical instruments. Like the Da Vinci SP system, the surgeon console has a closed 3DHD viewer and other people in the operating theatre can view the procedure on the vision cart. The vision cart also has functionality to control aspects of the system. The Da Vinci Xi system has additional functionality to the Da Vinci X system. But, both systems are built on the same arms, use the same vision cart, console and core instruments, and are indicated for the same procedures. The systems collect data on usage metrics such as time, date, kinematics and procedure information. The Da Vinci X and Xi systems have the broadest indications for use of all the technologies in this early value assessment. They can be used for general surgery, gynaecology, thoracoscopic and urology procedures, and nipple-sparing mastectomy with reconstruction, in children and adults. They can also be used for transoral otolaryngology, but this is restricted to benign or malignant tumours classified as T1 and T2 in adults.

Hugo robotic-assisted surgery system (Medtronic)

2.5 The Hugo robotic-assisted surgery system includes a system tower, a surgeon console and arm carts. Up to 4 arm carts can be used at once, each hosting 1 surgical instrument or endoscope. They are designed to be portable between operating theatres. The system tower has a touchscreen interactive display for the surgical team. It enables communication between the surgeon console and the arm cart or carts. The surgeon console has an open 3DHD touchscreen display. If only 1 arm is being used, it can be controlled directly from the bedside using the system tower. The system collects technical and usage data. The Hugo robotic-assisted surgery system is indicated for specified general surgery, gynaecological and urological procedures, in adults when minimally invasive surgery is suitable.

Senhance Surgical System (Asensus)

2.6 Asensus did not provide a submission to NICE for this assessment, so the following description is based on information from publicly available sources and expert input. Up to 4 robotic arms can be used on the Senhance Surgical System, each hosting 1 instrument, or an existing laparoscopic vision system. The system can be used alongside standard laparoscopic trocars. All the Senhance system's instruments are reusable. The surgeon console has an open 3DHD display and integrated eye-tracking camera control that enables the surgeon to move the camera with their natural eye movements. The console also has haptic feedback functionality. Complete information on the indications for use was not publicly available.

Versius Surgical System (CMR Surgical)

2.7 The Versius Surgical System includes a bedside unit with an endoscope, 2 or 3 other bedside units with attachment ports for surgical instruments and a surgeon console with 3D video feed from the endoscope. The video feed on the surgeon console is open, so the surgeon and other people in the operating theatre can see the screen. The units are designed to be portable between operating theatres. The system has data collection capabilities for robot telemetry data, and with patient consent, surgical video and clinical data can be collected. An existing registry stores this data and is accessible to authenticated users through the Versius Clinical Insights app. This can be used by surgical teams to review performance on past surgeries and view registry data. The Versius Surgical System is indicated for colorectal, gynaecological, hepatobiliary, hernia, thoracic, upper gastrointestinal and urological procedures in adults.

Care pathway

2.8 Surgical procedures may be done through open surgery or minimally invasive surgery. Open surgery involves the surgeon making one or more incisions that are often large. Minimally invasive surgery is a method of doing an operation without having to make a large incision. This can be done using tools in a natural orifice or

through a small incision. Laparoscopy, endoscopy and hysteroscopy are common minimally invasive surgery techniques used for soft tissue procedures.

2.9 Robot-assisted surgery is a type of minimally invasive surgery. Robot-assisted surgery is already recommended in NICE's guideline on prostate cancer. The Department for Health and Social Care medical technology strategy and the NHS Health Education England Topol review have also predicted that use of robot-assisted surgery will expand over the next decade. NICE's guideline on prostate cancer and the NHS long-term plan both indicate that robot-assisted surgery supports innovation and improves effectiveness in specific interventions, such as prostatectomy. Because of the guideline recommendation and established practice of robot-assisted surgery for prostatectomy, this procedure was excluded from the scope of this assessment.

The comparator

2.10 The comparator is standard surgical care. This includes open surgery and standard minimally invasive surgery.

3 Committee discussion

The medical technologies advisory committee considered evidence on robot-assisted surgery for soft tissue procedures from several sources, including an early value assessment report, an overview of that report and an addendum to the report by the external assessment group (EAG). Full details are in the project documents for this guidance on the NICE website.

