HealthTech Programme

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

Draft guidance – Comments from consultation

Comment number	Consultee type	Section number	Comment	Notes for committee
Theme 1 – Recommendations				
1	Company	Consultation question – *Are the recommendations sound and a suitable basis for guidance to the NHS?*	The recommendations are sound, and a suitable basis for guidance to the NHS.	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.
2	Healthcare professional	Consultation question – *Are the recommendations sound and a suitable basis for guidance to the NHS?*	Yes. They are adequately broad (given the broad nature of the assessment).	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.
3	Healthcare professional	Consultation question – *Are the recommendations sound and a suitable basis for*	the recommendation is concerning as it relies heavily on industry to evidence an at present evidence free zone over a 3 year period.	Thank you for your comment. The final guidance and the evidence generation plan explain that the evidence can be generated by

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		guidance to the NHS?		various stakeholders, including companies.
4	Company	1.1	Medtronic welcome this recommendation for the use of RAS in the NHS with a view to help generate further evidence to support its continued use.	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.
5	Charitable organisation	Consultation question – *Are the recommendations sound and a suitable basis for guidance to the NHS?*	Yes. The recommendations for robotic-assisted surgery are sound and provide a strong basis for guiding its adoption in the NHS. For bladder cancer, these recommendations are particularly relevant given the complexity of surgeries like radical cystectomy, which often require intricate reconstruction. Bladder cancer surgeries using robotic-assisted surgery involve a steep learning curve, with short- and long-term outcomes like cancer clearance, lymph node removal, and recovery times dependent on surgeon experience. Tracking progress through metrics such as operative time, complication rates, and conversion to open surgery is essential. Centres new to robotic-assisted surgery may benefit from mentorship and partnerships with high-volume centres to improve outcomes during the early stages of adoption. Monitoring cost-effectiveness is equally important. Metrics such as shorter hospital stays, lower readmission rates, and better quality of life should guide investments. High-volume centres could act as hubs, ensuring efficient use of resources while supporting less experienced centres.	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.

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6	Professional organisation	Consultation question – *Are the recommendations sound and a suitable basis for guidance to the NHS?*	The broad recommendations are reasonable given the evidence, but they are not sufficiently comprehensive.	Thank you for your comment. It has been considered by the medical technologies advisory committee.
Theme 2 – approach to evidence review				
7	Company	Consultation question – *Has all of the relevant evidence been taken into account?*	This assessment has been undertaken in a short period of time. NICE and the EAG describe a 'pragmatic' approach to literature review and cost modelling. Whilst this 'pragmatic' approach may have saved time, it has resulted in a narrow and inappropriate review instead of a systematic review, and also a cost model that does not illustrate the true value of RAS. UK and (some European) studies, of which there are few, have been prioritised via this 'pragmatic' approach. Evidence from US and global studies have been de-prioritised even where patient populations are similar and show similar health characteristics. As a result, all relevant evidence has not been taken into account and therefore clinical and economic summaries as well as recommendations are not as comprehensive as they could have been.	Thank you for your comment. The search and selection approach used reflect the pragmatic approach to identifying evidence. Due to the large volume of literature, the EAG considered it not feasible to review all the evidence available for robotic platforms in all soft-tissue procedures. In recognition that potentially relevant evidence may have been missed, the EAG was tasked with reviewing additional clinical and economic studies. It produced an addendum to the assessment report, which included 10 additional studies and summarised 17 recent systematic reviews.

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				The committee considered this evidence and concluded that the direction of the evidence from the additional studies and the systematic reviews complements the findings from the original assessment report (see section 3.16 in the guidance).
8	Company	Consultation question – *Has all of the relevant evidence been taken into account?*	Clinical Effectiveness: Rationale and methodology for the 'prioritised' evidence is not clear leading to many publications with relevant evidence being excluded from the guidance and consequently not taken into account by the evidence generation plan	Thank you for your comment. The final guidance and the evidence generation plan have been updated to refer to the ongoing MAYFLY study. Please also see the response to comment 7.
9	Company	General	Guidance Development Process: This assessment has been undertaken in a short period of time. NICE and the EAG describe a 'pragmatic' approach to literature review and cost modelling. Whilst this 'pragmatic' approach may have saved time, it has resulted in a narrow and inappropriate review instead of a systematic review, and also a cost model that does not illustrate the true value of RAS. UK and (some European) studies, of which there are few, have been prioritised via this 'pragmatic' approach. Evidence from US and global studies have been de-prioritised even where patient populations are similar and show similar health characteristics. As a result, all relevant evidence has not been taken into account and therefore clinical and economic summaries as well as	Thank you for your comment. The committee recognised that there are potential inequality considerations related to access to robot assisted surgery. It concluded that equitable provision of robot-assisted surgery based on need rather than current configuration is key (see section 3.10 in the guidance). The committee also noted that the NHS England robot-assisted surgery steering group may be influential in moderating this with future national strategy. Please also see the response to comment 7

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			recommendations are not as comprehensive as they could have been. Patient Equality Issues: The conclusions and recommendations of the assessment, which are based on the narrowly focused evidence review, and cost model may restrict the spread of RAS which in turn may lead to the prolonged inequality of patient access to RAS. This may in turn reduce the number of research opportunities into differing populations of patients.	
10	Company	General	Recommendations: Excluding prostatectomy has excluded published evidence related to other outcomes listed in the Evidence Generation Plan. For example, surgeon learning curve, clinical effectiveness, Quality of life and length of stay.	Thank you for your comment. Robot-assisted surgery for prostatectomy was excluded because the procedure is considered established practice in the NHS.
11	Healthcare professional	Consultation question – *Has all of the relevant evidence been taken into account?*	Unfortunately, I still consider the search strategy incomplete. For many years, there was a single robotic surgical system (da Vinci) resulting in reports not necessarily explicitly naming the system used in publications. Many of these studies have been excluded from the assessment.	Thank you for your comment. Please see the response to comment 7.
Theme 3 – Included evidence				
12	Company	Consultation question – *Has all of the relevant evidence been taken into account?*	The overall review of the available evidence for the Robot-assisted surgery for soft-tissue procedures: early value assessment is pragmatic, and a good summary of the current evidence gaps. We are disappointed with the decision to exclude a large prospective registry database that has been published in	Thank you for your comment. The EAG's evidence review prioritised comparative evidence and did not include single-arm studies for outcomes where comparative evidence was available, hence the

