NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Medical Technologies Evaluation Programme

HTE40 Robot-assisted surgery for soft tissue procedures (provisional title)

Scope

July 2024

1 Introduction

The topic has been identified by NICE for consideration for early value assessment (EVA). The objective of EVA for MedTech is to identify the most promising technologies in health and social care where there is greatest need and where the evidence base is still emerging. It will provide an early indication to the system that they could be used while evidence is generated. The process will enable the technologies to be recommended for use only if further data is collected before NICE makes a final evaluation. NICE's Prioritisation Board ratified Robot-assisted soft-tissue surgery as potentially suitable for an EVA by the medical technologies evaluation programme (MTEP).

2 Description of the technologies

2.1 Purpose of the medical technology

Approximately 1 in 10 people have a surgical procedure in the UK, each year. Surgical techniques can be broadly categorised into open and minimally invasive surgery (MIS). In open surgery, large cuts are made to open the body so that the area for the procedure can be seen and accessed directly. The aim of MIS is to do the procedure with less damage to the body than open surgery. MIS includes conventional laparoscopic surgery, natural orifice surgery with existing equipment and robot-assisted surgery (RAS). In conventional laparoscopic surgery, a tiny camera (laparoscope) and specially designed tools are put into the body through small cuts and the tools are operated from outside the body. Conventional laparoscopic surgery has been used in the UK since the 1980's and NICE recommends its use with standard arrangements for many soft-tissue procedures in the NHS (see appendix A). Natural orifice surgery is used in some specialties like head and neck surgery and for some upper-gastrointestinal, colorectal and gynaecological procedures. The area that needs to be operated on is accessed by existing openings in the body, like the mouth, anus or vagina. Specially designed

cameras and tools are passed through these openings, meaning that no cuts on the outside of the body are needed to do the procedure.

RAS for soft-tissue procedures is an enhanced form of minimally invasive surgical techniques because a camera is used to visualise inside the body and tools are operated from outside the body. But, in RAS, the tools are usually attached to one or more robotic arms that are controlled by the surgeon from a console, near the operating table.

Robotic platforms for soft-tissue procedures are expensive and require specific training, but they may have several benefits to patients, surgeons and the wider NHS system. Many potential benefits are the same as for other minimally invasive surgical techniques if compared with open surgery. Benefits may include reduced pain, bleeding, length of hospital stay and recovery time. When RAS is compared with other minimally invasive surgical techniques, there may be technical and ergonomic benefits which could increase precision and control. These could lead to less surgical complications meaning the procedure is less likely to be converted to open surgery. There may be less scarring, shorter length of stay and faster recovery time for people having soft-tissue procedures. There may be benefits to the surgeon, including reduced strain and technical demand when doing the procedure. This may also mean that MIS could be offered to people or for procedures that were too technically challenging to do with other minimally invasive surgical techniques, or could be offered by surgeons that previously could not do MIS for some procedures. Both prospects could increase access to MIS across many surgical specialties and procedures. There may also be benefits for the wider NHS system; reduced length of stay, fewer readmissions and less recurrence of disease could reduce cancer and elective surgery waiting lists.

RAS is already recommended in some cases in the NICE Guideline for Prostate cancer: diagnosis and management (2021). RAS for prostate cancer is routinely commissioned in the NHS (NHSE Clinical Commissioning Policy: Robotic-assisted surgical procedures for prostate cancer, 2015). In other specialties and procedures, RAS is at different stages of maturity in terms of evidence and usage. In 2019, a Royal College of Surgeons (RCS) report on the future of surgery predicted major expansion of RAS over the next 10 years, and in 2023, they published a guide to good practice for RAS. This has been echoed by the Department of Health and Social Care (The Topol Review: Preparing the healthcare workforce to deliver the digital future, 2019) and Association of British HealthTech Industries (ABHI RAS network white paper, 2022). The MedTech strategy: One year on (2024) reported that the development of an implementation plan for a robot assisted surgery registry is a key milestone for 2024 to 2025. This will form part of the wider NHS England Outcome and Registries Programme.

2.2 Product properties

This section describes the properties of the technologies based on information provided to NICE by manufacturers and experts and information available in the public domain. NICE has not carried out an independent evaluation of this description.

In 2022, the RCS estimated that over 1.8 million RAS procedures were done internationally and it was available in more than 100 UK hospitals (RCS, 2023).

