

ROBOTIC-ASSISTED SURGERY



ROBOTIC-ASSISTED SURGERY: A PATHWAY TO THE FUTURE

A guide to good practice July 2023



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1. The current state of robotics in surgery

Robotic-assisted surgery (RAS) was first introduced in the UK in the late 1990s. with robotic systems such as AESOP and ZEUS, followed by the da Vinci system in 2000. Since then, over 12 million operations have been performed across 70 countries, with over 1.8 million in 2022 alone and several newer robotic platforms emerging in recent years. In 2018, a College-led commission on the future of surgery predicted the rapid expansion of RAS across the UK and internationally due to its proposed advantages in ergonomics and operative precision, as well as its potential for improving training and service practices. Historically, cardiac surgery pioneered RAS with urology driving adoption in conditions such as prostatectomy, where it has been able to demonstrate a reduction in intraoperative blood loss, length of hospital admission and risk of positive resection margins. For many other surgical specialties, RAS is still experimental, but it has seen an increase in uptake over the last ten years, and it is currently available in more than 100 hospitals in the UK.

Nevertheless, wide recognition of the potential and the adoption of robotics has not moved as quickly as other surgical innovations, with the level of robotic adoption varying significantly across different surgical specialties. This was due partly to the acquisition and running costs of the technology and partly to the difficulty of obtaining complex enough evidence to understand the full impact of the implementation of RAS in the healthcare system. Despite the centralised approaches in Wales and Scotland, the lack of a national strategy in England and Northern Ireland has meant that the use of robotics is often based on local availability, resources and expertise rather than patient suitability and care. There are currently no consistent standards for established surgeons and surgical teams, let alone services wishing to transition from open or conventional minimally invasive surgery to an independent RAS practice. There is also limited access to the required training, assessment, feedback and support necessary to perform robotic surgical procedures competently and safely, and no clear definition of roles and responsibilities for the hospital, trust/health board, surgeon, robotic company, proctor or the regulators.

1.1 AIMS OF THIS DOCUMENT

This document discusses some of the challenges and promises of robotic surgery and the potential future application of robotics. It makes recommendations for sound governance practices that can lead to the safe adoption and expansion of robotic surgery in UK hospitals and proposes a structured pathway for established surgeons who want to transition to RAS. Finally, it aims to identify the relevant roles and responsibilities of key stakeholders for ensuring safe and sustainable independent practice in robotic surgery.

2. The promise and challenge of RAS

The implementation of RAS has been considered disruptive, in the sense that its innovation has the potential to bring about radical change in the field. On the one hand, it can be seen as another tool for improving the technical aspects of surgery, with many operations being similar to their laparoscopic counterpart requiring similar decision making and operative techniques. On the other hand, it has the potential to introduce a complete transformation of surgical provision: widespread implementation of RAS requires new areas of knowledge and full-service realignment, including reconfiguration of space for larger equipment, workforce training, new clinical pathways and potentially a different configuration of the surgical team. As such, multiple stakeholders need to be considered: not only patients and surgeons but also commissioners, regulators, policymakers, industry and others. The emergence of new companies providing robotic equipment adds to the complexity with differing platforms, consoles and delivery systems.

The multidirectional implications of robotic technology make the assessment of its benefits and downsides very complex. So far, there has yet to be a clear consensus on how these should be measured, and which outcomes or benchmarks should be used to determine its clinical and economic value. As such, a number of stakeholders remain uncertain, seeing it as slower and more costly than laparoscopic surgery, certainly in the learning phase.

Nevertheless, studies across a variety of surgical procedures seem to demonstrate

significant advantages of RAS, particularly when performed by experienced robotic surgeons, on appropriately selected patients and in advanced programmes. These advantages include increased patient satisfaction, reduced postoperative pain, more efficient use of anaesthetics, reduced perioperative blood loss, fewer blood transfusions, improved bed utilisation, shorter hospital stays, faster return to work and family, and lower rates of return to theatre. To benefit from the potential advantages of RAS, however, any investment in purchasing robots needs to be accompanied by proper planning for its introduction into the service. This includes the potentially long learning curve for surgeons and theatre teams before these efficiencies can be observed at a large scale.

In the area of patient safety, the suggested benefits are significant. For example. most platforms provide a magnified. three-dimensional image of the surgical site: tremor elimination: motion scaling and instruments that increase freedom of movement, while newer platforms include even more enhanced technologies such as eve tracking and haptic feedback-all these in combination can be argued to increase precision and reduce the likelihood of error. At a time when there is less exposure of trainee surgeons to in-depth procedural training, RAS could allow for increased safety across the spectrum of case complexity and expand the capacity of the surgical workforce more broadly.

