

CONFIDENTIAL UNTIL PUBLISHED

**NATIONAL INSTITUTE FOR HEALTH AND CARE
EXCELLENCE**

EARLY VALUE ASSESSMENT PROGRAMME

Early value assessment guidance consultation document

**Robot-assisted surgery for orthopaedic
procedures: early value assessment**

Guidance development process

Early value assessment (EVA) guidance rapidly provides recommendations on promising health technologies that have the potential to address national unmet need. NICE has assessed early evidence on these technologies to determine if earlier patient and system access in the NHS is appropriate while further evidence is generated.

The medical technologies advisory committee has considered the evidence and the views of clinical and patient experts. EVA guidance recommendations are conditional while more evidence is generated to address uncertainty in their evidence base. NICE has included advice in this guidance on how to minimise any clinical or system risk of early access to treatment.

Further evidence will be generated over the next 2 years to assess if the benefits of these technologies are realised in practice. NICE guidance will be reviewed to include this evidence and make a recommendation on the routine adoption of this technology across the NHS.

This document has been prepared for public consultation. It summarises the evidence and views that have been considered, and sets out the recommendations made by the committee. NICE invites comments from registered stakeholders, healthcare professionals and the public. This document should be read along with the [evidence](#).

CONFIDENTIAL UNTIL PUBLISHED

The advisory committee is interested in receiving comments on the following:

- Has all of the relevant evidence been taken into account?
- Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?
- Are the recommendations sound, and a suitable basis for guidance to the NHS?

Equality issues

NICE is committed to promoting equality of opportunity, eliminating unlawful discrimination and fostering good relations between people with particular protected characteristics and others. Please let us know if you think that the recommendations may need changing to meet these aims. In particular, please tell us if the recommendations:

- could have a different effect on people protected by the equality legislation than on the wider population, for example by making it more difficult in practice for a specific group to access the technology
- could have any adverse effect on disabled people.

Please provide any relevant information or data you have about such effects and how they could be avoided or reduced.

Note that this document is not NICE's final guidance on robot-assisted surgery for orthopaedic procedures. The recommendations in section 1 may change after consultation.

After consultation, NICE will consider the comments received. The final recommendations will be the basis for NICE's early value guidance.

Key dates:

Closing date for comments: 07/01/2025

1 Recommendations

Can be used while more evidence is generated

1.1 Five technologies can be used in the NHS during the evidence generation period as an option for robot-assisted surgery for knee or hip replacements in children, young people and adults. The technologies are:

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

These technologies can only be used:

- if the evidence outlined in the evidence generation plan 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 (as outlined in [NICE's evidence generations plan](#)). They should contact NICE annually to confirm that evidence is being generated and analysed as planned. NICE may withdraw the guidance if these conditions are not met.

1.3 At the end of the evidence generation period (2 years), the company should submit the evidence to NICE in a form that can be used for decision making. NICE will review the evidence and assess if the technology can be routinely adopted in the NHS.

Can only be used in research

- 1.4 More research is needed on SkyWalker for robot-assisted surgery for knee or hip replacements in children, young people and adults before it can be used in the NHS.
- 1.5 Access to SkyWalker should be through company, research, or non-core NHS funding, and clinical or financial risks should be appropriately managed.

What evidence generation and research is needed

- 1.6 Evidence generation and more research is needed on:
- health-related quality of life, including patient-reported outcome measures
 - immediate consumables and resourcing associated with surgery, including:
 - preoperative 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).
 - characteristics of people having the procedure, such as age, body mass index and American Society of Anesthesiologists risk score
 - population subgroups, such as people from Southeast Asian backgrounds

CONFIDENTIAL UNTIL PUBLISHED

- where in the country the procedures are done.

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.