Robotic systems for soft-tissue procedures are used in operating theatres. They include one or more robotic arms that hold a tiny camera (endoscope) and other surgical tools, and a console with video feed from the endoscope. The tools are designed to be compatible with the specific robotic system they attach to. The surgeon typically operates the robotic arm or arms from the console, inside the operating theatre, whilst other operating theatre staff are present. RAS systems are complex and require dedicated training programmes for the whole operating team. Some systems have in-built data collection capabilities which can be used for performance tracking, service operational audits and registry data collection.

Compared with conventional laparoscopic procedures, there is less national guidance on the use of RAS for soft-tissue procedures. Several NHS commissioning policies have considered RAS for soft-tissue procedures. Aside from the prostate cancer policy published in 2015, RAS is also routinely commissioned for use in the Clinical Commissioning Policy: Robotic assisted surgery for early kidney cancers that are unsuitable for conventional laparoscopic surgery (2016).

At a similar time, RAS was not routinely commissioned for lung resection for primary lung cancer, oesophago-gastric cancers, bladder cancer or trans-oral surgery for throat and voice box cancers.

Aside from the NICE Guideline for prostate cancer, the NICE Guideline for colorectal cancer (2020) recommends that robotic surgery should only be considered within established programmes that have appropriate audited outcomes. The following NICE guidance explicitly evaluates RAS for soft-tissue procedures:

- Robot assisted kidney transplant NICE Interventional procedures guidance 609. Use with special arrangements was recommended for people with obesity who would not otherwise be able to have a kidney transplant without significant risk of morbidity. When open surgery is suitable for people, the committee recommended RAS should be used only in research.

- Totally endoscopic robotically assisted coronary artery bypass grafting NICE Interventional procedures guidance 128, recommended with special arrangements.

Often, NICE's Interventional Procedures programme has considered RAS to be a minor variation of laparoscopic procedures in terms of safety and efficacy. RAS is acknowledged as a variation of other minimally invasive approaches in the following NICE Guidance: minimally invasive radical hysterectomy for early-stage cervical cancer, bilateral cervicosacropexy or vaginosacropexy using mesh for pelvic organ prolapse, laparoscopic ventral mesh rectopexy for internal rectal prolapse, sacrocolpopexy using mesh to repair vaginal vault prolapse, sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse, endoscopic radical inguinal lymphadenectomy, transoral carbon dioxide laser surgery for primary treatment of oropharyngeal malignancy, laparoscopic cystectomy, laparoscopic prostatectomy for benign prostatic obstruction, and laparoscopic radical prostatectomy.

Consideration of RAS in this EVA will assess whether it shows clinical and cost-effectiveness in soft-tissue procedures. The EVA will assess what gaps there are in the evidence base to enable full clinical and cost-effectiveness evaluation. The evidence gap analysis will identify key outcomes that should be used for future evidence generation, and may inform the development of the RAS outcomes registry (MedTech strategy: One year on (2024).

Robotic platforms are here defined as a technology that enables minimally invasive surgery to be done across multiple interventional surgical procedures. They have one or more mechanical arms to which an endoscope and surgical instruments are attached. The operator controls the apparatus from a remote console.

For this EVA, NICE will consider robotic platforms that are used for soft-tissue procedures, that meet the following criteria:

1. Are intended for use for:
    - adult or paediatric populations
    - procedures for cancer or benign disease in at least one of the following specialties:
        - urology (excluding prostatectomy)
        - gynaecology
        - colorectal
        - head and neck
        - thoracic

- upper gastrointestinal (including bariatric and oesophago-gastric surgery)
- general (including hernia repair)
- hepato-pancreato-biliary
- transplant
- breast
- reconstructive and plastic surgery

2. have a CE or UKCA mark and, if applicable, meet the standards within the digital technology assessment criteria (DTAC).

3. are being used in the NHS or will be available for use in the NHS within the next 12 months.

Further detail on the included technologies is summarised in table 1.