Despite this evolution of robotic technology over the last 10–20 years, there is still

considerable work to be carried out by all relevant stakeholders to overcome the challenges it poses. The elevated cost of commercially available robotic equipment is often cited as one of the reasons for the slower adoption of robotic technology. It is difficult to quantify precisely the costeffectiveness of robotic adoption-a number of studies suggest that RAS will always be more costly to the NHS due to the cost of acquisition, training and maintenance of the robotic system, including the cost of disposables and energy use. It is likely that such costs can eventually be reduced by improving clinical outcomes alongside application to a larger volume of patients and by taking account of efficiencies such as possibly reduced operating time and reduction in length of hospital stay, both of which can be improved when the surgical team is experienced and welltrained in RAS. It is possible that the costs of purchasing and maintaining the robotic system may also reduce through commercial negotiation, particularly as more companies bring systems to market

One of the main challenges of RAS is the lack of consistent and sufficiently comprehensive data to adequately evaluate robotic technological advancements, such as collaborative multicentre cohort studies, registries and large datasets that can reveal patterns, trends and associations across the spectrum of relevant surgical procedures (including in relation to human behaviours and team interactions). This means that there need to be more ways to generate evidence for evolving technology, including real world evidence as well as randomised trials with a meticulous investigation across all specialties that utilise RAS to demonstrate improved instrumentation accuracy, operative efficiency and patient safety.

In addition, there is currently no national, multi-stakeholder strategy to support the adoption and growth of RAS, and no robust regulatory framework to delineate the responsibilities between the technology and the surgeon and to determine the roles and relationships of the various stakeholders. This inevitably results in variations in governance processes and in the availability of robotic technology and has an adverse impact on quality control and equity of access for patients.

It is essential that national training standards are developed to enhance the readiness of the workforce to meet the rapidly expanding robotic technology. National guidelines are needed to standardise several aspects of RAS practice, such as the metrics needed to quantify quality, skills and expertise and to determine competence. This includes the nature of tasks that should be evaluated. minimum volumes of procedures and relevant clinical outcomes. Standardisation can also include a provisional selection of procedures that are suitable for RAS. although it is important not to be too prescriptive on this as the field is still evolving.

The next sections of this document will aim to put forward a series of principles and recommendations for establishing a robust training programme on RAS and for introducing RAS into service.

3. Establishing a training pathway for RAS

There are no established protocols or minimum requirements for robotic training of either established surgeons or surgeons in training, although a number of organisations have developed curricula to expose surgeons to basic robotic technology. Such training may vary based on the specialty, procedure and the various tasks involved, but they should entail both technical and non-technical skills, including decision making, troubleshooting and effective communication. Training in robotic surgery can generally be divided into four sequential stages: e-learning, device training, simulation and hands-on procedure-based training.

Although the scope of this document is limited to established consultant surgeons and those in a fellowship programme. given the increasing adoption of robotic surgery and the likely future need for more proficient robotic surgeons, we recommend the introduction of a structured and validated curriculum of core. preprocedural skills in robotic surgery across all stages of surgical training. This will support the general competence and early development of relevant knowledge and skills and will allow trainees to be prepared for procedure-based training in robotic surgery when the opportunity arises (Burke et al 2023).

3.1 MINIMUM REQUIREMENTS OF ROBOTIC SKILLS TRAINING

We recommend that a minimum training in robotic skills should include the following:

- Online training. This should be a combination of generic and platform-agnostic skills to ensure early career surgeons are safe to enter a robotic theatre. Basic training in specific systems, normally specified by the respective robotic system provider, can introduce learners to the various components of specific robotic platforms, common applications and troubleshooting tips, and include an assessed component that leads to a certificate of completion.
- Virtual reality training, competencybased and using a console-based skills simulator and/or wet lab training (a minimum of nine hours and dexterity/accuracy scores above 90% for all parameters). Learners here obtain hands-on experience with the functionality of the robotic platform. Wet lab training enables the learner to take particular steps of the procedure either in a cadaver training centre or on simulated models. Simulation allows for progress through the learning curve and can be transferable to the clinical setting. Most simulators have a variety of exercises dedicated to technical training for camera clutching, instrument manipulation and switching, use of surgical energy and others.

A dedicated curriculum should include didactic instructions for:

- robotic systems/basic console orientation
- cognitive skills training
- psychomotor skills training
- · team training/communication skills
- basic and intermediate surgical skills.
- Observership (bedside training). There are currently two ways through which surgeons are introduced to robotics: through a fellowship or as a consultant already in post. The requirements of observership and the interaction with the trainer will be slightly different in each case:
 - Observership for a Robotic Fellow. This includes observing and assisting in robotic surgery performed by an existing robotics-trained surgeon, probably from the learner's own hospital. Under supervision, learners should be familiar with all aspects involved with proper and optimal set up to provide safe and efficient care, while maximising the utility of robotic technology. This includes instruction on the following tasks:
 - operating theatre set-up and patient position
 - choice of port placement based on the case
 - effective communication with operative staff when docking the robot
 - docking robotic arms to patient ports and instrument insertion
 - principles of instrument exchange/ camera manipulation
 - assistant port side selection and utilisation
 - emergency undocking
 - serving as first assistant to the robotics-trained surgeon for a minimum of ten cases.