Potential benefits of use in the NHS with evidence generation

- **Access:** While conventional orthopaedic surgery is widely available, robot-assisted orthopaedic surgery is currently limited to a small number of hospitals in the UK. If future evidence shows that robot-assisted surgery improves patient outcomes, it could be more widely implemented across the UK. This would allow more people the choice of conventional or robot-assisted orthopaedic surgery.
- **System benefit:** A key benefit of robot-assisted surgery is the precise positioning of the implant. This allows the surgeon to position and align the implants in the correct position for each person. An individualised approach to surgery may improve patient satisfaction following surgery and reduce the demand for revision surgery.
- **Clinical benefit:** Clinical evidence comparing robot-assisted surgery with conventional surgery suggests that improvements in patient-reported outcomes and complications are similar. Implant alignment was consistently better with robot-assisted surgery than with conventional surgery. But the committee was uncertain about the best way to measure alignment and if better alignment results in better clinical outcomes.
- **Resources:** More accurate joint replacement may improve patient satisfaction and shorten recovery time, reducing the need for follow-up appointments with GPs, surgeons and physiotherapists, and the prescription of pain management medicines.
- **Equality:** Robot-assisted surgery may improve access to surgery for people who are at higher risk. This includes older people and people with a high body-

mass index or multimorbidity. People from Southeast Asian backgrounds may also experience greater benefits from robot-assisted surgery for knee replacements due to anatomical differences that can result in poor alignment with conventional surgery.

Managing the risk of use in the NHS with evidence generation

- **Training:** All members of the surgical team must be trained on each robotic technology 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 was based on the limited evidence available including utility values with a high degree of uncertainty. Results from the modelling were highly sensitive to the utility values used. For total or partial knee arthroplasty, the results suggest the technologies in this guidance are not likely to be cost-effective and for total hip arthroplasty, the CORI and Mako platforms may be cost-effective. For a robust economic assessment more evidence is needed to inform the parameters for each technology. This guidance will be reviewed within 2 years and the recommendations may change. Take this into account when negotiating the length of contracts and licence costs.
- **Patient outcomes:** Experts and the identified evidence suggest that adverse events are rare and unlikely to differ between robot-assisted surgery and conventional surgery. But, adverse events should still be captured in future evidence to ensure the safety of robot-assisted surgery in the NHS.
- **Equality:** Robot-assisted surgery may not be suitable for people with mental or neuromuscular conditions, conditions affecting joint articulation or, with some technologies, people who are pregnant or have kidney disorders. Conventional surgery may be more appropriate for these people.
- **Access:** Introducing robot-assisted surgery could potentially increase geographic inequalities in the availability of surgery. Regional adoption should be monitored to ensure access to robot-assisted surgery is not limited to

people living in central locations where there are high-volume centres. An NHS England robot-assisted surgery steering group has been assembled to address some of these challenges.

2 The technologies

- 2.1 Robot-assisted surgery is a type of surgery where robotic technologies are used to support the work of the surgeon. These technologies provide real-time imaging and feedback, allowing joint replacement procedures to be done with more precision, flexibility and control than is possible with conventional techniques. Robotic technologies vary in their functionality, imaging requirements, and compatibility with implants. All technologies in this evaluation are 'closed', which means they can only be used with implants made by the company that makes the robotic technology. This is as opposed to technologies that are 'open', which can be used with different implants.
- 2.2 Six technologies were identified for this early value assessment. Recommendations were made for all 6 technologies. Technology characteristics are summarised in table 1.

ApolloKnee System (Corin)

- 2.3 The ApolloKnee robotic-assisted surgical platform is indicated for total knee arthroplasty (TKA) and replaces the OMNIBotics System. This technology includes BalanceBot technology, which captures soft tissue data through a full range of motion to help with alignment and balancing of the knee. No preoperative imaging is needed and the platform is directly affixed to the person having surgery via a fixation system, using indirect cutting that aligns with a guide.

CORI Surgical System (Smith+Nephew)

- 2.4 The CORI Surgical System is indicated for primary TKA, partial knee arthroplasty (PKA) and total hip arthroplasty (THA), as well as total knee revision. It replaces the NAVIO Surgical System. This technology is handheld and allows image-free 3D modelling of the joint in surgery. It requires the surgeon to directly cut the bone with boundary control provided by the system.