Versius Surgical System (CMR Surgical)

The Versius Surgical System includes a bedside unit with an endoscope (visualisation unit), 2 or 3 other bedside units with attachment ports for surgical instruments and a surgeon console with 3-dimensional video feed from the endoscope. The surgical instruments are specially designed for use with the Versius system. They are wristed, meaning they mimic the movement of the human arm. The video feed on the surgeon console is open, so other people in the operating theatre can see the screen, as well as the surgeon. The units are designed to be smaller than other soft-tissue robotic systems, meaning the whole system is portable between theatres and can be used in standard operating rooms. The range of basic and advanced instruments that attach to bedside units is under continuous development. They enable endoscopic manipulation of tissue including grasping, cutting, blunt dissection, approximation, ligation, electrosurgery and suturing. During the procedure, the surgeon controls the robotic arms from the console, with the theatre nursing team present in the operating theatre.

It is designed for use across a range of soft-tissue procedures in adults aged 18 and over (see Table 1). The system has data collection capabilities for robot telemetry data, and with patient consent, surgical video and clinical data can be collected. There is an existing registry that stores this data and is accessible to authenticated users via the Versius Clinical Insights app. This can be used by surgical teams to review performance on past surgeries and interact with registry data.

Da Vinci Surgical System (X and Xi)

The Da Vinci (X and Xi) Surgical Systems include a surgeon console, a patient cart and a vision cart. The patient cart is positioned next to the patient in the operating theatre. It has 4 arms which hold the endoscope and up to 3 surgical instruments that are specially designed for use with the system. The wristed instruments are designed to move like the human hand, but with more range of motion. Each instrument does different tasks such as grasping, suturing, or tissue manipulation. During a procedure, the surgeon controls the robotic arms and instruments using hand and foot controls on the console. The console has a 3-dimensional, high-definition closed viewer which feeds the video from the endoscope. The vision cart duplicates the image seen in the surgeon console closed viewer, so the rest of the surgical team can see the procedure. The vision cart also has functionality to control parts of the system. The instruments attached to each arm on the patient cart can be changed during the procedure.

The 2 Da Vinci systems in mainstream UK use are Da Vinci X and Xi (respectively models IS4200 / IS4000). The Da Vinci Xi system has additional functionality but both systems are built on the same arm, use the same vision cart, console and core instruments and are indicated for the same procedures. The systems collect data on usage metrics such as time, date, kinetmatic and procedure information.

The Da Vinci (X and Xi) systems are designed to be used for a range of soft-tissue procedures in adults and children (see Table 1). The number and type of staff needed to use the Da Vinci platform varies by procedure, but includes a surgeon and operating room and nursing staff.

Da Vinci SP Surgical System

The Da Vinci SP system is designed for single port or natural orifice surgery. This may enable procedures in narrow surgical spaces to be done. Rather than being attached to a patient cart with 4 individual arms as in the Da Vinci X and Xi systems, up to 3 instruments and the endoscope are attached to a patient cart with 1 arm. Specially designed surgical instruments can be used, but not all instruments that can be used on the X and Xi models can be used on the SP, and not all instruments used on the SP can be used on the X and Xi models.

The Da Vinci SP model is CE marked for UK use but is a newer system than the X and Xi (CE mark was given in January 2024). It is indicated for use in adults for endoscopic abdominopelvic, thoracoscopic, transoral otolaryngology, and breast surgical procedures, with exclusions (see Table 1). This technology may have more pronounced and additional benefits to other technologies in the evaluation because of the single-port access, such as cosmetic outcomes and quality of life. It may also be quicker and simpler to do

the surgery and MIS may be offered for a broader range of procedures because there is only 1 arm, meaning alternative access routes might be possible to use.

Hugo RAS (Medtronic)

The Hugo RAS system has 3 key components: the system tower, the surgeon console and the arm carts. The system tower includes computers, systems and generators attached to a touchscreen interactive display for the operating room team. It enables communication between the surgeon console and the arm cart or carts, but can also be used without the surgeon console for manual control of 1 arm cart at the bedside, or alone for visualisation during conventional laparoscopic surgery. The surgeon console has an open, high-definition, 3-dimensional display, and an interactive touchscreen display. Up to 4 arm carts can be used at once. Each arm cart can host 1 surgical instrument or endoscope. They are designed to be portable. A range of compatible wristed articulating surgical instruments can be used for grasping, cutting, blunt and sharp dissection, approximation, ligation, electrosurgery, and suturing. During a typical procedure, the surgeon controls the robotic arms using hand and foot pedals from the console, with the theatre nursing team present in the operating theatre. If only 1 arm is being used, it can be controlled directly from the bedside using the system tower.

The Hugo RAS system is indicated for use in specified urological, gynaecological and general surgery procedures, and in adults that MIS is suitable for. The system collects technical and usage data.