- Observership for an established
 Consultant Surgeon. This includes observing and/or assisting in robotic surgery performed by a proctor, likely visiting the proctor's hospital. Under supervision, learners should be familiar with all aspects involved with proper and optimal set-up to provide safe and efficient care, while maximising the utility of robotic technology. This includes instruction on the following tasks:
 - operating theatre set up and patient position
 - choice of port placement based on the case
 - effective communication with operative staff when docking the robot
 - docking robotic arms to patient ports and instrument insertion
 - principles of instrument exchange/ camera manipulation
 - assistant port side selection and utilisation
 - emergency undocking
 - Observing proctor and/or proctor's operative videos for a minimum of ten cases. We recommend that the surgical team (including nurse, surgical assistant and anaesthetist) should visit the proctor's hospital for at least one of their operating lists.
 The nuances of the proctor's surgical technique can then be gleaned from more detailed study of the proctor's own operative videos.
- Operating at the console for a minimum number of procedures under the guidance of a proctor or robotically trained surgeon. In the learning phase, and depending on the platform used, it is essential to have

a dual console system or equivalent, where the proctor or robotically trained surgeon can take control at any point, with an approach of graduated autonomy. Learners should perform a specified minimum number of cases on dual console (or equivalent, depending on the platform) before they are signed off for independent practice.

 Sign off for platform proficiency and independent robotic practice to an oversight committee (see next section). Upon completion of the above stages of training, the learner graduates with a certificate that enables them to apply for accreditation to practise independently.

3.2. DETERMINING COMPETENCE AND PROFICIENCY

Up until recently, competence was based on case observations by proctors, usually designated by the company. Case volumes alone should not be sufficient to determine competence. Ideally, there would be evidence of competence based on agreed metrics and clinical outcomes, which are collected, recorded and monitored through a local oversight committee in charge of maintaining quality. Video recording of cases is often a good way for surgeons to learn from mistakes and become more efficient, so we recommend that surgeons provide evidence of video-recording of cases for review before being signed off as competent and proficient.

It is important to note also that competence and proficiency may be device- or platformspecific, and further training with additional robotic cases may be required for a different platform.

An example of metrics to demonstrate competence can be the following:

- Completion of five core simulator skill exercises with a passing score of 90% every two years.
- Case logs from recent two years must perform at least 20 procedures per year, in these two years.
- Failure in the above will result in caseproctoring for the next two cases.
- Surgeons who are inactive for more than 90 days must complete core simulator exercises with a passing score above 90%.
- Surgeons performing more than 50 cases in two years will be exempt from the above.

It is important to note that the criteria for qualifying as a proctor need to be based on multidimensional assessment that takes into account volumes of procedures but also goes beyond mere volumes to include clinical benchmarks and the demonstrable ability to train and educate others.

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4. Developing the robotic surgical team

Safe and successful surgery always depends on effective teamwork of the wider surgical team, with every member contributing and playing a part in a complex division of labour. When it comes to robotic surgery in particular, several studies (eg, Jayne et al 2017 and Randell et al 2023) demonstrate that building effective robotic teams is integral to successful robotic programmes.

When planning for the introduction of RAS, it is important that each hospital has a surgical workforce strategy in place that focuses on capacity building and appropriate training for surgical care practitioners, robotic assistants and nurses, so that they are able to work confidently with surgical robots. The Royal College of Surgeons of England has developed a robotic surgery module in its recently revised surgical care practitioner curriculum that lavs out the minimum theoretical. clinical and technical skills for working as part of a RAS team in a given surgical specialty and can be used as a basis for the training of the wider surgical team.

When developing robotic teams, it is particularly important to take into account how the introduction of RAS alters the

nature of the surgical work, including the absence of tactile feedback for the operating surgeon, who may not be scrubbed and be far away from the bedside theatre team. Using robots has a significant impact on the division of labour in the team: as the robotic equipment enables the surgeon to do more, the role of the surgical assistant changes and there is a different distribution of tasks among team members, different professional jurisdictions and a different way of coordinating the surgical workflow, including the need for the assistant surgeon to communicate information to the operating surgeon who may not have visual contact with the patient. It is imperative that there is a clear understanding of each member's respective role and responsibilities, and a defined framework for verbal and nonverbal communication between members of the surgical team who may not be close to each other.

Hospitals should therefore focus on more than just training surgeons or individual members of the surgical team in isolation, but make plans for the training of whole teams, including team evaluation processes and assessment benchmarks.

5. Introducing RAS into surgical services

There are currently no national standards for introducing and maintaining a successful programme of RAS in hospitals, including adequate further training, accreditation of skills and ongoing quality improvement. This section outlines individual roles and responsibilities for all key stakeholders involved in the successful introduction and governance of the programme, alongside basic principles for building and maintaining competence and quality.

5.1 THE HOSPITAL TRUST/HEALTH BOARD

While developing a robotic surgery programme, a hospital trust or a health board will ensure that it has developed processes and procedures for safe and continued training of its workforce (surgeons and theatre staff), infrastructure (sterilisation, theatres) and service agreements with the provider robotic company for 24/7 technical support.

The robotics programme in each individual hospital trust/health board should be overseen by an oversight committee, eg, a 'Robotics Surgery Governance Group (RSGG)' with responsibility for ensuring the safe delivery of robotics surgery for patients. Once established, this RSGG would meet on a quarterly basis and comprise representatives from the surgical directorates undertaking robotics surgery, theatres, audit and governance lead.