Mako SmartRobotics (Stryker)

- 2.5 The Mako SmartRobotics system is indicated for TKA, PKA and THA. This technology requires a preoperative CT scan that is sent to a specialist to create a patient bone model. This is uploaded to the system to guide the surgeon. The technology uses an arm-based cutting tool attached to a moveable base station and requires the surgeon to directly cut the bone with haptic boundary control provided by the system.

ROSA Knee System (Zimmer Biomet)

- 2.6 The ROSA Knee System is indicated for TKA. This technology has optional preoperative imaging that can assist with placement of the robotic arm. The technology provides intra-surgery feedback, uses an arm-based cutting tool attached to a moveable base station and uses indirect cutting that aligns with a guide.

SkyWalker (MicroPort MedBot)

- 2.7 The SkyWalker system is indicated for TKA and THA. This technology requires a preoperative CT scan for planning. It uses an arm-based cutting tool attached to a moveable base station and requires direct cutting.

MicroPort MedBot did not respond to requests for information but informed NICE that the SkyWalker system is being prepared for introduction to the NHS.

VELYS Robotic-Assisted Solution (Johnson & Johnson)

2.8 The VELYS Robotic-Assisted Solution is indicated for TKA. This technology provides intra-surgery feedback and imaging, uses an arm-based system that is attached to a base station and requires direct cutting with boundary control provided by the system.

Table 1 Characteristics of the technologies

Technology (company)	Indications	Robotic arm or handheld	Direct or indirect cutting	Image-based or imageless	Open or closed system
ApolloKnee (Corin)	TKA	Robotic arm	Indirect	Imageless	Closed
CORI (Smith+Nephew)	TKA, PKA, THA, revision TKA	Handheld	Direct	Imageless	Closed
Mako SmartRobotics (Stryker)	TKA, PKA, THA	Robotic arm	Direct	Image-based	Closed
ROSA Knee (Zimmer Biomet)	TKA	Robotic arm	Indirect	Imageless	Closed
SkyWalker (MicroPort MedBot)	TKA, THA	Robotic arm	Direct	Image-based	Closed
VELYS (Johnson & Johnson)	TKA	Robotic arm	Direct	Imageless	Closed

Abbreviations: THA, total hip arthroplasty; TKA, total knee arthroplasty; PKA, partial knee arthroplasty.

Care pathway

2.9 The technologies are indicated for knee or hip joint replacements, which are the most common orthopaedic procedures done in the NHS. Knee and hip joint replacement surgery involves replacing damaged parts, or the whole, of the knee or hip joint with metal or plastic implants. The most common reason for a joint replacement is osteoarthritis. Other less-common causes include, but are not limited to, rheumatoid arthritis, gout and injuries, all of which result in joint pain, stiffness or both. In the past year there were about 125,000 knee procedures and over 100,000 hip replacements done in the UK (1). The [Royal College of Surgeons' \(RCS\)](#)

Field Code Changed

CONFIDENTIAL UNTIL PUBLISHED

[Future of Surgery report](#) predicted that the rapid expansion of robot-assisted surgery across the UK will increase access for many people.

- 2.10 The [NICE guideline on joint replacement \(primary\): hip, knee and shoulder](#) describes the current care pathway. Conventional surgery relies on 2-dimensional X-ray images that allow surgeons to map the target site for the implant and what it will look like after implantation. Extra- or intra-medullary jigs (guides) are used to make cuts at a predetermined angle. The cuts are made by the surgeon, removing the damaged part of the bone using a manually controlled saw. Once removed, implants are aligned and manually placed over the cuts, using guides and tools to achieve the best fit. The process is reliant on a surgeon's skill and judgement, and this may result in variations in precision and alignment.

The comparator

- 2.11 The comparator is conventional surgery using manual techniques. Some surgeons may use computer-assisted navigation to help with orthopaedic procedures, but this is not standard care in the NHS so it was not included as a comparator.

3 Committee discussion

[NICE's medical technologies advisory committee](#) considered evidence on 6 technologies for robot-assisted surgery in orthopaedic procedures from several sources. These include an early value assessment report by the external assessment group (EAG), and an overview of that report. Full details are in the [project documents for this guidance on the NICE website](#).