Table 1. Included technologies.

Technology name	Company / developer	Main components	Intended population and procedures	Delivery mode	Data collection functionality	Regulatory approval
Versius	CMR surgical	• bedside unit with an endoscope (visualisation unit), • 2 or 3 bedside units • wristed instruments that attach to bedside units. • surgeon console with open 3D video feed from the endoscope	• People aged 18 and over • Procedures in thoracic, upper gastrointestinal, colorectal, gynaecology, hepatobiliary, hernia and urology specialties. • Use for transoral robotic surgery is under investigation.	• Used in an operating theatre. • Once positioned in the room, the bedside units are remotely operated from the surgeon console. • Designed to be portable between operating theatres.	• Robot telemetry data, and with patient consent, surgical video and clinical data. • There is an existing registry that stores this data and is accessible to authenticated users via the Versius Clinical Insights app.	Certified to market in the UK under MDR 757173 R000
da Vinci X and Xi Surgical Systems (respectively models IS4200 / IS4000)	Intuitive	• Patient cart with 4 arms that host surgical instruments • Wristed instruments that attach to the arms, including the endoscope • Surgeon console with closed viewer • vision cart that duplicates the endoscope video and	• Indicated for use across urological surgical procedures and laparoscopic general, gynecologic, general thoracoscopic, nipple sparing mastectomy with reconstruction, and transoral otolaryngology surgical procedures restricted to benign tumors	• The system is used in an operating theatre. • Once positioned in the room, the patient cart is remotely operated from the surgeon console.	Usage metrics such as time, date, kinematic and procedure information.	Certified to market in the UK (complies with MDR 2017/745)

		has arm cart control functionality	and malignant tumors classified as T1 and T2, and for benign base of tongue resection procedures. • Adults, across the full range of indications for use • Children across indications for use except for otolaryngeal procedures.			
da Vinci SP Surgical System (SP1098)	Intuitive	• Patient cart with 1 arm hosting endoscope and 3 instruments • Surgeon console with closed viewer • Wristed instruments that attach to the arm, including the endoscope • vision cart that duplicates the endoscope video and has arm cart control functionality	• Indicated for use in minimally invasive endoscopic abdominopelvic, thoracoscopic, transoral otolaryngology, and breast surgical procedures. • Indicated for use in adults • A list of procedures that are not suitable for use of the Da Vinci SP system that fall under these umbrella categories is given in the supplement to the user guide.	• The system is used in an operating theatre. • Once positioned in the room, the patient cart is remotely operated from the surgeon console.	Usage metrics such as time, date, kinematic and procedure information.	Certified to market in the UK (complies with MDR 2017/745)
Hugo Robotically Assisted Surgery System.	Medtronic	• System tower with operating room interactive display	• Procedures in urology, gynaecology and general surgery	• The system is used in an operating theatre.	Technical and usage data.	Certified to market in the UK under MDR 738197 R000

		• Arm cart hosting instruments. Up to 4 arm carts can be connected to the system tower. • Surgeon console with open display, interactive display and hand and foot controls. • Wristed instruments that attach to the arm carts, including the endoscope.	• Adults for whom MIS is suitable.	• Once positioned in the room, the arm carts are remotely operated from the surgeon console. If one arm cart is being used, it can be operated using the system tower. • The arm carts are portable.		

3 Target surgical procedures

Up to 8 million people are estimated to have surgery in the UK every year. Many of these procedures can be done with either open or minimally invasive surgical techniques. For this EVA, the target population is adults or children having a surgical procedure on soft tissues in the following specialties:

- Urology, excluding prostatectomy and including but not limited to the following procedures:
    - Cystectomy (radical, partial and simple)
    - Nephrectomy (radical, partial and simple)
    - Bladder substitution/ urinary diversion
    - Cyst removal
    - Adhesiolysis
    - Pyeloplasty
    - Ureterectomy
    - Ureteral reimplantation/reconstruction
    - Adrenalectomy
    - Lymphadenectomy
    - Mitrofanoff procedure
    - Bladder diverticulum removal
    - Bladder stone removal
    - Vasovasectomy
    - Ureterectomy