Its terms of reference will be defined by each individual hospital trust/health board. These will include the following:

- ensuring RAS is conducted in a safe manner by an appropriately trained surgeon
- approving new programmes/ departments intending to develop RAS
- approving proposals for new procedures to be performed with RAS before their submission to the New Interventions and Procedures Committee (NIPC)
- facilitating less complex cases to be carried out robotically if deemed beneficial for training
- signing off surgeons for platform competence/proficiency and independent robotic practice
- developing a surgical workforce strategy that builds capacity and ensures appropriate training for the wider surgical team, including surgical care practitioners, robotic assistants and nurses (see section Developing the surgical team)
- overseeing audit and outcome data of established and new RAS procedures
- providing recording equipment/facilities for all robotic operations for the purposes of audit and/or assessment
- encouraging innovation and research in the field of RAS in a secure governance framework
- devising a streamlined process of temporary contracts for UK and Recognised International Proctors, which bypasses protracted Human Resources checks.

Independent practice (sign-off and full accreditation)

- Surgeons would be granted permission to practise RAS after completing the minimum required number of proctored cases as outlined above; and after submitting completed proctoring forms and a letter of competence from their surgical proctor to the RSGG.
- Such permission for independent practice should consider the differences in robotic platforms and, where appropriate, it should be deviceor platform-specific.
- Full accreditation would be granted to the submitting surgeon after a satisfactory audit of outcomes of their first ten cases had been reviewed and approved by the RSGG. Where the necessary expertise was not available locally, audited outcomes would be submitted to a national or international expert for review, as required.
- Where possible, we strongly recommend that surgeons start a robotic surgery practice in collaboration with at least one other surgeon—this can provide valuable peer support and safeguard against isolation.

5.2 THE SURGEON

Surgeons wishing to incorporate robotics surgery into their scope of practice would first have to demonstrate completion of the following requirements:

- evidence of an approved, fully costed business case for a specific procedure(s), signed off by the Clinical Director
- approval by the 'New Intervention Procedure Committee' (or similar body with the same function)
- a letter of support from the applying surgeon's Clinical Director.

Once all the above requirements had been met, surgeons would submit the documentary evidence to the RSGG to apply for structured training on the robotics surgical system (or another robotics system, as applicable). This would be primarily to ensure that training and resources were coordinated and utilised as efficiently as possible. Structured training would comprise the mandatory elements mentioned in the previous section of this document.

It would be the responsibility of each surgeon/hospital trust/health board to fund and support training as required. All surgeons would be required to provide documentary evidence of completion of all elements of the training.

The only permitted exemptions would be in the case of fellowship-trained robotics surgeons and also newly appointed consultants who were already independently performing robotic surgery at other hospital trusts/health boards—they would not be required to repeat elements of the training. The hospital trust/health board may, however, request that the surgeon's first few robotic cases should be proctored by a recognised proctor as they would be working in a new environment and with a new surgical team.

To be considered a fellowship-trained robotics surgeon, an applicant would need to demonstrate that they had successfully completed no less than 6–12 months' training at a nationally and/or internationally recognised centre for robotic surgery and training. Required documentation could include the following:

 details of the specific robotics training Fellowship undertaken, including information regarding the amount of time spent on the following elements: theoretical training; the number of simulator sessions; dry-lab training and operations performed as an assistant and console time undertaken

- a completed robotics training logbook
- a certificate of completion of robotics training, or alternatively, a letter of support from a robotics training supervisor confirming satisfactory completion of specific robotics training

Established robotics surgeons, newly appointed to a respective hospital trust and intending to continue offering robotics surgery, would need to submit the following:

- a letter of support from the lead clinician at their previous employing trust, confirming their competence to perform robotics surgery, and a copy of their most recent appraisal
- a completed surgical logbook demonstrating surgical outcomes from the last 12 months of robotics surgical procedures
- accreditation requirements for robotics surgical practice as outlined below.

5.3 THE ROBOTIC COMPANY

It will be the responsibility of the company supplying a robotic system to ensure that:

- its system is provided with 24/7 technical support;
- it will develop well-defined training pathways for surgeons and theatre staff, which are compliant with good clinical practice and recommended that it is accredited by RCS England. This will include online training modules, simulation and technical training on the robotic system;
- it will organise for the surgical team to visit the proctor hospital;
- it will arrange for the proctor to come over to train the surgeon and the surgical team until the surgeon is deemed fit for an independent practice by the RSGG;
- it is responsible for keeping a register

of RAS proctors (UK and European) with a clear delineation of each proctor's device- or platform-specific area of expertise;

 it will also keep a register of handdominance, to match a left-handed surgeon with a left-handed proctor where this is feasible.

5.4 THE PROCTOR

Every attempt should be made to utilise existing robotics-trained surgeons already employed in a department. This would not only be the most cost-effective solution for the hospital trust/health board but would also provide more robust governance measures than external 'drop-in' proctors who would have no specific allegiance.