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			high impact journals (see below - links to publications in BMJSIT & Annals of Surgery) and has not been included in the evidence, when one of the draft conclusions on the current evidence gap is that more real-world data is required. We believe CMR's clinical registry addresses the key criteria in the NICE real-world evidence framework. • https://pubmed.ncbi.nlm.nih.gov/37036097/ • https://pubmed.ncbi.nlm.nih.gov/36865989/	exclusion of these two registry studies.
13	Company	Consultation question – *Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?*	The summaries of clinical and cost effectiveness are well considered, pragmatic interpretations of the evidence, and serve as a very good starting point for the next stage of the process. Given that NICE have concluded RCT's are not always appropriate for research in medical device evaluation, we would suggest that NICE consider further optimising the levels of data, using the IDEAL framework. CMR's research strategy has followed the IDEAL framework. See the below paper published in Nature Medicine, which highlights the benefits of following the IDEAL framework for surgical device introduction: - https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(09)61116-8/abstract - https://www.nature.com/articles/s41591-024-02836-8	Thank you for your comment, it has been considered by the medical technologies advisory committee and the NICE evidence generation team.
14	Healthcare professional	Consultation question – *Are the summaries of clinical and cost effectiveness*	Broadly speaking yes. This is very complex given the number of systems, payment models and sub-specialty specific outcomes	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.

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		reasonable interpretations of the evidence?		
15	Healthcare professional	Consultation question – *Has all of the relevant evidence been taken into account?*	There is very little evidence available	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.
16	Healthcare professional	Consultation question – *Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?*	no	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.
17	Healthcare professional	1.4	there is no evidence to support this at present. In UK healthcare most surgeons operate at most one day a week on average and the rest of the week contains duties including emergency duties all of which affect retirement plans, a less physically demanding single day will not affect the entire working week - surgeons do not only operate	Thank you for your comment. It has been considered by the medical technologies advisory committee. Section 1.4 of the guidance outlines outcome measures where future evidence generation is needed. No action needed.
18	Healthcare professional	1.4	there is no evidence that robotic techniques can reduce waiting lists. In general the operative time for a robotic procedure is longer than for open surgery and comparable	Thank you for your comment. It has been considered by the medical technologies advisory committee. Section 1.4 of the guidance outlines

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			to lap surgery so there is no increased efficiency on a theatre list	outcome measures where future evidence generation is needed. No action needed.
19	Healthcare professional	1.4	what is the evidence that the need for additional treatment after surgery is decreased? Does this mean chemo/radiotherapy/further surgery? This statement needs clarification	Thank you for your comment. It has been considered by the medical technologies advisory committee. Section 1.4 of the guidance outlines outcome measures where future evidence generation is needed. The guidance should be read along with the evidence generation report, which provides additional detail about the evidence that needs to be generated.
20	Healthcare professional	1.4	these assumptions are?	Thank you for your comment. The respective section has been amended to refer to the sections of the guidance where the assumptions are detailed.
21	Company	Consultation question – *Are the recommendations sound and a suitable basis for guidance to the NHS?*	Recommendations regarding the draft evidence generation plan are confusing. The document outlines the use of real-world data to generate evidence but also states that NICE prefer randomised clinical trial evidence. We would ask that NICE is specific about it's definition of 'comparative treatment effects' and also specify which indications and systems they want to see this evidence generated for. If randomised clinical trial evidence is required, the 3-year period that NICE have set for this evidence to be generated and fully published is unrealistic.	Thank you for your comment. The evidence generation plan notes that well-conducted randomised controlled trials are the preferred source of evidence for assessing comparative treatment effects, if these are able to address the research gap. In this specific case, the evidence generation plan has recommended that the ongoing

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				REINFORCE, MAYFLY and MASTERY studies could deliver comparative evidence addressing the evidence gaps for resource use, clinical impact of RAS technologies and the learning curve associated with implementation of RAS technologies. Alongside this, the Cancer Outcomes and Services Dataset (COSD) and real world observational studies should be used to supplement the data from the REINFORCE, MAYFLY and MASTERY studies.
22	Company	General	Evidence Gap Review: Evidence on surgeon learning curve is challenging as each surgeon learns at a different pace. Learning curve is also specific to both procedure and RAS system type. The Intuitive Da Vinci training programme is the only RAS programme accredited by the Royal College of Surgeons of England. Intuitive is the largest provider of robotic-assisted surgical technology training to be accredited by the Royal College of Surgeons of England. Intuitive would ask that a similar training standard is made applicable to all RAS systems used within the NHS. The Da Vinci platform includes both a dual console option and simulator options linked by a digital ecosystem which vastly enhances surgeon learning. Over 45,000 Da Vinci RAS procedures will be performed within the NHS in 2024 by over 1300 fully trained Da Vinci	Thank you for your comment. The EAG recognised that there are likely to be variations in the costs associated with different surgical settings, related to the different pricing structures of robotic platforms, staff involved in the procedure, maintenance, training, and the learning curve associated with the platforms. The EAG conducted scenario analyses including different pricing structures and assumptions (see section 8 in the assessment report). The EAG explained that the purpose of the

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			surgeons in the UK. These statistics once again differentiate the Da Vinci X/Xi systems from other platforms. There are many publications for many prioritized procedures to address the outcomes listed in the evidence gap/evidence recommendations, however they were excluded from this assessment. All capital and consumable costs related to da Vinci systems are documented within the NHS procurement framework which NICE has access to. Technology selection: The number of indications (and therefore procedures) that are regulatory approved vary across RAS platforms. Cost effectiveness is impacted by number of surgeries (as in the greater the number of surgeries, the more cost effective a RAS system becomes) The Da Vinci X/Xi systems have by far the largest number of licensed indications making utilisation of the systems much easier to achieve, which in turn can positively impact cost effectiveness. This parameter was not considered within the cost model	economic evaluation was to assess the overall potential of robotic platforms to support surgical care across specialties. It is beyond NICE's remit of early value assessment to make recommendations related to training standards and curricula.
23	Company	Consultation question – *Has all of the relevant evidence been taken into account?*	No. Medtronic believe that not all the evidence has been considered.	Thank you for your comment. Please see the response to comment 7.
24	Charitable organisation	Consultation question – *Has all of the relevant evidence been*	We believe so. Robotic-assisted surgery offers benefits for bladder cancer patients, including shorter hospital stays, fewer complications, and quicker recovery, especially for complex surgeries like radical cystectomy. It shows promise in	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.