- Gynaecology, including but not limited to the following procedures:
    - Benign, simple, partial, supracervical and total hysterectomy
    - Salpingectomy
    - Oophorectomy
    - Sacrocolpopexy
    - Abdominal/pelvic lymphadenectomy
    - Tubal anastomosis
    - Ovarian cystectomy
    - Renal cystectomy
    - Resection of endometriosis
    - Omentectomy
    - Parametrectomy
    - Lysis of Adhesions
    - Myomectomy
    - Orthotopic or heterotopic human ovarian tissue transplantation

- Colorectal including but not limited to the following procedures:
    - Colectomy (including hemi-colectomy)
    - Polypectomy
    - Rectopexy
    - Hernia repair
    - Rectal resection
    - Total mesorectal excision

- Head and neck, including but not limited to the following procedures:

    - Lateral oropharyngectomy (radical tonsillectomy)
    - Tongue base resection
    - Tongue base mucosectomy
    - Supraglottic laryngectomy
    - Thyroidectomy

- Thoracic, including but not limited to the following procedures:
    - Lung resection (including lobectomy and segmentectomy)
    - Resection of mediastinal tumours
    - Thymic surgery
    - Transaxillary decompression
    - Pneumonectomy

- Upper gastrointestinal including bariatric and oesophago-gastric surgery

- General surgery including hernia repair

- Hepato-pancreato-biliary including but not limited to:
    - Whipple procedure
    - Pancreatectomy
    - Appendicectomy
    - Heller-myotomy

- Transplant, including but not limited to the following procedures:
    - Lung transplant
    - Kidney transplant
    - Liver transplant

- Breast surgery, including but not limited to the following procedures:
    - Nipple sparing mastectomy with reconstruction

- Plastic and reconstructive surgery

Procedures in these specialties include surgery for cancer and procedures for benign disease. Between 2013 and 2021, approximately 56% of all independent cancer treatments were surgical resections (National Disease Registration Service, accessed May 2024).

3.1 Care pathway

The care pathway varies between different specialties and indications for the procedures in scope for this assessment. The intended place of RAS in the pathway is to:

- replace the standard of care surgical technique for the soft tissue surgical procedure

- give an alternative option for the soft-tissue surgical procedure.

Prostatectomy for cancer is the only procedure for which RAS is established in the NHS care pathway (NHS Clinical Commissioning Policy for prostate cancer, 2015).

Conventional laparoscopic surgery is recommended in NICE guidelines for the diagnosis and management of Colorectal cancer, Prostate cancer, Diverticular disease, Ectopic pregnancy, Pancreatitis, Endometriosis, Gallstone disease, and the clinical guideline for Fertility problems: assessment and treatment (see Appendix A).

The Rapid cancer diagnostic and assessment pathways include information on the Faster Diagnosis Standard, which aims to ensure diagnosis within 28 days of an urgent suspected cancer referral or following a screening referral. This includes optimal timed pathways for suspected prostate, colorectal, lung, oesophago-gastric, gynaecology and head and neck cancer. New optimal pathways have been published for some faster progressing cancers like pancreatic cancer, which aim to deliver a diagnosis even more quickly.

The NHS England cancer programme Spring update 2024 aims to get NHS patients prompt access to innovative treatments; minimally invasive surgical techniques including RAS are considered to be a core part of this because of the potential to reduce recovery times.

3.2 Patient issues and preferences

People should be supported by healthcare professionals to make informed decisions about their care, including the use of digital technologies. Shared decision making should be supported so that people are fully involved throughout their care (see the NICE guideline on shared decision making).

One of the intended benefits of RAS is to provide an alternative approach to minimally invasive soft-tissue surgical procedures. As well as the potential to increase options for patient preference and choice, RAS may have several benefits to patients (see patient-level outcomes in table 2).

Robotic surgery comes with the same potential risks as other minimally invasive surgical options. As with other surgical techniques that involve a medical device, there are considerations for the patient about the risk of technical malfunction, and specialist training for the surgical team is needed. Equipoise when explaining options to the patient, joint decision making and full informed consent are key.

4 Comparator

RAS will be compared with surgical standard of care. For most surgeries this will be laparoscopic or thorascopic surgery. For some procedures, like the Whipple procedure or bladder removal, the only current option is open surgery. For head and neck surgery, the main comparator is radical radiotherapy.