Where this is not possible—for example, where there are no robotically trained surgeons in a specific department or in the UK—mandatory requirements for robotics proctors would be as follows:

- a surgeon already accredited to perform robotics surgery elsewhere and who had performed more than 100 robotics procedures (platform-specific)
- a surgeon with their own library of prerecorded operative videos demonstrating the surgical techniques or procedure they plan to teach
- a surgeon on the respective robotics company's list of approved surgical proctors
- Once appointed, the same surgeon would attend all proctored cases for the robotics trainee to ensure appropriate safety and progression. For the sake of continuity and consistent oversight, we recommend avoiding the use of multiple proctors other than in exceptional circumstances.
- A proctor would be required to be a surgeon in the same specialty as the training surgeon and be familiar with both the robotics and non-robotics

form of the surgery. Ideally, they would be on hand to assist with specific issues pertaining to positioning, system docking and instrumentation and system troubleshooting. It would, however, be expected that from time to time, the proctor might be required to perform components of the surgery; for example, to assist in a difficult dissection and to ensure that the surgery was completed in a timely fashion.

- All visiting surgical proctors would require a letter of authority from Human Resources, indicating that they were indemnified by the hospital trust/health board to supervise robotics training.
- Every effort should be made to avoid the occurrence of adverse events at the hospital trust. As such, all training surgeons would be required to undertake a minimum of ten proctored surgical cases before being considered for independent surgical practice. Exceptions would include fellowshiptrained robotics surgeons who would be required to undertake a minimum of five proctored cases.
- Established robotics surgeons from outside the hospital but recently employed may still require observation by an internal trust/health board proctor for a minimum of three cases. Each proctored case would be signed off by the surgeon, proctor and scrub nurse or anaesthetist for submission to the RSGG.

5.5 THE GENERAL MEDICAL COUNCIL

The General Medical Council (GMC) needs to define its role and responsibility in developing a safe RAS practice in the UK.

As the number of surgeons and surgical specialities seeking to develop RAS is expected to increase in the UK, there will invariably be a need to rely on RAS proctors from Europe or the US as there will be very few or no proctors available in certain specialities in the UK.

We would welcome a confirmation from the GMC that they will offer temporary registration to internationally recognised proctors and world-renowned surgeons who may agree to come over to train UK surgeons for a short period (3–6 months).

Under current arrangements a European/ US proctor may come over and advise but cannot legally take over part of the robotic procedure in case of a difficulty. This exposes the patient, surgeon and the trust to great jeopardy. This remains one of the major factors for the slow development of RAS in the UK when compared with Europe and the US.

A mechanism needs to be developed under which a proctor could be given a temporary registration (3–6 months) by the GMC on the recommendation of the hospital trust's medical director.

There is a need to develop (in concert with the surgical royal colleges and surgical specialty associations) a national register/ audit of patients undergoing RAS, or to adapt existing audits to incorporate comprehensive new datasets to capture this information.

Hospital Trust/ Health Board	Surgeon	Proctor	Robotic Company	GMC
Develop a process and procedures for safe and continued training of its workforce (surgeons and theatre staff), infrastructure (sterilisation, theatres), service agreements with robotic company for 24/7 technical support Develop a robotic surgery governance group with clearly defined TORs Devise a streamlined process of temporary contracts for proctors	Apply for and undertake structured training in RAS Online training programme (as specified by respective robotics system provider) Undertake a specified number of robotic procedures under the guidance of a proctor Sign off from RSGG for independent robotic practice Participate in continuous audit of robotic surgical outcomes	A surgeon who has already performed more than 100 robotics procedures and is registered as a robotics proctor Attend all surgical cases to ensure appropriate safety and progression Assist with all aspects of surgery including trouble-shooting and performing components of the surgery Would advise RSSG on the sign-off of the trainee surgeon	Its system is provided with 24/7 technical support Develop well- defined training pathways for surgeons and theatre staff in concert with RSGG Arrange for the proctor visits to train the surgeon and the surgical team until the surgeon is deemed fit for an independent practice by the RSGG Keep a public, device-specific register of RAS proctors (UK and European)	Must devise a mechanism of temporary registration for a recognised proctor on the advice of the medical director of a hospital trust/ health board Develop in concert with surgical royal colleges and surgical speciality associations a national register/audit of patients undergoing RAS

5.6 OTHER KEY CONSIDERATIONS

Selection of cases: There must be careful consideration around which cases should be selected for the initial cases of robotic surgery. We recommend learners start with easier cases and non-severely comorbid patients before gradually stepping up to more complex cases. High body mass index (BMI) is one of the main determinants of surgical difficulty in robotic surgery, as intracorporeal fat tends to obscure normal anatomy and compounds the challenge of lack of tactile feedback. Learners should aim to restrict training cases to those with a BMI below 35.

• **Consent:** The College's guide *Consent: Supported Decision-Making* sets out the information that surgeons should provide to patients as part of the consent process. This includes the purpose and expected benefit of the treatment, what it involves, the likelihood of success, the material risks of the procedure and the alternative options. Even if a surgeon cannot offer all alternatives, they should be familiar enough with the relevant literature to refer the patient to the right service/professional. When it comes to new technologies such as RAS, it is essential that the consent discussion also includes information about:

- the innovative nature of the procedure
- the surgeon's learning curve and their specific experience with the technology
- the presence or absence of a surgical proctor for the procedure
- the risks and benefits of the procedure, including possible unforeseeable or unknown risks or outcomes
- alternatives to the innovative procedure.