Unmet need and potential benefits

3.1 Access to minimally invasive surgery can depend on the physical characteristics of the person, the type of condition and the type of procedure. Experts said that robot assistance can make minimally invasive surgery an option for some procedures and for people who did not have this option before. Expert opinions and evidence in the external assessment report indicated that improved ergonomics with robot assistance makes it easier for surgeons to do technically challenging surgery. So, some procedures that could only be done through open surgery can now be done using minimally invasive techniques. Also, more surgeons may be able to do more challenging surgery. Experts said that the technologies have made it possible for different specialties to collaborate on complex multidisciplinary procedures. Experts said that the groups of people that minimally invasive surgery could become available to will vary between specialties and procedures. But, experts gave examples such as people with multimorbidity, people with high body mass index, and people needing complex surgery or neoadjuvant treatment. Experts said that hospitals with robotic systems and training programmes may attract candidates for surgical training.

Implementation

3.2 The committee noted that a wider NHS England robot-assisted surgery steering group is coordinating national strategies for training, procurement and implementation of robot-assisted surgery services, and guidance on surveillance of robot-assisted surgery programmes. The committee highlighted that national strategy from the steering group on the procurement and implementation of new

robotic systems may reduce inequalities to access (see section 3.10).

3.3 Many centres already have a robotic system and most of the technologies included in this assessment are already used in the NHS. The committee noted that some centres will be newly introducing a robotic system. Many centres will aim to maximise benefits from existing robotic systems, and some may aim to expand their robot-assisted surgery service. The NHS England robot-assisted surgery steering group has noted that there is rapid adoption in some specialties such as colorectal and gynaecological surgery. But, adoption and expansion are unequally distributed across the UK and across specialties. A coordinated approach to provide for future demand is part of the remit of the NHS England robot-assisted surgery steering group.

Technical considerations

3.4 The committee noted that the included technologies have different indications for use. Currently, only the Da Vinci X and Xi systems are indicated for use in children. NHS centres should only use the technologies within their specified indications for use and with appropriate regulatory approval including Digital Technology Assessment Criteria (DTAC) approval. The scope for this assessment does not include robot-assisted surgery for prostatectomy. Experts said that the robotic systems have different physical features and capabilities that may make some more suited to particular procedures. The EAG said that the economic analysis represented 3 different costing structures to procure a robotic system (upfront, leasing and free-loan). But it made the committee aware that other costing structures are available. The EAG said there was little information available on costing structures other than upfront costing.

Training

3.5 Training for the whole surgical team is essential for each robotic system being used in each centre. The team will also need to be able to convert robot-assisted procedures to other surgical techniques. Experts said that while basic robotic skills can be delivered in a device-agnostic way, more advanced training is system-specific and training in 1 system cannot be directly transferred to

another. Retraining is also needed when there are developments in the technology, which may come at additional cost. But, experts said that people who are trained in 1 robotic system may learn how to use another robotic system more quickly. Companies said that most training costs are included with the cost of the robot, but if additional teams need training after initial training has been completed, this is sometimes not included. Experts said that there may be enough experience in the existing team to train additional staff or teams within a centre.

3.6 Experts said that training to do minimally invasive surgical procedures may be better with robot assistance than for standard minimally invasive techniques like laparoscopy. Experts said that digital and hardware features support this. For example, many systems have virtual training environments. Experts also said that the Da Vinci systems have dual console capabilities so the lead surgeon and a trainee can operate the tools at the same time during a procedure. But, some experts said there may be few opportunities for registrars to do surgical procedures alongside the lead surgeon because they may not be needed for the procedure.

3.7 Training for robot-assisted surgery is not currently part of the national trainee curriculum for most specialties. Experts said that the learning curve extends beyond formal training, and that clinical outcomes and efficiencies would not be maximised until the end of the surgeon and centre learning curve was reached. The committee noted that creating or standardising national training curricula for robot-assisted surgery may fall under the remit of the NHS England robot-assisted surgery steering group (see section 3.2).

3.8 Some experts said that loss of surgical skills in open surgery or other minimally invasive techniques may be a concern. But, evolving national curricular and training programmes should mitigate this.