5 Scope of the assessment

Table 2 Scope of the assessment

Populations	People (adults or children) having a soft-tissue surgical procedure. Soft-tissue surgery includes those done in the following specialties: • Urology (excluding prostatectomy) • gynaecology • colorectal • head and neck • thoracic • upper gastrointestinal including bariatric and oesophago-gastric surgery • general (including hernia repair) • hepato-pancreato-biliary • transplant • breast • plastic and reconstruction surgery The following subgroups have been identified: • Children and young people under the age of 18 • Procedures for cancer • Procedures for benign disease
Interventions (proposed technologies)	• RAS with Da Vinci X and Xi (Intuitive) • RAS with Da Vinci SP (Intuitive) • RAS with Versius (CMR Surgical) • RAS with Hugo RAS system (Medtronic)
Comparator	RAS will be compared with standard surgical care.
Healthcare setting	Admitted patient services including emergency and elective surgery.
Outcomes	**Primary outcomes** Patient level:

	• Conversion to open surgery (for RAS compared with other minimally invasive surgical techniques only) • Rate of MIS (other minimally invasive surgical techniques and RAS) compared with open surgery after RAS was introduced • Intraoperative and post-operative complications (e.g. Clavien-Dindo score) • Health-related quality of life Surgeon level: • Procedure-related discomfort and ergonomics (e.g. SURG-TLX) Organisation level: • Volume of procedures • Length of hospital stay • Capacity and wait list reduction **<u>Secondary outcomes</u>** Patient level: • Days alive and out of hospital at 30 days • Length of hospital stay (for RAS compared with open surgery only) • Post-operative pain • Satisfaction • Intraoperative blood loss (for RAS compared with open surgery only) • Revision surgery for the same indication Condition/specialty specific outcomes: • Survival rate (cancer) • Need for adjuvant treatment (cancer) • Feeding tube dependency (head and neck) Surgeon level: • Career longevity and musculoskeletal injury • Human factors • Learning curve Organisation level: • Readmission at 30 days • Operating time • Staffing requirements

Time horizon	The time horizon for estimating the clinical and economic value should be sufficiently long to reflect any differences in costs or outcomes between the technologies being compared.

6 Other issues for consideration

Characteristics of the technologies

- Some technologies can be used for some but not all procedures in the scope (see table 1).
- Different specialties may share the same robotic system, within the same hospital.
- Some technologies are designed to be portable between operating theatres (can go in lifts and through standard sized doors) whilst others are very large and may need purpose built operating theatres to host them. The impact of these adjustments for installation on capital cost or theatre downtime may be considered. How much robots are moved between theatres to enable sharing between specialties in practice and its impact on patient, surgeon and organisation level outcomes may be explored. The floorspace and practicalities of working with the robot in theatre may also be considered.

Evidence

- Different technologies have different levels of evidence and usage, across the NHS and within different specialties.
- Many of the patient level outcomes can be affected by factors unrelated to the use of RAS, for example unanticipated pathology. But, this applies to the comparators as well as RAS.
- If evidence is available, it may be necessary to examine the effect of the learning curve on outcomes.

Care pathway

- Different procedures have different care pathways, and the volume of procedures and indications means it is infeasible to map all of them. There are commonalities among cancer pathways.
- National policies and pathways may change over the coming months in response to national programmes running independently from the evaluation.

Safety

- Safety issues may fall into 2 categories: device failures and user errors.
- Device failures may include electrical and system faults or failures and elements of the hardware breaking.
- Due to their complexity, there is a learning curve associated with the use of RAS systems. Without adequate training there may be an increased risk of surgeon errors. In systems with multiple arms, there may be issues with arm collision if not positioned correctly.

Costs

- Various procurement options are available for each technology, including outright purchase, leasing, consumable-based and usage-based agreements.
- These technologies have high capital cost and come with associated costs for installation, instruments, additional sterilisation, consumables, energy utilisation, maintenance (like repairs, servicing and software upgrades), additional staff and training.
- Device sharing schemes may be considered between different specialties.
- Depending on whether a hospital is newly purchasing and setting up a robotic platform and service, or expanding the service of an existing platform, there may be different associated costs.
- The HTAi best practice considerations for the assessment of RAS recommend that the time horizon should consider the clinical outcome and the level of decision maker (i.e., national vs local). They recommend that malignant disease may require time horizons of over 5 years, while benign disease may only require 2–4 years.