Unmet need and potential benefits

- 3.1 The [NHS Long Term plan \(2019\)](#) identified musculoskeletal conditions as one of the key long-term conditions responsible for a substantial amount of poor health in the population. Since 2019, musculoskeletal problems have been among the top 3 reasons for sickness absence in the UK, and

CONFIDENTIAL UNTIL PUBLISHED

in 2022 this equated to 19.5 million workdays ([Office for National Statistics report on sickness absence in the UK labour market: 2022](#)). Despite the high volume of orthopaedic procedures being done in the UK, satisfaction with procedures is low. [NHS data on patient-reported outcome measures for hip and knee replacement procedures \(2021-2022\)](#) reported that 64.5% and 77.6% of people rated satisfaction with knee and hip replacements, respectively, as 'excellent' or 'very good'. Commonly cited causes of dissatisfaction include persistent pain, stiffness and unmet expectations of the operation ([DeFrance and Scuderi 2022](#)). While not always warranting revision surgery, these post-surgery outcomes may negatively affect health-related quality of life. This can lead to more follow-up appointments and increased prescription of pain medication and cause continued disruption to activities of daily living. The main conceptual benefit of robot-assisted surgery is improving the precision of the implant positioning and consistency of the surgeon's work. Robot-assisted surgery allows the surgeon to position the implant relative to the person's native anatomy and joint alignment, with a higher degree of precision and confidence. Conceptually, this will result in better patient outcomes by improving recovery from surgery, reducing pain and stiffness, and allowing a quicker return to activities of daily living. Robot-assisted surgery may enable more knee replacement procedures to be done as partial replacements rather than total replacements. This could improve recovery because partial replacements have fewer complications, shorter recovery times and shorter lengths of stay, as outlined in the [NICE guideline on joint replacement \(primary\): hip, knee and shoulder](#).

Implementation

- 3.2 The committee noted that there is a wider NHS England robot-assisted surgery steering group. The steering group coordinates national strategies for training, procurement and implementation of robot-assisted surgery services, and produces guidance on surveillance of robot-assisted surgery programmes. The committee also noted the [British Orthopaedic](#)

CONFIDENTIAL UNTIL PUBLISHED

[Association's guidance on robotics in orthopaedics](#), which provides a tool kit for hospitals when setting up a new musculoskeletal robotic surgical service.

- 3.3 The committee was aware that some technologies included in this assessment are already being used in the NHS. Clinical experts highlighted that the robotic technology adopted by an NHS trust is likely to be influenced by which implants are already in use for conventional surgery. Trusts are likely to favour technologies made by companies with whom there is an established relationship. The committee was also aware of the widespread use in other countries of robotic technologies, including for indications beyond those in the scope of this assessment. The committee agreed that in the future, developments in technology may influence the selection of robotic technologies by expanding the available indications.

Training

- 3.4 Training for the whole surgical team is essential for each robotic technology used in each centre. The NHS England steering group has formed a subcommittee that is in the process of producing guidance for training as part of its guidance on robot-assisted surgery. Experts said that training is technology-specific but that people who are trained in 1 robotic technology may be quicker to learn how to use other robotic technologies. Companies said that training costs are usually included in the cost of the robotic technology, including when the technology is updated. But, experts noted that training time for NHS staff should be included in the economic model, acknowledging that training will need to be repeated for new staff and to maintain competencies.

Patient considerations

- 3.5 Most people have joint replacement procedures to reduce the pain and stiffness in their joints, which is usually associated with osteoarthritis. Successful joint replacement surgery helps restore function in the affected

joints and allows people to resume daily activities. Clinical experts highlighted that patient dissatisfaction following conventional surgery is quite common, with many people needing ongoing pain medication and other support to help them manage. The experts advised that robot-assisted surgery has potential to improve patient satisfaction. A patient expert spoke of their positive experience of robot-assisted surgery for a knee replacement. The committee agreed that this commentary was helpful to understand the perspectives and experiences of people having robot-assisted surgery. It acknowledged that while this is difficult to capture in research, efforts should be made to better understand patient quality of life after robot-assisted surgery for joint replacement.