Resourcing

3.9 Experts said that the number of staff needed to do robot-assisted surgery is usually the same as other surgical techniques, but the composition and expertise of the team may be different.

Equality considerations

3.10 In NHS practice, minimally invasive surgery is done less often in areas of the country that are more deprived than in those that are less deprived. Also, there has been lower uptake of robot-assisted surgery in some areas of the UK than others. The highest volume centres are mostly in or around London. Experts said that the geographic placement of additional robotic systems, and the availability of training, resources and staff to implement robot-assisted surgery services for soft tissue procedures, could worsen these disparities. These concerns were reiterated by patient organisation and patient expert feedback. The NHS England robot-assisted surgery steering group may be influential in moderating this with future national strategy. It is 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.

Patient considerations

3.11 Responses from 5 patient organisations said that shorter length of stay, faster recovery, and faster return to work and usual activities were among the key perceived benefits of robot-assisted surgery among patients. Patients believe that robot-assisted surgery could widen access to minimally invasive surgery. Also, patients reported experiencing fewer side effects, and less pain and scarring. Patient experts reiterated these points in the committee meeting.

3.12 Patient organisations and experts said that the main concerns were around access to robot-assisted surgery, including the need to travel and wait times if there are not enough robots available. They reflected the potential of these factors to exacerbate health inequalities. Also, patient organisation submissions and patient experts said that clear and transparent information about robot-assisted surgery and reassurance about quality assurance was needed because it is an unfamiliar method of surgery. The patient organisations and the patient experts were aware of the high cost of the technologies and saw this as a concern.

Clinical effectiveness

3.13 The EAG did literature searches across 8 databases and 2 clinical trial registries for studies that named eligible technologies. A total of 492 full texts were retrieved and examined. In addition, 62 relevant studies identified from company submissions were considered. The EAG prioritised studies most relevant to the UK on a per-technology basis as outlined in the protocol for this assessment. They prioritised comparative studies, done in the most UK-relevant contexts, that explicitly assessed the technologies in scope. Twenty comparative studies were prioritised for assessment:

- 1 UK-based randomised controlled trial (RCT)
- 5 non-randomised prospective studies
- 4 historically controlled cohort studies
- 10 retrospective cohort studies, including 2 done in the UK.

Evidence for all 5 technologies was included in the EAG report, but the amount of evidence per technology differed. Most of the evidence (13 out of 20 studies) was for Da Vinci X and Xi. The committee noted that this technology has been in use the longest and is currently the most used in the UK. The Senhance Surgical System was used in 2 studies, whereas the Hugo robotic-assisted surgery system, Versius Surgical System and Da Vinci SP were used in 1 study each. The EAG noted that, in the prioritised evidence, there was only 1 RCT, few studies were done in the UK and the studies were small. All the prioritised evidence compared the technology against laparoscopic surgery or open surgery. Colorectal, hernia repair, gastrointestinal, gynaecological, pancreatic, testicular and urological surgical procedures were represented in the prioritised evidence. The EAG noted that none of the studies explored the generalisability of clinical findings across different specialties. The committee heard from experts that robot-assisted surgery practices differ in the UK compared with Europe and the US, so evidence from those regions may not be generalisable to the NHS.

3.14 Experts said that the effect of learning curve on outcomes was the most important factor that limited interpretation of the evidence and generalisability of

findings. Experts said evidence from outside the UK may be useful to understand clinical outcomes from surgeons and centres that are further along the learning curve. But, they said evidence from outside the UK on the learning curve itself may be less relevant. This is because the time taken to move along the learning curve is affected by opportunity and volume of surgery, which differs between the UK and other countries. Experts said there may be limited generalisability for outcomes between procedures in different specialties and studies. For example, length of hospital stay may depend on factors unrelated to the surgical technique used.

3.15 The committee commented that there was little evidence in paediatric groups. It noted that only 1 technology is indicated for use in children (Da Vinci X and Xi). Experts said that fewer UK centres currently use robot-assisted surgery in children compared with adults.

3.16 Experts noted that there is additional evidence that did not meet the EAG's search and inclusion criteria. In response to a call to experts and companies for additional evidence that could fill evidence gaps in the report, the EAG included 10 additional studies in an addendum to its report:

- 5 RCTs
- 1 RCT with economic analysis
- 1 large real-world database study
- 1 case-control survey of surgeon ergonomics
- 1 matched cohort study
- 1 retrospective comparative study.