The learning curve refers to the increased risks to patients during the time in which a surgeon or surgical team gain competency in a new procedure. It applies where the original innovator is gaining experience in the new technique but also where the technique is performed in different hospitals by other surgeons (Soomro, 2019). Patients and their families must know when they are participating in innovation, so it is essential that surgeons are transparent and particularly tell their patients when they carry out a procedure for the first time. Lack of transparency when it comes to material information and the availability of other options can result in furthering disparities in healthcare literacy, which in turn is correlated with lower socioeconomic status.

Managing conflicts of interest: Surgeons must be open about any conflict of interest arising for both the surgeon and their organisation. Such conflict can arise from their relationship with the companies that manufacture the innovative technology, particularly where this leads to significant financial or reputational gain. Surgeons should disclose to their patients all relationships with companies that manufacture technology used as part of their operation. Conflicts may also arise where the patient has been referred to, or has specifically asked to see, a particular surgeon because they are known to undertake an innovative procedure, placing pressure on the surgeon to undertake the procedure even though an alternative might be more suitable for that particular patient. There may be financial incentives for both the surgeon and for healthcare providers to offer an innovative procedure, in terms of the fees paid. In these situations, conflicts can arise for both the surgeon and the organisation. Oversight mechanisms for the surgical innovation must exclude any temptation to encourage patients to participate in innovation over an established procedure or to overstate its benefits. The natural desire to obtain positive outcomes when implementing new technologies may lead to bias in patient management decisions, as well as in data collection and reporting. At all times. surgeons must preserve the best interests of their patient and uphold ethical standards when making decisions about the application and dissemination of new technologies.

Registers: For registers to be effective and to adequately support the safe and consistent expansion of RAS, they must be accessible. In this document. we have therefore recommended that each company keeps a public register of RAS proctors with a clear description of their experience and expertise in any given device. In due course, we would like to see a single, international register across all companies. This should be companyfunded and hosted by an independent organisation such as the Healthcare Quality Improvement Partnership, preferably led by the surgical roval colleges.

Mentoring: Other than proctorship, which is an essential part of RAS training, the College also recommends that surgeons seek a surgical mentor throughout their career but particularly when taking on a new role and in the early stages of their independent RAS practice. Proctorship includes hands-on training, feedback and oversight in the clinical setting, as well as an assessment of the surgeon's skills and competence before practising independently. Mentoring, on the other hand, is an informal (albeit structured) supportive relationship with an experienced colleague who can guide and support another surgeon at any stage of their career regarding their personal and professional development. The mentor achieves this by listening and talking to the mentee in confidence. The mentoring relationship can include a re-examination of the surgeon's ideas or career goals, identifying further learning, skills improvement and wider professional development needs, and can provide support in difficult situations.

6. A pathway to the future

The 21st century has brought an increasing variety of less invasive ways to treat disease and to carry out surgery. In addition to being a tool in the surgeon's toolkit. robotics and computer-assisted technology in particular have the potential to provide a pathway to the future not just by improving the technical or mechanical aspects of surgery but also by providing enhanced vision around preoperative or intraoperative imaging. Incoming technologies in surgery can support intraoperative decision making through rapid pattern recognition and by converting data to information in a way that can support the operating surgeon's judgement and perception and steer them away from danger or error.

Digital surgery can also enhance training through the integration of digital tools into the surgical curriculum, including telementoring and teleproctoring. Such technologies can provide more sophisticated ways of benchmarking training progress and introduce better and more accessible simulation training. They can also drive improvements in patient care by converting large data into valuable information that accurately measures technical performance, identifies poor surgical outcomes and advances equity of access to surgery. As such, they can offer better value to society at large when it comes to understanding and responding effectively to the population's surgical needs.

It is possible that robotic surgery will eventually reach an era where a robot could either perform preprogrammed tasks, thereby complementing human performance, or learn from its own experience through a feedback sequence of good and poor outcomes. This is probably a long way in the future and comes with significant additional ethical and systemic considerations. This makes the proper and cautious evaluation and meticulous comparative effectiveness research of RAS even more important. Any future developments need to proceed with transparency and sufficient assurances of patient privacy and confidentiality of data through high-security platforms and appropriate regulation. Decisions need to be based on objective research that considers the full implications of using new technologies, not just at the individual level but also at a systemic and societal level.

It is also important to establish the right relationship with industry, being clear and transparent about what constitutes a conflict of interest and establishing an effective dialogue that will benefit both patients and surgical education.

The College is committed to working with surgeons, patients, industry partners, regulators and commissioners to achieve and maintain a high standard of surgical training and practice so as to realise the benefits of RAS for hospitals, surgeons and patients. To find out more about the College's work on robotic surgery, please visit our website at www.rcseng.ac.uk.