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		taken into account?	reducing surgical risks and improving recovery compared to open surgery or standard minimally invasive techniques. However, the current relevant evidence has limitations. Few studies focus on long-term outcomes like survival, cancer recurrence, and post-surgery quality of life. These are crucial for patients undergoing life-altering surgeries such as bladder removal or bladder-sparing procedures. There is also limited data on surgeon performance during and after the steep learning curve for these techniques, particularly in high-volume centres. Future research should prioritise tracking patient outcomes, including continence and quality of life, and collecting long-term data through bladder cancer registries. Studying centres with established expertise in robotic surgery will help refine best practices and ensure patients receive the best possible care."	
25	Charitable organisation	Consultation question - *Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?*	Yes. Robotic-assisted surgery provides benefits for bladder cancer patients, especially for complex procedures like radical cystectomy. Its enhanced precision allows surgeons to navigate delicate anatomy more effectively, preserving urinary and sexual function while achieving complete tumour removal. This precision also reduces the risk of damage to surrounding tissues, improving both cancer control and overall patient outcomes. In terms of short-term results, robotic-assisted surgery is comparable to standard minimally invasive techniques, offering reduced blood loss, shorter hospital stays, and quicker recovery times. Moreover, robotic-assisted surgery makes minimally invasive surgery possible for patients with higher risks, such as those with obesity or other health	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.

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			conditions, offering smaller incisions, reduced pain, and faster recovery times. Procedures involving challenging pelvic anatomy or extensive lymph node dissection particularly benefit from the superior dexterity and three-dimensional visualisation that robotic-assisted surgery provides. Robotic-assisted surgery also improves the surgeon's experience. Bladder cancer surgeries are lengthy and physically demanding, with traditional techniques often causing surgeon fatigue and increasing the likelihood of errors. Robotic-assisted surgery enables surgeons to operate from a comfortable, ergonomic console, reducing strain and improving precision, particularly in high-volume centres.	
26	Professional organisation	Consultation question – *Has all of the relevant evidence been taken into account?*	No. A systematic review of the available evidence may provide useful additional information. While recognising the lack of meaningful randomised controlled trials in this area, the evidence should include large cohort studies and account for the heterogeneity in the documented outcomes. The report summarises the potential benefits of RAS, but needs to include the limitations of minimally-invasive surgery in standard laparoscopy which are addressed by the robotic platforms, such as enhanced tremor effects, poor vision, straight instruments and poor ergonomics. The EVA includes other benefits that RAS systems offer, including enhanced visualization, dexterity, and precision, which may	Thank you for your comment, it has been considered by the medical technologies advisory committee. The potential benefits of using robot-assisted surgery in the NHS are outlined in section 1 of the guidance.

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			improve outcomes in specific soft tissue procedures. Evidence to date suggests potential advantages, including: • Improved intraoperative precision, particularly in complex anatomies. • Reduction in perioperative complications through minimally-invasive techniques. • Enhanced patient recovery profiles, with shorter hospital stays and lower postoperative pain levels.	
27	Professional organisation	Consultation question – *Are the summaries of clinical and cost effectiveness reasonable interpretations of the evidence?*	The summaries are reasonable interpretations of the limited evidence that has been considered.	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.
28	Professional organisation	General	1. Clinical evidence A. There is reference to benefits of robotic surgery in endometriosis in NICE draft document. 1 in 10 women suffer from endometriosis [3] which affects nerves and organ function of these patients. There are numerous studies published to support robotic assistance in these patients is beneficial [4, 5, 6]. B. Traditionally open surgery is the standard of care for ovarian cancer surgery. However, the recently published MIRRORS prospective cohort study demonstrated the feasibility and potential benefits of robotically assisted surgery for women on chemotherapy for advanced stage ovarian cancer with a pelvic mass of up to 8cm diameter undergoing interval cytoreductive surgery. MIRRORS demonstrated greatly reduced hospital stay with little or no need for HDU bed	Thank you for your comment. It has been considered by the medical technologies advisory committee. Experts from the gynaecology specialty were invited and attended the second committee meeting.

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			occupancy, greatly reduced blood loss with no transfusion, faster recovery and earlier re-commencement of chemotherapy with no increased risk of complications compared to historical and concurrent control groups. Patient experience and feedback was also extremely positive towards this novel approach. An NIHR approved pilot randomized controlled trial is currently well underway in three UK Cancer Centres to further assess this possible role for robotic surgery with a view to a subsequent large UK led multicentre RCT, examining both oncological outcomes as well as quality of life and health economics. A similar NIHR approved pilot RCT, MIRRORS-Frozen, using the same approach has recently commenced investigating the role of robotic surgery for women with possible early-stage ovarian cancer presenting suspicious complex pelvic masses up to 8 cm diameter, as again many women suffer the side effects and risks of traditional laparotomy for what often proves to be benign or low risk ovarian pathology. [7] C. Obesity and type 2 diabetes are major risk factors for uterine cancer, and women with a high body mass index are at greater risk of complications and conversion to open surgery, which are associated with delayed recovery and failure to receive adjuvant chemotherapy or radiotherapy, increasing their risk of cancer recurrence and shorter survival. Robotic surgery has been shown to be associated with a short recover period in this population, with significantly fewer complications [8] lower cost [9], and faster return to baseline health [10] and shorter operating time compared with standard laparoscopic surgery[11]. Prospective data collected from one UK centre over 10 years has shown that adoption of robotic surgery as part of an enhanced recovery	