The studies either did not specify which robot was used (but the model could be inferred given the date and location of the study), or used older models of the robotic systems included in the scope of this assessment. The EAG also reviewed and summarised 17 recent systematic reviews. The committee considered the evidence in the addendum and concluded that the additional evidence generally supported the findings of the 20 prioritised studies. This was that robot-assisted surgery is generally comparable with standard

minimally invasive surgery across a range of outcomes.

Costs and resource use

3.17 The EAG developed a cost-comparison model to investigate the potential benefit of robot-assisted surgery over a 1-year time horizon. It explained that modelling a longer time horizon would be associated with substantial uncertainty because of the differences in procedures, populations and surgical settings. But, the EAG did a scenario analysis to investigate the long-term benefit needed for robot-assisted surgery to be cost effective. The committee agreed that the EAG's approach was suitable for modelling multiple procedures and populations in light of the uncertainty for most outcomes. Over a 1-year time horizon, the cost-comparison base case and scenario analysis found that robot-assisted surgery for soft tissue procedures was likely to be cost-incurring. But, the scenario analysis indicated that it could plausibly become cost effective if robot-assisted surgery led to long-term quality-adjusted life year (QALY) gains. The EAG and experts emphasised that the range of scenario analyses should be considered carefully alongside the base case because the scope included a wide variety of potential procedures, patients, robot utilisation and costing structures.

3.18 In the base case, the technologies were estimated to increase healthcare costs. These were driven by the upfront cost of the robot and additional consumable equipment needed to do the procedures. Short-term costs that could be reduced by robot-assisted surgery (for example, from reduced complications, readmissions and surgery conversions) were not considered likely to outweigh the cost of using the technologies. All short-term scenarios led to cost-incurring results, but results were more favourable when robot-assisted surgery replaced open surgery instead of standard minimally invasive surgery. See section 8.3.1 of the report for more details on the scenario analysis. One-way sensitivity analysis showed that the key drivers of the model were likely:

- proportion of surgeries that were open surgery, standard minimally invasive surgery and robot-assisted surgery
- length of surgery

- conversion rates to open surgery
- disposable component costs for robot-assisted surgery.

3.19 In the long-term scenario analysis, the EAG found that if people who had robot-assisted surgery gained at least 0.1 QALYs (equivalent to 36.5 days in full health) compared with other surgery, then robot-assisted surgery could plausibly be cost effective. Experts generally agreed that this was feasible over a longer-term time horizon than 1 year. Some experts said that it may be more feasible in some specialties and procedures than others. This is because the gains would likely come from reduced severity of disease or reduced disease progression. Long-term clinical benefits, reduced operation times and high use of the robot when it has been purchased outright or leased would also make long-term cost-effectiveness more likely. The EAG said that benefits may have been underestimated if data used to populate the model was more representative of surgeons and centres that were still on the learning curve, rather than those that were operating at the end of their learning curve.

Differences in costs between robotic systems

3.20 The cost of the robot was a key driver of the base-case findings. The EAG investigated 3 cost structures (upfront, leasing, free-loan) and all were cost-incurring in the short-term. Robot-assisted surgery was least cost-incurring with the leasing cost structure, and most cost-incurring with a free-loan cost structure, because of higher costs per procedure. But, this was based on assumptions and limited data for the leasing and free-loan costing structures. There was good data to support analysis with an upfront costing structure. The committee noted that alternative costing structures not captured in the analysis may be available to centres, which might also affect affordability and cost effectiveness.

3.21 The EAG noted that there are differences in per-procedure costs between robotic systems and between different procedures. Some surgical instruments used on the robotic arms are single-use and some are reusable. This can vary between individual instruments and across robotic systems. While increased utilisation of the technology was found to make cost effectiveness more likely, budgetary

costs would also increase because of per-procedure costs.

3.22 The EAG noted that a fixed life cycle for the systems was factored into the model, and this was varied in a sensitivity analysis. Companies informed the committee that centre-level agreements for the upgrade or maintenance work needed to continue using the platform may be negotiated with manufacturers in practice.