Equality considerations

- 3.6 The committee noted that the introduction of robot-assisted surgery may increase the safety of orthopaedic surgery for people at higher surgical risk. Some people may be denied conventional joint replacement surgery because of the associated risk of surgery. This includes older people and people with a high body-mass index or multiple comorbidities. Robot-assisted surgery allows enhanced preoperative planning, potentially reducing the risk of complications in people at higher risk. Experts advised that robot-assisted surgery may improve outcomes for people who need different surgical alignments, such as people with bow-leggedness, which is most common in people from Southeast Asian backgrounds. For some people, robot-assisted surgery may not be possible because of the difficulty of attaching sensors to the bone. These groups were identified by the EAG as people with mental or neuromuscular disorders that affect control of the knee joint, and people with insufficient bone quality or mass. It also noted that people with conditions that prevent full articulation of the hip joint may not be able to have robot-assisted surgery for a total hip arthroplasty (THA). The committee acknowledged that while robot-assisted surgery may not be suitable for everyone, conventional surgery

CONFIDENTIAL UNTIL PUBLISHED

will still be available. This means that everyone who needs joint replacement surgery can have appropriate care.

- 3.7 The committee was aware that robotic technologies are expensive and may not be viable in all centres. Experts told the committee that robotic technologies are most commonly obtained through volume-based contracts, whereby NHS trusts commit to a number of procedures each year. This approach to purchasing means that robotic technologies are more likely to be cost-effective in high-volume orthopaedic centres. The committee was also aware that the high cost of the technologies means that robot-assisted surgery is more widely available in the private sector. The committee noted that limiting access to robot-assisted surgery to these hospitals may exacerbate existing inequalities. The committee also noted that robot-assisted surgery may be more beneficial in complex surgical cases. These cases are typically done in lower volume centres, with more prehabilitation and rehabilitation, as well as more advanced planning because of the associated surgical risks. In the future, the NHS England robot-assisted surgery steering group may be influential in moderating access to robot-assisted surgery with a national strategy. The steering group 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.

Clinical effectiveness

- 3.8 The committee considered evidence for all 6 technologies from 26 publications and 2 national joint registries. The majority of the evidence was in total knee arthroplasty (TKA), with less evidence identified in partial knee arthroplasty (PKA) and THA. Evidence was prioritised by the EAG per robotic technology, to identify data for all primary outcomes per technology. The study designs of the included evidence ranged from randomised controlled trials to retrospective cohort studies. This represents the wide spectrum in the quality of, and the outcomes in, the evidence base for each robotic technology. The EAG's report summarised

CONFIDENTIAL UNTIL PUBLISHED

the limitations of the evidence. The key considerations were a lack of randomised evidence for THA and large variations in the quality and quantity of evidence across all 3 procedures. The committee was reminded of the uncertainties in the evidence that were considered when forming recommendations. The committee agreed that robot-assisted surgery broadly showed non-inferiority with conventional surgery in primary outcomes. These included length of hospital stay, complications, patient-reported outcome measures (PROMs), utilities and surgical revisions. The committee noted that alignment, which was a secondary outcome, was consistently better with robot-assisted surgery. But the evidence did not suggest that this resulted in better PROMs or clinical outcomes.

- 3.9 The key outcomes considered by the committee were PROMs, which is linked to the unmet need. Clinical experts reiterated that patient dissatisfaction was a key issue experienced in clinical practice. This is often because the procedure does not meet people's expectations because they experience continued pain and stiffness after the procedure, which results in the need for further support. PROMs were reported in a number of different ways, using different scales and follow-up times. This limited the ability of the EAG and committee to draw conclusions. Most PROMs showed no difference between robot-assisted surgery and conventional surgery. When statistically significant differences were seen, the benefit tended to be from robot-assisted surgery. But, the committee noted that many of these differences were below the minimally clinically important difference, which limited the certainty of their clinical significance. The committee acknowledged that there were uncertainties in the PROMs data. It suggested that further evidence generation should focus on reducing these uncertainties through larger studies that will inform future economic modelling.
- 3.10 Revisions were also considered to be a key outcome by the committee, because of the negative effect that revision surgery has on health-related