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			program has been shown to greatly increase the utilization of MIS from 30% to over 90% despite a significant increase in the number and proportion of morbidly obese patients over time [12]. Recently published 10-year survival data from an RCT of robot assisted laparoscopic surgery vs. standard laparoscopic surgery, conducted in Finland 2010-2013 has revealed a possible slight survival advantage for those treated robotically, even among a lower BMI scandinavian population [13]. D. BIARGS has published RCOG SIP summarising role of robotic surgery in gynaecology. There is no mention of this study in the document [14].	
29	Healthcare professional	General	Did you not find the iROC trial A recent RCT we did of robotic verus open cystectomy in urology published in JAMA Effect of Robot-Assisted Radical Cystectomy With Intracorporeal Urinary Diversion vs Open Radical Cystectomy on 90-Day Morbidity and Mortality Among Patients With Bladder Cancer: A Randomized Clinical Trial | Oncology | JAMA | JAMA Network. Days alive and out of hospital reported in iROC. Also the RCT of robotic prostatectomy from Australia. Robot-assisted laparoscopic prostatectomy versus open radical retropubic prostatectomy: early outcomes from a randomised controlled phase 3 study - The Lancet Further follow up studies reported too	Thank you for your comment. The initial study selection excluded studies where the model of the robot was not clearly stated. The EAG relaxed this criterion for the addendum, and the study would have been eligible for inclusion in the addendum. However, the EAG did not believe that the trial significantly changes the conclusions from the original evidence review. The original evidence review and the addendum have shown that robotic surgery has advantages over open surgery; this study reaches the same conclusions. The second study in the consultee's comment is on

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				prostatectomy, which is out of scope for this assessment.
30	Healthcare professional	General	Average use on HES is 350-400 cases Average lifespan 7 years Currently proportion of colorectal surgery RAS 2024 is 24% Gynae is 15% Nephrectomy is 30% Cystectomy 70% RALP 98% HES source All these procedures are likely to reach >90%.	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.
31	Healthcare professional	General	We have published all these observational data based on national registries 1. A 'real-world' standard for radical prostatectomy: Analysis of the British Association of Urological Surgeons Complex Operations Reports, 2016–2018 - Joseph B John, John Pascoe, Sarah Fowler, Thomas Walton, Mark Johnson, Jonathan Aning, Benjamin Challacombe, Rory Bufacchi, Andrew J Dickinson, John S McGrath, 2023 2. Contemporary standards in UK nephrectomy practice: Analysis of the British Association of Urological Surgeons Complex Operations Reports, 2016–2018 - John Pascoe, Joseph John, Sarah Fowler, Krishna Narahari, Ben Challacombe, Andrew Dickinson, John S McGrath, 2023 3. 4. Introduction of robot-assisted radical cystectomy within an established enhanced recovery	Thank you for your comment. Please see the responses to comments 7 and 12.

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			programme - Miller - 2017 - BJU International - Wiley Online Library They aren't RCTs and this is just a few of them but they real world data on complication rates etc.	
32	Healthcare professional	General	Surgeons' display reduced mental effort and workload while performing robotically assisted surgical tasks, when compared to conventional laparoscopy | Surgical Endoscopy We did quite a lot of research in this area. This is one of our outputs but there are others.	Thank you for your comment. The studies referenced in this comment are on simulations, rather than from a real-world context. Studies on simulations were not eligible for the evidence review based on the EAG's selection criteria.
33	Healthcare professional	General	10.3 recommending RCTs feels outdated. We have shown they are almost impossible to recruit to in this area and too slow. They also measure wrong outcomes as one would expect it to be equivalent to MIS. Need to look at longer terms as the report recommends.	Thank you for your comment. Please see the response to comment 21.
Theme 4 – Technology-specific outcomes				
34	Company	General	Technologies: A large % of the total evidence for RAS has been generated via the Da Vinci multiport platforms (X/Xi and prior models). This is not sufficiently called out in the guidance, and neither is the fact that evidence generated on one platform, is not transferrable or applicable to other platforms. This is a key point made by several of the expert surgeons advising the NICE Committee on multiple occasions. Clinical	Thank you for your comment. Section 3.13 of the guidance explains that most of the evidence in the EAG's evidence review was for the Da Vinci platforms. Section 3.23 of the guidance has been amended to clarify that future evidence generation should be platform-specific.

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			equivalence to Da Vinci X/Xi has not been demonstrated by other RAS systems It is not clear why DTAC applies to RAS systems, despite manufacturers writing to TADA for clarification. Relevant comparators to RAS will be specific to both procedure and RAS system type	DTAC assessment may be required for RAS systems that store and utilise patient data.
35	Company	General	Committee Discussion: Clinical Effectiveness: Rationale and methodology for the 'prioritised' evidence is not clear leading to many publications with relevant evidence being excluded from the guidance and consequently not taken into account by the evidence generation plan The Da Vinci X/Xi multiport systems differ from other RAS platforms in terms of their development/adoption/evidence. Some of the conclusions and recommendations from this EVA can be interpreted as all robotic platforms have similar evidence bases and evidence gaps. This is not the case when comparing evidence volumes/quality, install base, adoption, number of procedures performed and trained surgeons for this platform within the NHS to other available systems. Evidence is both procedure and RAS system specific. The EAG report excluded all studies that did not specify the RAS system used, even when only a single system was licensed for use (Da Vinci X/Xi). This resulted in many relevant published studies not being considered. This may have been done to reduce time taken to produce the report	Thank you for your comment. Section 3.13 of the guidance explains that most of the evidence in the EAG's evidence review was for the Da Vinci platforms. Please also see the response to comment 7. The EAG's justifications for the conceptual model design are detailed in section 8.2 of the assessment report.

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			but has led to bias in the literature review, draft guidance and draft evidence generation plan. Cost model: the one-year time horizon has significant limitations. Length of stay is a key driver of 'down-stream' cost avoidance linked to cost effectiveness, yet the parameter was excluded from the model even though published evidence on this topic is available	
Theme 5 – Equality				
36	Company	Consultation question – *Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?*	We have believe NICE has completed an unbiased assessment of equality issues that need special consideration for the currently available technologies.	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.
37	Healthcare professional	Consultation question – *Are there any equality issues that need special consideration and are not covered in the medical technology*	No	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.