7. References

Peer-reviewed literature

- 1. Aradaib M, Neary P, Hafeez A et al. Safe adoption of robotic colorectal surgery using structured training: early Irish experience. J Robot Surg 2019; 13: 657–662.
- 2. Baumbach JA, Willburger R, Haaker R et al. 10-year survival of navigated versus conventional TKAs: a retrospective study. Orthopedics 2016; 39: S72–S76.
- Burke JR, Fleming CA, King M et al. Utilising an accelerated Delphi process to develop consensus on the requirement and components of a pre-procedural core robotic surgery curriculum. J Robot Surg Published online February 9, 2023. doi: 10.1007/s11701-022-01518-2.
- 4. Camp C, O'Hara J, Hughes D et al. Short-term outcomes and costs following partial nephrectomy in England: a population-based study. Eur Urol Focus 2018; 4: 579–585.
- Cole A, O'Neill P, Sampson C et al. Barriers to uptake of minimal access surgery in the United Kingdom. OHE- Health Economics and Outcomes Research ; March 2018. https://www.ohe.org/publications/barriers-uptake-minimal-access-surgeryunited-kingdom/
- 6. Cool CL, Jacofsky DJ, Seeger KA et al. A 90-day episode-of-care cost analysis of robotic-arm assisted total knee arthroplasty. J Comp Eff Res 2019; 8: 327–336.
- Fleming CA, Ali O, Clements JM et al. Surgical trainee experience and opinion of robotic surgery in surgical training and vision for the future: a snapshot study of panspecialty surgical trainees. J Robot Surg 2022; 16: 1073–1082.
- 8. Fu H, Yan CH, Cheung A et al. Robotic-arm assistance simplifies hip arthrodesis conversion to total hip arthroplasty. Arthroplast Today 2020; 6: 877–887.
- Gonzalez-Martinez J, Bulacio J, Thompson S et al. Technique, results, and complications related to robot assisted stereoelectroencephalography. Neurosurgery 2016; 78: 169–180.
- Hampp EL, Scholl L, Faizan A, et al. Comparison of iatrogenic soft tissue trauma in robotic-assisted versus manual partial knee arthroplasty. Surg Technol Int 2021; 39: 419–426.
- Hughes D, Camp C, O'Hara J et al., 2016. Health resource use after robot-assisted surgery vs open and conventional laparoscopic techniques in oncology: analysis of English secondary care data for radical prostatectomy and partial nephrectomy. BJU Int 2016; 117: 940–947.
- Jayne D, Pigazzi A, Marshall H et al. Effect of robotic-assisted vs conventional laparoscopic surgery on risk of conversion to open laparotomy among patients undergoing resection for rectal cancer: the ROLARR randomized clinical trial. JAMA 2017; 318: 1569–1580.
- Jiang B, Pennington Z, Azad T et al. Robot-assisted versus freehand instrumentation in short-segment lumbar fusion: experience with real-time image-guided spinal robot. World Neurosurg 2020; 136: e635–e645.

- 14. Lam K, Abràmoff MD, Balibrea JM et al. 2022. A Delphi consensus statement for digital surgery. NPJ Digit Med 2022; 5: 100.
- Lonjon N, Chan-Seng E, Costalat V et al. 2015. Robot-assisted spine surgery: feasibility study through a prospective case-matched analysis. Eur Spine J 2016; 25: 947–955.
- Kayani B, Konan S, Pietrzak JRT et al. latrogenic bone and soft tissue trauma in robotic-arm assisted total knee arthroplasty compared with conventional jig-based total knee arthroplasty: a prospective cohort study and validation of a new classification system. J Arthroplasty 2018; 33: 2496–2501.
- 17. Kayani B, Tahmassebi J, Ayuob A et al. A prospective randomized controlled trial comparing the systemic inflammatory response in conventional jig-based total knee arthroplasty versus robotic-arm assisted total knee arthroplasty. Bone Joint J 2021; 103-B: 113–122.
- Kayani B, Konan S, Tahmassebi J et al. An assessment of early functional rehabilitation and hospital discharge in conventional versus robotic arm assisted unicompartmental knee arthroplasty. Bone Joint J 2019; 101-B: 24–33.
- Kayani B, Konan S, Tahmassebi J et al. Robotic-arm assisted total knee arthroplasty is associated with improved early functional recovery and reduced time to hospital discharge compared with conventional jig-based total knee arthroplasty: a prospective cohort study. Bone Joint J 2018; 100-B: 930–937.
- Kayani B, Konan S, Tahmassebi J et al. A prospective double-blinded randomised control trial comparing robotic arm-assisted functionally aligned total knee arthroplasty versus robotic arm-assisted mechanically aligned total knee arthroplasty. Trials 2020; 21: 194.
- 21. Khlopas A, Sodhi N, Sultan AA et al. Robotic arm-assisted total knee arthroplasty. J Arthroplasty 2018; 33: 2002–2006.
- 22. Lawrie L, Gillies K, Davies L et al. 2022. Barriers and enablers to the effective implementation of robotic assisted surgery. PloS One 2022; 17: e0273696.
- 23. Marchand RC, Sodhi N, Khlopas A et al. Coronal correction for severe deformity using robotic-assisted total knee arthroplasty. J Knee Surg 2018; 31: 2¬–5.
- 24. Moss EL, Morgan G, Martin AP et al. Surgical trends, outcomes and disparities in minimal invasive surgery for patients with endometrial cancer in England: a retrospective cohort study. BMJ Open 2020; 10: e036222.
- Naziri Q, Cusson BC, Chaudhri M et al. Making the transition from traditional to robotic-arm assisted TKA: what to expect? A single surgeon comparative-analysis of the first-40 consecutive cases. J Orthop 2019; 16: 364–368.
- 26. Patel V. Future of robotics in spine surgery. Spine 2018; 43: S28.
- Ramsay C, Pickard R, Robertson C et al. Systematic review and economic modelling of the relative clinical benefit and cost-effectiveness of laparoscopic surgery and robotic surgery for removal of the prostate in men with localised prostate cancer. Health Technol Assess 2012; 16: 1–313.
- 28. Randell R, Greenhalgh J, Hindmarsh J et al. 2019. How do team experience and relationships shape new divisions of labour in robot-assisted surgery? A realist investigation. Health (London) 2021; 25: 250–268.