CONFIDENTIAL UNTIL PUBLISHED

quality of life. Revision data was limited in the published clinical evidence because of small sample sizes, short follow-up, and because they are relatively rare events. So the EAG considered data from the National Joint Registry (NJR) to be the most robust and relevant data to the NHS. The NJR did not contain enough robot-assisted surgery procedures to allow comparisons of revision rates to be made with conventional surgery. Additional work with the NJR that links with the NHS's Hospital Episode Statistics, would allow revision rates to be compared between robotic and conventional surgery with long-term follow up. A clinical expert highlighted that the Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) contains separate revision data for robot-assisted surgery and conventional surgery. But this showed no statistically significant difference between surgical methods. Robot-assisted surgery is more established in Australia, so this registry contains more robot-assisted surgery data with longer follow up. The EAG noted that, compared with the NJR data, the population in the AOANJRR data differed in mean age and American Society of Anesthesiologists risk score. The committee considered evidence from both national registries, but accepted that differences between the UK and Australian healthcare systems limit the generalisability of the data from the AOANJRR. The committee concluded that the AOANJRR data was useful in demonstrating the growth of robot-assisted surgery in other countries but was not generalisable to the NHS. So further revision data should be sought from the NJR to inform future economic modelling.

- 3.11 The learning curve was a primary outcome and was discussed by the committee, which deemed it to be a minor clinical concern. The EAG identified multiple single-arm studies for this outcome. They showed that between 6 and 30 cases are needed to achieve proficiency (although the definition of proficiency varied between studies). This was supported by the clinical experts and the companies. The clinical experts explained that learning is usually supported by the company. The committee agreed that

CONFIDENTIAL UNTIL PUBLISHED

the learning curve may have economic implications, but it is not a concern when considering the clinical effectiveness of robot-assisted surgery.

- 3.12 The EAG suggested that improved ergonomics and surgeon quality of life with robot-assisted surgery could be important considerations for surgeon acceptability. Experts did not agree that this was a key benefit of robot-assisted surgery and no consensus was reached on whether the physical and cognitive burden is increased or reduced. The committee agreed that this benefit was plausible, but that the evidence to support it is limited.
- 3.13 The committee noted that the Mako platform had the most mature evidence for all 3 procedures, with randomised controlled trials for knee procedures and prospective evidence for THA. The other 4 technologies that have a conditional recommendation for use during the evidence generation period had less evidence and it was generally lower quality. But the committee was convinced that the evidence was sufficient to support their use. The committee heard that all 5 technologies that have conditional recommendations for use during the evidence generation period are in use or planned to be in use in the UK and will submit data to the NJR. Experts explained that robotic technologies for orthopaedics typically target knee procedures first, before expanding their indications. For this reason, only 3 technologies in this evaluation are indicated for THAs. Experts advised that if an adopted technology's indication was expanded, it is likely that the centre would use it for the new indication. This was an important consideration in the conditional use during the evidence generation period recommendation for robot-assisted surgery for THA, which had a less mature evidence base. Experts advised that although robotic technologies work in different ways, they all aim to improve the precision of implant positioning. They added that this is still an emerging field within orthopaedic surgery. Experts noted that each robotic technology in the scope has its own specific implants. They explained that all implants must undergo benchmarking through an Orthopaedic Data Evaluation Panel rating to demonstrate safety before

CONFIDENTIAL UNTIL PUBLISHED

they are used in the NHS. This also indicates the safety of the robotic technology. The committee noted that the NJR can tag information related to specific implants and robotic technologies. It agreed that this would allow variations in outcomes related to specific platforms to be identified. The committee concluded that the benefits seen in the evidence for Mako could be similar in the other 4 technologies that have less mature evidence. So it decided to make a conditional recommendation for use during the evidence generation period for the 5 technologies.