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		consultation document?		
38	Company	Consultation question – *Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?*	The conclusions and recommendations of the assessment, which are based on the narrowly focused evidence review, and cost model may restrict the spread of RAS which in turn may lead to the prolonged inequality of patient access to RAS. This may in turn reduce the number of research opportunities into differing populations of patients.	Thank you for your comment. Please see the response to comment 9.
39	Charitable organisation	Consultation question – *Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?*	Yes. Access to robotic-assisted surgery for bladder cancer is often determined by the availability of specialised centres, leaving rural and economically deprived areas with limited options. This creates a system where patients in urban, well-funded regions benefit from advanced care, such as shorter recovery times and fewer complications, while others are left with open surgery, which involves longer recovery and greater risks. A national strategy should ensure that robotic systems, training programmes, and care teams are distributed equitably. High-volume centres could act as regional hubs, supporting smaller centres through training and mentorship. Financial strategies such as government subsidies, NHS trust collaborations, or leasing models could help hospitals in underserved regions acquire and maintain robotic systems. High utilisation of these systems in bladder cancer	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed. Please also see the response to comment 9.

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			surgeries would justify investment and improve cost efficiency. Workforce development is essential, especially in rural areas. Nationally coordinated training programmes, incentives for staff to work in underserved areas, and tele-mentoring could help bridge gaps in expertise. Patient-centred approaches, including subsidised travel, clear information about robotic-assisted surgery, and community outreach, would further reduce barriers to care. Regular NHS reporting on robotic-assisted surgery availability and outcomes would ensure inequalities are addressed.	
40	Professional organisation	Consultation question – *Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?*	Equity of access to RAS systems for surgeons and trainees remains a key issue and should be a particular focus of this early value assessment. To ensure equitable access and sustainability, the following factors should be considered: Healthcare Equity: Implementation strategies must address potential disparities in access to robotic technologies across regions and institutions, and NICE should provide guidance on this rather than merely highlight the issue. There is good evidence that male and female brains process 3D and stereoscopic cues differently. Software and system design should account for these differences to avoid disadvantage for surgeons and patients. Clinical Indications: NICE should provide clear guidance on the specific indications where robotic-assisted approaches offer a demonstrable advantage. Real-World Evidence: Continuous monitoring of outcomes via national registries will be crucial to refining practice and	Thank you for your comment. NICE is committed to promoting equality and ensuring equal opportunity. The recommendations in the guidance are within NICE's remit. The committee considered the equality issues. The final recommendations are for use of the technologies. This EVA considers all technologies and procedures and so has not been indication specific. Future work (e.g. any full guidance after the evidence generation period) may be specialty- or indication-specific.

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			ensuring patient benefit. RCS England is best placed to guide and advice on this based on 30 years of experience in supporting and facilitating good quality surgical research.	
Theme 6 – Staff training				
41	Healthcare professional	Consultation question – *Are there any equality issues that need special consideration and are not covered in the medical technology consultation document?*	training - there are detrimental effects of robotics to both training in robotics for trainees and training in other modalities for trainees.	Thank you for your comment. It has been considered by the medical technologies advisory committee. Training considerations are described in sections 3.5, 3.6, 3.7 and 3.8 of the guidance.
42	Professional organisation	General	2. Training We have developed and implemented robotic training curriculum in UK gynaecology RCOG training, which has gone through GMC assessment. There is no mention of this in the document. (www.biargs.org.uk) RCOG Robotic SITM with BIARGS curriculum. www.rocg.org.uk BIARGS was first UK society to raise awareness regarding importance of team training in robotic surgery. There is significant training required in human factor while working in robotic theatre [15]. There is no reference to this in the NICE document. www.biargs.org.uk. 3. Ergonomics (There is no reference to this in NICE draft document). Our team have published in ergonomics and implications for future of surgeons, a growing concern given the predominantly female gynaecology workforce and rising patient obesity rates [16,17,18]. In future 90% of	Thank you for your comment. The EAG's economic modelling aimed to estimate the average impact of integrating RAS across a range of clinical procedures to reflect the early and exploratory nature of the assessment. Due to a lack of procedure-specific data the EAG aimed to capture the average impact of integrating RAS across a range of clinical procedures, rather than focusing on more granular procedure-level evidence or guidelines. The EAG noted the limitations of this approach and the

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			gynaecologists in the UK are expected to be female [19,20], thereby creating even greater issues with occupational injuries and staff health [9]. There are also training implications, as well as staff and patient health and safety issues, given that certain procedures are more feasible with robotic-assisted surgery as compared to laparoscopic surgery [21]	fact that training requirements are likely heterogenous across clinical areas (see section 9.2 in the assessment report). The EAG explained that including reference to specific training guidelines may fall outside of the scope of the EVA process. It considered the studies referenced in this comment, but concluded that they are not eligible for inclusion in the EAG review as they are studies on simulations in a laboratory context, rather than studies in a real-world context.
43	Healthcare professional	General	If appropriate can reference that the NHSE RAS steering committee is specifically considering how the NHS would plan for and support training in RAS against a backdrop of scaling up the availability of RAS	Thank you for your comment. This has been reflected in section 3.7 of the guidance.
Theme 7 – Cost effectiveness				
44	Professional organisation	General	4. Economics Our team have published health economic studies showing cost saving benefits with robotic-assisted surgery [22]. We hope reviewers will take these points into consideration. Recently gynaecology teams have shown significant improvement in efficiency with weekend robotic HIT lists being used to reduce gynaecology waiting lists. This has been possible due to less physical fatigue of the operating team during robotic surgery compared to conventional laparoscopic or open surgery. Committee	Thank you for your comment. As part of the pragmatic literature review conducted for this early value assessment, the EAG prioritised studies that provided comparative, UK-specific data to ensure relevance to the local context and decision-making processes. However, the referenced study has been included in the addendum to

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			members would only become aware of this through gynaecological representation.	the assessment report. The EAG acknowledged the additional points raised regarding operational efficiencies and reduced physical fatigue for surgical teams. But it also explained that the outcomes should be interpreted cautiously given the analysis is not from a UK perspective.
45	Healthcare professional	1.4	robot-assisted surgery is at present NOT cost effective. Health economic modelling for this technology is complex and open to misinterpretation - I do not think industry with commercial pressures can be relied upon to provide accurate real world evidence assessing all the factors in NHS practice.	Thank you for your comment. The evidence generation plan has recommended that the REINFORCE, MAYFLY and MASTERY studies in addition to data from Cancer Outcomes and Services Dataset (COSD) should be used to deliver comparative evidence addressing the evidence gaps for resource use, clinical impact of RAS technologies and the learning curve associated with implementation of RAS technologies in the NHS. This will provide accurate real-world evidence relevant to NHS practice. The guidance will be reviewed after further evidence has been generated before final recommendations for the system are made.