Training

- Typically, training is included as part of the capital cost when a robot is first introduced to a hospital. But, if new teams or individuals need to be trained by the company later on, this will usually incur an extra cost. It isn't always necessary for the company to train new users of the platform.
- It might be easier to train surgeons to do RAS than other types of surgical techniques because of the characteristics of the technologies. For example, the trainer can easily see what the trainee is doing on a screen and platforms can have virtual environments to do training

exercises. Some systems collect data to give summary metrics on surgical performance.

- Gynaecological surgical training is the only specialty in which RAS is part of the curriculum. This is device agnostic training, and device-specific training is needed in addition to this. When logging training, general surgery trainees can select if a procedure is done open, laparoscopic or robotic. Other curriculums will not change for 5 years so training to use robotic platforms will remain a post-fellowship training role in the meantime.

- RAS may increase access for surgeons to train to do minimally invasive surgery. Because surgery is physically demanding it may mean that surgeons who were not physically able, can now do it.

7 Potential 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. Age, sex, socioeconomic status, disability, race, sexual orientation, pregnancy and religion or belief are protected characteristics under the Equality Act 2010.

There may be some inequalities in access to MIS that may be worsened by RAS. A UK analysis of routinely collected data, linked to hospital episode statistics, found access to MIS for colorectal surgery is related to socioeconomic and geographical factors. Robotic platforms are expensive and if the placement of robotic systems is limited to larger, urban hospitals with more resources to procure and maintain the system and staff needed to use the system, access to RAS may exacerbate existing regional inequalities.

One of the proposed benefits of RAS is increased access to MIS because some procedures may not have been offered as MIS before RAS. This could be because the indication, or characteristics of the patient, or both meant that the procedure was high-risk. It could also be because of surgeon experience or physical constraints of the anatomy and laparoscopic tools. Some indications, procedures and patient characteristics that may mean that other minimally invasive surgical techniques would not be a suitable approach to do the surgery include:

- Tumours requiring multiple organ resection
- People with high BMI or obesity
- People with frailties or older adults (aged 65 and over)
- Procedures deep within the pelvic region
- Transoral procedures

- Indication or patient-specific anatomical characteristics (e.g. large uterus)

Age is a protected characteristic, and many people may be covered by the Equality Act 2010 if their condition has had a substantial adverse impact on normal day to day activities for over 12 months or is likely to do so. In the absence of RAS, open surgery would be used for people that meet one or more of these criteria. RAS may enable MIS to be done in these groups.

RAS can be used to treat many types of cancer. All people with cancer are covered by the disability provision of the Equality Act 2010 from the point of diagnosis.

8 Potential implementation issues

National level support is anticipated as a requirement for the roll-out of RAS because of the capital costs and requirements for staff training and physical characteristics of the theatres needed to host some robotic platforms. The Royal College of Surgeons have published a good practice guide for RAS training. Some technologies have already been purchased and are already in use in many hospitals across the UK, whilst others are newer and used in fewer hospitals.

It may be possible to calculate how a robotic system could be shared between specialties with information about length of procedure. But, sharing a robotic system between specialties may be complex to implement in practice.

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Appendix A Related NICE Guidance: Laparoscopic procedures

Interventional procedures guidance

- Standard arrangements recommendations for urological cancers include:
    - Laparoscopic cryotherapy for renal cancer (2011) NICE interventional procedures guidance 405
    - Laparoscopic augmentation cystoplasty (including clam cystoplasty) (2009) NICE interventional procedures guidance 326
    - Laparoscopic cystectomy (2009) NICE interventional procedures 287
    - Laparoscopic deroofing of simple renal cysts (2007) NICE interventional procedures guidance 226
    - Laparoscopic nephrolithotomy and pyelolithotomy (2007) NICE interventional procedures guidance 212
    - Laparoscopic insertion of peritoneal dialysis catheter (2007) NICE interventional procedures guidance 208
    - Laparoscopic radical prostatectomy (2006) NICE interventional procedures guidance 193
    - Laparoscopic partial nephrectomy (2006) NICE interventional procedures guidance 151
    - Laparoscopic nephrectomy (including nephroureterectomy) (2005) NICE interventional procedures guidance 136
    - Laparoscopic live donor simple nephrectomy (2004) NICE interventional procedures guidance 57
    - Laparoscopic pyeloplasty (2004) NICE interventional procedures guidance 46

- Standard arrangements recommendations for gynaecology include:
    - Minimally invasive radical hysterectomy for early-stage cervical cancer (2021) NICE interventional procedures guidance 639
    - Laparoscopic techniques for hysterectomy (2007) NICE interventional procedures guidance 239