- 3.14 The committee were told that the company that produces SkyWalker did not respond to the request for information from NICE, and so the EAG relied on publicly available information. So limited clinical evidence from a single non-UK retrospective cohort study containing 30 participants per arm was identified for the SkyWalker platform. This evidence showed mixed effects of the technology on complications and operating time, with no difference seen in PROMs. Also, no technology costs were available for the SkyWalker platform, so the EAG was unable to produce an economic model. The committee concluded that a recommendation for research only was appropriate for the SkyWalker platform.

Costs and resource use

Published economic evidence

- 3.15 The EAG identified 4 published economic evaluations done in the UK that were relevant to the decision problem, 3 of which investigated PKA and 1 in THA. An additional study that investigated a generic robot-assisted surgery device, and 1 company submission were also assessed. In all economic evidence, robot-assisted surgery was shown to be potentially cost-effective, with an incremental cost-effectiveness ratio (ICER) below £20,000 per quality-adjusted life year. The EAG noted several limitations across the 4 evaluations, including failure to consider servicing costs, not including implant costs and applying differences in revision rates. These limitations are all important considerations in decision making. The

positive findings from the identified evidence were considered by the committee. It factored these into discussions around the uncertainty of the economic evidence, and concluded that these published models provide some evidence that robot-assisted surgery may be cost effective.

Economic modelling

- 3.16 The EAG developed a Markov model that was applicable to TKAs, PKAs and THAs and was based on 3 published economic evaluations. Clinical and costing parameters specific to TKA, PKA and THA were used to produce 3 separate sets of results, 1 for each procedure. Base-case results showed that none of the robotic technologies were likely to be cost effective for TKA or PKA, and that the Mako and CORI platforms were both potentially cost-effective for THA. The committee acknowledged that the results were from a conceptual economic model that was built around several assumptions and highly uncertain utility inputs. This was reflected in the confidence intervals around the ICERs, with all robotic technologies being potentially cost effective for TKA and PKA when using the upper limit of utility values. The committee agreed that further evidence generation to reduce uncertainties in utilities and clarify some assumptions would provide a more certain economic model. This would allow a more complete understanding of the cost effectiveness of robot-assisted surgery.
- 3.17 A key limitation that the committee discussed was the use of the utilities for Mako for all the technologies because of a lack of utility data for the other technologies. The committee acknowledged that further evidence generation should focus on collecting utility data for each individual technology to better understand if there are differences between them. The utilities for knee procedures were taken from randomised controlled trials, and those for THA were from a prospective propensity score matched cohort study. The committee acknowledged the limitations of the utility data. This included small sample sizes for the knee procedure data, which contributed to large variations around point estimates, and a lower

CONFIDENTIAL UNTIL PUBLISHED

quality evidence source for the hip procedure data. Both of these raised concerns about the accuracy of the values used in the model. The committee identified more PROMs data as a key area for further evidence generation to reduce uncertainties in the model.

- 3.18 The EAG's model assumed that there was no difference in revision rates, mortality rates and length of stay between robot-assisted surgery and conventional surgery arms. Assumptions were based on the best available evidence. Real-world data from national joint registries was used for revisions and mortality, and NHS Digital Hospital Admitted Patient Care Activity data was used for length of stay. All assumptions were supported by clinical expert opinion. Revision rates in the NJR were too low to demonstrate any difference between surgical methods. Data from the AOANJRR was deemed non-generalisable to the NHS and showed no statistically significant differences between surgical methods when adjusted for confounding factors. The same assumption was made for mortality rates, with the NJR showing no difference between surgical methods. There was no data reporting differences in the length of stay between surgical methods. These assumptions were explored in the sensitivity analysis, but most of the results showed that robot-assisted surgery was not cost effective. The committee agreed that more data to inform the assumptions could be used to reduce uncertainties in future economic modelling.
- 3.19 The committee acknowledged that, because of a lack of data, several assumptions were made in the economic modelling and some parameters could not be included. It noted that differences in resource use during and after surgery were not included. The different impacts on the surgeon and operating team, operating times and procedure volume were also not included. The committee considered staff time during training to be an important consideration for future economic modelling. It concluded that more detailed data on resource use for robot-assisted surgery and conventional surgery could be used to inform a more robust economic

CONFIDENTIAL UNTIL PUBLISHED

model. This would reduce uncertainties in the results of future economic modelling.