Evidence gap review

3.23 The committee concluded that there was enough evidence of a potential benefit of robot-assisted surgery technologies for soft tissue procedures for them to be used in the NHS while further evidence is generated. The main evidence gaps for soft tissue procedures (excluding prostatectomy) are:

- **Learning curve**: The EAG noted that most studies did not clearly report the level of surgeon and centre experience of using the robotic system, or adjust for it. Learning curve was characterised or measured in different ways when studies did report it. Experts emphasised that differences in findings across a range of outcomes may be attributable to the surgeon and centre learning curve. The EAG noted that potential cost effectiveness may be underestimated if surgeons and centres were operating on the learning curve during the study.
- **Resource use**: There was little information on the costs of setting up and training staff for a robot-assisted surgery service for soft tissue procedures. This will likely vary depending on the mixture of procedures being done. Also, resource use during surgery including healthcare professional resource and consumables was difficult to quantify.
- **Costing structures to procure a robotic system**: There was little information on available costing structures to model cost effectiveness, other than for upfront cost for each system. Costing structures other than the 3 modelled in the EAG's analysis may be available to trusts. Costs of the robotic system and consumables drove incremental costs associated with robot-assisted surgery in the base-case analysis.
- **Outcomes**: The prioritised studies did not have evidence for some outcomes

listed in the scope of this assessment. Little or no evidence was available for:

- health-related quality of life
- procedure-related discomfort and ergonomics for the surgeon
- rates of minimally invasive surgery compared with open surgery after centres introduce robot-assisted surgery
- volume of procedures and robot utilisation
- hospital capacity and wait list reduction, and
- long-term outcomes, including:
  - return to normal activities
  - survival and
  - need for revision surgery.

    Limited data on some of these outcomes may have limited the economic model. Also, rates of conversion to open surgery, complications, and outcomes including length of hospital stay and health-related quality of life were key drivers in the economic model. Robust evidence, adjusted for learning curve, is needed on these outcomes.

- **Surgeon experience:** Evidence on ergonomics for the surgeon and procedure-related discomfort (for example, using the SURG-TLX outcome measure) will help the committee understand how the technologies are benefitting surgeons.

The committee concluded that further evidence should be generated to address the identified evidence gaps. Specialist committee members noted that it should be clear from the evidence which robotic system has been used. The committee noted that head-to-head studies may be difficult to do. Experts explained that whenever this is the case, other study designs, including non-inferiority studies, can be considered. The committee noted the potential of using real-world data for evidence generation. It also noted

the potential benefits for the NHS of collecting long-term evidence across different robot-assisted surgery platforms at the system level, such as through a national registry.

3.24 Experts made the committee aware of 3 ongoing UK trials on robot-assisted surgery that may have relevant data to contribute to a future assessment:

- The REINFORCE trial, a real-world, in-situ trial evaluating the introduction and scale-up of robot-assisted surgical services in the NHS, and its impact on clinical and service delivery, effectiveness and cost. This is a stepped-wedge randomised trial with process evaluation and economic evaluation (NIHR131537).
- The MASTERY study measuring the quality of surgical care and setting benchmarks for training using Intuitive Data Recorder technology (ISRCTN 273555).
- The MAYFLY study assessing the clinical, economic and efficiency outcomes of using robot-assisted surgery for outpatient procedures in England (IRAS ID 327536).

4 Committee members and NICE project team

Committee members

This topic was considered by NICE's medical technologies advisory committee, which is a standing advisory committee of NICE.

Committee members are asked to declare any interests in the technologies to be evaluated. If it is considered there is a conflict of interest, the member is excluded from participating further in that evaluation.

The minutes of each committee meeting, which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

Additional specialist committee members and professional experts took part in the discussions and provided expert advice for this topic.

Specialist committee members

David Chuter
Lay member

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NICE project team

Each evaluation assigned to a team consisting of 1 or more health technology analysts (who act as technical leads for the topic), a technical adviser, a project manager and an associate director. An evidence generation team lead and implementation team lead were also assigned for this topic.

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Technical analysts

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Update information

Minor changes since publication

December 2025: Health technology evaluation 21 has been migrated to HealthTech guidance 742. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-7692-8