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Theme 8 – General				
46	Company	1.2	Medtronic would like clarification on who or which department we will be required to contact to provide updates on the following: 1. evidence generation agreement(s), 2. confirm data is being generated and final submission of evidence.	Thank you for your comment. Manufacturers of the technologies included in the guidance will be contacted by NICE following publication of the guidance to provide further details on how NICE monitors evidence generation.
47	Company	1.4	It would be helpful if you could provide a website or link to this steering committee.	Thank you for your comment. This is not currently available but please contact NICE with any queries and we will endeavour to address these.
48	Healthcare professional	General	I have no comments on either document and agree with what has been written.	Thank you for your comment. It has been considered by the medical technologies advisory committee. No action needed.
49	Professional organisation	General	We write on behalf of gynaecological patients within the UK who have suffered inequality in healthcare over decades. We are extremely concerned regarding the NICE Committee membership who will be making decisions regarding the use of robotic-assisted surgery within NHS. This committee does not have any representation from a gynaecologist, a grave omission, which will undoubtedly reinforcing the gender health divide and disadvantage many patients requiring gynaecology treatment. In 2013 NICE made recommendation on robotic prostatectomy surgery based on two small studies from two single hospitals [1, 2]. The main outcome in this decision-making was maintaining	Thank you for your comment. Please see the response to comment 28.

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			pelvic autonomic nerve function, i.e. sexual function, rather than cancer outcomes. This has led to sex discrimination and bias in favour of male patients, and over the past decade male patients have benefited from robotic surgery, whereas relatively few women have benefitted form access to robotic gynaecological surgery, with the majority of hysterectomies in the UK still being performed by the abdominal route.	
50	Professional organisation	General	BIARGS is a charity interested in providing the best surgical care and outcomes for gynaecological patients. Females comprise of 50% of UK population (34.5 million) and a high proportion of women have gynaecological problems at some stage of their life, whether it be benign conditions such as endometriosis, fibroids or incontinence, or a gynaecological cancer (>20,000 new diagnoses every year in the UK). Therefore, we strongly feel women population will be disadvantaged by not having a gynaecologist representative at the NICE robotic decision-making committee and this decision will have significant implications for women's health and exacerbate the gender health divide. We note some of our members had applied but were excluded, as they were perceived to have a conflict of interest. We are sure that that there must be many gynaecologists with no conflict of interest who would be willing to help and represent women's healthcare if given the chance. Application notification should have been open and send to specialist societies and the Royal College of Obstetricians and Gynaecologists. We therefore request that please re-consider inclusion of gynaecologist in the Committee membership.	Thank you for your comment. Please see the response to comment 28.

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Theme 9 – Comments on evidence generation plan				
51	Company	Consultation question – *Is there any ongoing study in addition to the REINFORCE trial and the MASTERY cohort study that we may have missed and could be used to address any evidence gaps?*	CMR Surgical has a prospective clinical registry, running across multiple sites, with clearly defined fields, that evaluates safe implementation and patient outcomes. This is a very large objective database that will continue to provide real-world evidence of safety and efficacy. We believe this would provide robust data on the performance and development of the Versius system, and therefore help NICE to reach its stated goals. We would be happy to share the structure and style of the registry with other robotic platform providers if they felt that would be of benefit.	Thank you for your comment. NICE has noted that CMR Surgical has a prospective clinical registry, running across multiple sites. The evidence generation plan is not restrictive towards what needs to be done to ensure that the evidence gaps are addressed. As such, CMR Surgical using its registry is a viable approach to addressing the evidence gaps for the Versius systems. At a later stage of the evidence generation process, NICE may contact the company to share the structure and style of the registry with other robotic platform providers.
52	Healthcare professional	Consultation question – *Is there any ongoing study in addition to the REINFORCE trial and the MASTERY cohort study that we may have missed and could be used to*	Mayfly study (https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/mayfly/)	Thank you for your comment. Section 3.3 in the evidence generation plan has been amended to highlight the MAYFLY study.

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		address any evidence gaps?		
53	Company	Consultation question – *Is there any ongoing study in addition to the REINFORCE trial and the MASTERY cohort study that we may have missed and could be used to address any evidence gaps?*	Not ongoing studies but newly published studies since the commencement of the EVA: COMPARE study: Comparing perioperative outcomes of Oncologic Minimally invasive laparoscopic, da Vinci robotic, and open Procedures: A systematic Review and meta-analysis of the Evidence-2024. Mitzman et al "Minimally Invasive Surgery Deserts: Is there a role for Robotic Assisted Surgery?" – 2024	Thank you for your comment. Please see the response to comment 7.
54	Company	General	Purpose of Document: Recommendations regarding the draft evidence generation plan are confusing. The document outlines the use of real-world data to generate evidence but also states that NICE prefer randomised clinical trial evidence. We would ask that NICE is specific about their definition of 'comparative treatment effects' and also specify which indications and systems they want to see this evidence generated for. If randomised clinical trial evidence is required, the 3-year	Thank you for your comment. The evidence generation plan notes that well-conducted randomised controlled trials are the preferred source of evidence for assessing comparative treatment effects, if these are able to address the research gap. In this specific case, the evidence generation plan has recommended that the ongoing REINFORCE, MAYFLY and MASTERY studies could deliver comparative evidence addressing the evidence gaps for resource use, clinical impact of RAS technologies