- 3.20 The committee noted that technology costs vary between purchasing options and that the cost can often be negotiated. This was confirmed by company representatives who outlined several purchasing options. For example, volume-based contracts, where trusts prespecify an annual procedure volume with greater discounts for more procedures. The EAG's model base case assumed a procedure volume of 250 cases per year. But, the committee noted that there is significant variation in the procedure volume between trusts, so this is not generalisable across the UK. The committee agreed that flexibility in price may be beneficial in high-volume centres. But, it may limit the nationwide feasibility of robot-assisted surgery if lower volume centres want to adopt the technology (see [section 3.7](#)). The committee accepted that assuming a single procedure volume across all centres was a limitation of the model and suggested that this should be explored in the evidence generation plan.
- 3.21 The committee were aware that the implant accounted for the majority of the per-patient cost of robot-assisted surgery. All technologies evaluated in this early value assessment are closed systems. This means they must be used with platform-specific implants produced by the company. The committee noted that the cost of the implant is also negotiable, potentially meaning that robot-assisted surgery could become cost effective in the future with increased uptake. The NHS England steering group advised that procurement is within its scope and may have a role in negotiating implant prices at a national level. The committee agreed that more consistent pricing across the UK would benefit the nationwide adoption of robot-assisted surgery and would benefit future economic modelling for the whole NHS.

Evidence gap review

3.22 The committee agreed that there were evidence gaps in all technologies assessed in this early value assessment. It noted in particular that, for THA, Mako only had limited non-randomised evidence and CORI had no evidence within scope. The committee discussed which outcomes were most important to inform future decision making. Impact on patient quality of life and resource use were prioritised as key areas for further evidence generation. More accurate technology-specific utilities data and more data on resource use could be used to improve the certainty of the economic modelling. The clinical impact of robot-assisted surgery in different subgroups was also identified as an area for further evidence generation, but with lower priority. It was given a lower priority because it does not directly affect the economic modelling or the overall efficacy of robot-assisted surgery across the NHS. But, the committee did agree that robot-assisted surgery may be more beneficial in some groups. For example, people who are at higher risk or people from a Southeast Asian background, in whom bow-leggedness is more common and can result in alignment challenges with conventional surgery. It concluded that further evidence should be generated to inform where robot-assisted surgery should be adopted to provide the greatest benefit to people having orthopaedic procedures. The committee agreed that it is important that future evidence collects information on variables that may confound findings on the effectiveness of robot-assisted surgery. The committee concluded that gathering information on these variables is important for future decision making, especially when assessing data from national joint registries.

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.

CONFIDENTIAL UNTIL PUBLISHED

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 the medical technologies advisory committee meetings](#), which include the names of the members who attended and their declarations of interests, are posted on the NICE website.

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

Specialist committee members

Usman Bhatti

Post-CCT knee fellow in trauma and orthopaedic surgery, Health Education England North West

Andrew Port

Consultant orthopaedic surgeon, South Tees Hospitals NHS Foundation Trust

Jonathan Rees

Institute director, Botnar Institute for Musculoskeletal Sciences, University of Oxford

Paul Baker

Consultant in trauma and orthopaedics, South Tees Hospitals NHS Foundation Trust

Rebecca Dickens

Lay member

NICE project team

Each medical technologies guidance topic is assigned to a team consisting of 1 or more health technology assessment analysts (who act as technical leads for the topic), a health technology assessment adviser and a project manager.

Toby Sands and Ivan Maslyankov

Health technology assessment analysts

CONFIDENTIAL UNTIL PUBLISHED

Bernice Dillon

Health technology assessment adviser

Catherine Pank

Project manager

ISBN:

DRAFT