- Standard arrangements recommendations for breast surgery include:
    - Laparoscopic mobilisation of the greater omentum for breast reconstruction (2008) NICE interventional procedures guidance 253

- Standard arrangements recommendations for general surgery including the upper and lower gastrointestinal system include:
    - Single-incision laparoscopic cholecystectomy (2014) NICE interventional procedures guidance 508
    - Combined endoscopic and laparoscopic removal of colonic polyps (2014) NICE interventional procedures guidance 503
    - Laparoscopic gastrectomy for cancer (2008) NICE interventional procedures guidance 269
    - Laparoscopic distal pancreatectomy (2007) NICE interventional procedures guidance 204
    - Laparoscopic liver resection (2005) NICE interventional procedures guidance 135

NICE Guidelines

- Colorectal cancer (2020) NICE guideline NG151
- Prostate cancer: diagnosis and management (2019) NICE guideline NG131
- Diverticular disease: diagnosis and management (2019) NICE guideline NG147
- Ectopic pregnancy and miscarriage: diagnosis and initial management (2019) NICE guideline NG126
- Pancreatitis (2018) NICE guideline NG104
- Endometriosis: diagnosis and management (2017) NICE guideline NG73
- Gallstone disease: diagnosis and management (2014) Clinical guideline CG188
- Fertility problems: assessment and treatment (2013) Clinical guideline CG156

Other NICE guidance

- Laparoscopic surgery for colorectal cancer (2006) Technology appraisal guidance TA105
- Laparoscopic surgery for inguinal hernia repair (2004) Technology appraisal guidance TA83

Commissioning policies

- Clinical Commissioning Policy: Robotic assisted surgery for early kidney cancers that are unsuitable for conventional laparoscopic surgery (2016) - commissioned
- Clinical Commissioning Policy: Robotic assisted lung resection for primary lung cancer (2016) - not commissioned
- Clinical Commissioning Policy: Robotic assisted surgery for oesophago-gastric cancers (2016) - not commissioned
- Commissioning Policy: Robotic Assisted Surgery for bladder cancer (2016) - not commissioned
- Clinical Commissioning Policy: Robotic assisted trans-oral surgery for throat and voice box cancers (2016) - not commissioned

RAS acknowledged as a variation of MIS in the following:

- Minimally invasive radical hysterectomy for early-stage cervical cancer NICE Interventional procedures guidance 686
- Bilateral cervicosacropexy (CESA) or vaginosacropexy (VASA) using mesh for pelvic organ prolapse NICE Interventional procedures guidance 669
- Laparoscopic ventral mesh rectopexy for internal rectal prolapse NICE Interventional procedures guidance 618
- Sacrocolpopexy using mesh to repair vaginal vault prolapse NICE Interventional procedures guidance 583
- Sacrocolpopexy with hysterectomy using mesh to repair uterine prolapse NICE Interventional procedures guidance 577
- Endoscopic radical inguinal lymphadenectomy NICE Interventional procedures guidance 398
- Transoral carbon dioxide laser surgery for primary treatment of oropharyngeal malignancy NICE Interventional procedures guidance 484
- Laparoscopic cystectomy NICE Interventional procedures guidance 287
- Laparoscopic prostatectomy for benign prostatic obstruction NICE Interventional procedures guidance 275
- Laparoscopic radical prostatectomy NICE Interventional procedures guidance 193

Questions for the scoping workshop

Population

1. Is the term soft-tissue procedures meaningful and informative in the context of this evaluation?

2. Is the list of procedures outlined in the draft scope appropriate?

    a. Which specialties should we prioritise?

    b. Is it appropriate to exclude prostatectomy, given it RAS is established in the care pathway?

    c. Should any other subgroups be assessed?

Intervention

3. Is the definition of robotic platform appropriate and complete?

4. Are there any other technologies that should be included in this assessment?

Comparators

5. Is this the most appropriate comparator for this evaluation?

Outcomes

6. Are all of the listed outcomes suitable for inclusion in the assessment?

    a. Are the listed primary outcomes the most important?

Other considerations

7. Have all of the costs associated with the purchase and ongoing use of RAS systems been identified?

8. Are there any other potential equalities issues that should be considered?

9. Are there any other barriers to implementation that are relevant to the scope of the EVA?