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			period that NICE have set for this evidence to be generated and fully published is unrealistic. Support from NIHR is mentioned however details about how companies contact and work with the NIHR in reference to this EVA is not clear It would be useful to understand how guidance on commissioning and procurement will be developed and if there is opportunity for involvement of manufacturers but more importantly, the involvement of key clinical and non-clinical stakeholders such as RAS surgeons and hospital executives that have experience of implementing RAS pathways.	and the learning curve associated with implementation of RAS technologies. Alongside this, the Cancer Outcomes and Services Dataset (COSD) and real-world observational studies should be used to supplement the data from the REINFORCE, MAYFLY and MASTERY studies.
55	Company	General	Evidence Gaps: Long term cost effectiveness will be impacted by utilisation, length of stay, complication rates, staffing levels and surgeon learning curve. All of which are dependent on the procedure and RAS system used form an evidence perspective. It is therefore recommended that cost modelling be done by procedure on each RAS system. Additional evidence was presented to NICE and EAG however it was concluded by NICE that it did not change the conclusions of the early value assessment report due to the 'pragmatic' approach to the literature review process. There is published evidence on long term outcomes for RAS (Leitao 2023 – RECOURSE Study), however the EAG report and NICE have chosen to exclude these studies. Evidence on this, and other outcomes is specific to both procedure and RAS system type. Intuitive would like to draw attention to the recently published COMPARE study: Comparing perioperative	Thank you for your comment. Section 3.23 of the guidance has been amended to highlight that future evidence generation should be platform-specific.

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			outcomes of Oncologic Minimally invasive laparoscopic, da Vinci robotic, and open Procedures: A systematic Review and meta-analysis of the Evidence. It was referenced as 'academic in confidence' on our original RFI and was not published when additional evidence was requested of manufacturers. This study considers 230 procedure-specific 230 publications over 7 procedures: Outcomes that favour Da Vinci Multiport: Conversions: 56% less likely v Lap Blood transfusions: 21% less likely v Lap/75% less likely v Open 30-day complications: 10% less likely v Lap/44% less likely v Open Length of stay: 0.5 days shorter v Lap/1.9 days shorter v Open 30-day mortality: 14% less likely v Lap/46% less likely v Open 30-day readmissions: 9% less likely v Lap/29% less likely v Open 30-day reoperations: 11% less likely v Open	
56	Company	General	Approach of evidence generation Table 1 is based on evidence gaps identified following the 'pragmatic' literature review methodology employed by the EAG which excluded many relevant publications. Data to be collected - Organisational and information outcomes: Intuitive would like to draw attention to an additional recently published study – Mitzman et al "Minimally Invasive Surgery Deserts: Is there a role for Robotic Assisted Surgery?" – 2024	Thank you for your response. Please see the response to comment 7.

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57	Company	General	1. Increase the evidence generation period beyond 3 years While Medtronic welcomes this evidence generation plan and the essential 'Evidence gaps and ongoing studies' priority list outlined in Table 1, we wish to express our concerns regarding the feasibility of generating evidence outlined in the priority list for all the procedures identified in the EAG report, within the proposed 3-year timeframe. This is particularly challenging for the collection of long-term evidence, which may require extended follow-up periods to produce meaningful and actionable data acceptable to NICE. Additionally, while we understand that there may be opportunities to generate evidence via UK clinical databases and registries, this approach would likely necessitate further planning and coordination, potentially leading to delays beyond our control. We also recognise the risk of generating evidence that may be insufficient in quantity or breadth to meet NICE's requirements. To mitigate this, we respectfully request: a. Clarification on what volume or scope of evidence would be considered adequate to satisfy the evidence generation requirements. b. For the committee to consider an extension on the timeframe proposed from 3 - 5 years, as this will allow for challenges that may be encountered."	Thank you for your comment. While NICE agrees that 3 years is a challenging timeframe, the evidence generation team believes that it is sufficient to address the evidence gaps given that the REINFORCE, MAYFLY and MASTERY studies will report results within this period. These data, supplemented with data from other sources such as COSD should be sufficient to support future NICE decision making.
58	Company	1	Post consultation, further discussion with NICE around the approaches to the evidence generation would be desirable for all technologies included in this plan.	Thank you for your comment. Evidence generation was discussed during the second committee

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				meeting and the guidance and evidence generation plan have been amended to reflect the committee considerations and stakeholder feedback.
59	Company	1	Medtronic acknowledge the effort to establish an evidence generation plan for robotic assisted surgery (RAS) for soft tissue procedures and would like to thank NICE for the opportunity to provide our comments during the consultation period. While we support the commitment to generate further evidence to support the use of RAS for soft tissue procedures within the NHS, we have outlined some suggestions regarding specific aspects of the evidence generation plan to enhance its feasibility. For example: 1. Increase the evidence generation period beyond 3 years, 2. Template to provide consistency across technologies. 3. Most appropriate outcomes to capture the learning curve 4. Volume of procedures required to satisfy ‘adequate evidence’ recommendation 5. Clarification on whether evidence must be technology specific 6. Clarification on who or which department we contact to provide evidence generation updates. Further details are provided within the individuals comments below.	Thank you for your comment. Please see the response to comment 57 regarding an extension to the evidence generation period. Responses have been provided for each of your individual comments below.

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60	Company	2	2. Template to provide consistency across technologies. Medtronic appreciate that the evidence generation plan identifies essential evidence gaps, However, to ensure consistency we would kindly request that NICE provide a template data collection tool to ensure reliability and consistency across the different technologies. For example, further detailed guidance on specific outcomes and specific durations of interest. i.e. Learning curve - duration of surgery etc	Thank you for your comment. The evidence generation plan acts as guide for those collecting outcomes to fulfil the evidence gaps. The plan is not intended to be used as a study protocol for collecting data; as a result, NICE acknowledges that there may be variation in the data collected for different technologies. Section 3.4 of the plan provides guidance about specific outcome measures.
61	Company	2.1	3. Most appropriate outcomes to capture the learning curve. "Understanding the learning curve" is identified as an evidence gap. Clarification on the outcomes of interest and appropriate comparator for the learning curve is needed to ensure we fully understand the requirements for this area. The learning curve for each clinician and centre may differ between procedures and the outcome data produce may not be generalisable. This should be taken into consideration as a challenge when addressing this evidence gap. We request that NICE indicate the most appropriate outcomes to demonstrate the learning curve and whether a comparator is required (open, lap or if any). This will ensure reliability and consistency across the different technologies.	Thank you for your comment. NICE has amended section 2.1 of the plan to highlight that data collection on surgeon information and outcomes are most likely to capture the learning curve.

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62	Company	3.1	4. Volume of procedures required to satisfy ‘adequate evidence’ recommendation. We also recognise the risk of generating evidence that may be insufficient in quantity or breadth to meet NICE's requirements. To mitigate this, we request clarification on the minimum number of procedures to be considered adequate to satisfy the evidence generation requirements, per technology.	Thank you for your comment. Researchers will need to decide on an appropriate study size based on statistical calculations for their individual studies. Assistance on individual protocols may be sought from NICE Advice.
63	Company	3.2	5. Clarification on whether all evidence must be technology specific Medtronic acknowledge the summary provided on the evidence gaps, ongoing studies, data sources and evidence collection plan. However, we request that the committee consider providing additional clarity (in this section) on whether the evidence obtained and presented from the various data sources need to be technology specific, focusing on individual systems, or if it can be applicable across multiple technologies (multi-class).	Thank you for your comment. Technology specific data is ideal if available; if not, aggregated data across multiple technologies may be suitable.
64	Company	3.5	We acknowledge and appreciate the committee's recommendation to generate evidence during the 3-year period, with at least a 12-month follow-up data. However, we would like to highlight several practical challenges that may impact the feasibility of this timeline. 1. Data generation: While we understand that there may be opportunities to centralise evidence generation, this approach would likely necessitate further planning and	Thank you for your comment. Please see the responses to comments 57 and 62.

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			coordination with external stakeholders, potentially leading to delays beyond our control. 2. Adequacy of evidence: We also recognise the risk of generating evidence that may be insufficient in quantity or breadth to meet NICE's requirements. To mitigate this, we respectfully request clarification on the minimum volume or scope of evidence to be considered adequate to satisfy the requirements of the evidence generation plan. Given the challenges highlighted above, we kindly request for the committee to consider an extension on the timeframe proposed from 3 - 5 years, as this will allow for challenges that may be encountered. This may also provide an opportunity to strengthen the quality of data provided to further support the committee's decision-making process.	
65	Company	4	6. Clarification on who or which department we contact to provide evidence generation updates. Medtronic would like clarification on who or which department we will be required to contact in order to provide updates on the following: 1. evidence generation agreement(s), 2. confirm data is being generated and final submission of 3-year evidence.	Thank you for your comment. Manufacturers of the technologies included in the guidance will be contacted by NICE following publication of the guidance to provide further details on how NICE monitors evidence generation.
66	Charitable organisation	Consultation question – *Is there any ongoing study in addition to the REINFORCE trial and the MASTERY cohort study that we may*	We are not aware of any ongoing trials in bladder cancer.	Thank you for your comment. No action needed.

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		have missed and could be used to address any evidence gaps?		
67	Professional organisation	Consultation question – *Is there any ongoing study in addition to the REINFORCE trial and the MASTERY cohort study that we may have missed and could be used to address any evidence gaps?*	In addition to supporting REINFORCE and MASTERY, RCS England has supported the REINVENT study, which explores stakeholder views on RAS training and examines options to address barriers to implementation. RCS England has also provided pump-priming funding to six RAS research studies that may provide useful evidence. RCS England publications Future of Surgery (2018), Future of Surgery: Technology-Enhanced Surgical Training (2022), and our Good Practice Guide Robotic-assisted surgery: A pathway to the future (2023) and their extensive references should also be considered for inclusion in NICE guidance. These three documents give a clear picture of the current landscape and what we should aim for in the future. We have advocated for a phased and safe introduction of robotic-assisted systems in soft tissue surgery, coupled with: • Comprehensive data collection from pilot programs to inform national guidelines. • Ongoing collaboration between healthcare professionals, device manufacturers, and policymakers to address challenges related to training, cost, and implementation. • Transparent communication of evidence to both patients and clinicians, ensuring informed decision-making."	Thank you for your comment. Please see the response to comment 7.
68	Professional organisation	General	The Royal College of Surgeons of England welcomes the opportunity to contribute to the ongoing NICE early value assessment of robotic-assisted surgery (RAS) for soft-tissue	Thank you for your comment. The evidence generation plan describes the evidence gaps prioritised by the

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			procedures. [redacted], RCS England Council lead for the Future of Surgery and Robotic & Digital Surgery has participated in this process and prepared these comments. RCS England is committed to supporting surgical innovations that enhance patient care while upholding the highest standards of safety, efficacy, and equity. As a device-agnostic advisory body, our primary focus is to ensure that emerging surgical innovations and technologies such as RAS align with the principles of equity of access, patient benefit and safety, clinical efficacy, and value for the surgical workforce and overall healthcare system. RCS England supports the aims of this early value assessment, and recommends addressing the following points to facilitate a more robust methodology for appraising emerging technologies: Clinical Effectiveness: Comparative data against established open and laparoscopic techniques may demonstrate measurable improvements in patient outcomes, while recognising cost may be elevated. Safety and Training: The introduction of robotic systems must include strategies to mitigate the risks associated with the surgical learning curve, supported by standardised training pathways for surgeons. The REINVENT study, supported by RCS England cross-examines trainees' views and should be considered. Economic Impact: While upfront costs of robotic systems are significant, these must be weighed against potential long-term savings from improved patient outcomes, reduced complication rates, and resource utilisation efficiencies, examining the iceberg effect of NHS costs.	medical technologies advisory committee and proposes a pragmatic study methodology to enable data collection within the defined 3-year evidence generation period. Section 6 of the plan has been amended to highlight the willingness of the Royal College of Surgeons of England to participate in further evidence generation.