- 29. Robertson C, Shaikh S, Hudson J et al., 2022. The RoboCOS Study: development of an international core outcome set for the comprehensive evaluation of patient, surgeon, organisational and population level impacts of robotic assisted surgery. PLoS One 2023; 18: e0283000.
- Sánchez-Margallo FM, Sánchez-Margallo JA. Analysis of surgeons' muscle activity during the use of a handheld robotic instrument in laparoendoscopic singlesite surgery. In: Duffy VG and Lightner L (eds) Advances in Human Factors and Ergonomics in Healthcare, Advances in Intelligent Systems and Computing. Cham: Springer; 2017: 482.
- Scholl LY, Hampp E, Alipit V et al. Does the use of robotic technology improve surgeon ergonomic safety during TKA? EPiC Series in Health Sciences 2019; 3: 322–324 https://easychair.org/publications/open/62mV.
- 32. Shepherd JM, Harilingam MR, Hamade A. Ergonomics in laparoscopic surgery—a survey of symptoms and contributing factors. Surg Laparosc Endosc Percutan Tech 2016; 26: 72–77.
- Smith R, Patel V, Satava R. Fundamentals of robotic surgery: a course of basic robotic surgery skills based upon a 14-society consensus template of outcomes measures and curriculum development. Int J Med Robot 2014; 10: 379–384.
- 34. Soomro NA, Hashimoto DA, Porteous AJ et al. Systematic review of learning curves in robot-assisted surgery. Br J Surg 2020; 4: 27–44.
- 35. Suarez-Ahedo C, Gui C, Martin T et al. 2017. Robotic arm assisted total hip arthroplasty results in smaller acetabular cup size in relation to the femoral head size: a matched-pair controlled study. Hip Int 2017: 27: 147–152.
- Vigdorchik JM, Sharma AK, Aggarwal VK et al. The use of robotic-assisted total hip arthroplasty in developmental dysplasia of the hip. Arthroplast Today 2020; 6: 770– 776.
- 37. Wallace DJ, Vardiman AB, Booher GA et al. Navigated robotic assistance improves pedicle screw accuracy in minimally invasive surgery of the lumbosacral spine: 600 pedicle screws in a single institution J Robot Sur 2020; 16: e2054.
- Warwick Clinical Trials Unit. Robotic arthroplasty: a clinical and cost effectiveness randomised controlled trial for hips (RACER-Hip). June 2021. https://warwick. ac.uk/fac/sci/med/research/ctu/trials/racer-hip/patientsinfo/racer-hip_protocol_ v1.1_22_june_2021.pdf

Professional organisation and industry documents

- 1. Association of British HealthTech Industries, 2022. White Paper Robotic-assisted surgery and new models of surgical care.
- Association of Surgeons in Training and The Royal College of Surgeons of England, 2022. Future of Surgery: Technology Enhanced Surgical Training: Report of the FOS:TEST Commission, August 2022. DOI: 10.1308/FOS2.2022.
- 3. CMR Surgical, 2019. Feeling the strain: The physical and mental impact of performing surgery.
- 4. NHS England, 2015. National Commissioning Policies RAS procedures for prostate cancer.
- 5. NHS England, 2018. RAS for early kidney cancers that are unsuitable for conventional laparoscopic surgery.
- 6. Royal College of Surgeons of Edinburgh, 2023. Development of new robotic surgical services.
- 7. Royal College of Surgeons of England, 2014. Good Surgical Practice.
- 8. Royal College of Surgeons of England, 2015. The High Performing Surgical Team.
- 9. Royal College of Surgeons of England, 2018. Report of the Commission on the Future of Surgery.
- 10. Royal College of Surgeons of England, 2019. Surgical Innovation, New Techniques and Technologies A guide to good practice.
- 11. Royal College of Surgeons of England, 2022. Supported Decision-Making A guide to good practice.
- 12. Royal College of Surgeons of England, 2022. Working in the Independent Sector A Guide to Good Practice.
- 13. Royal College of Surgeons of England, 2022. The Curriculum Framework for the Surgical Care Practitioner.
- 14. Royal College of Surgeons of England, 2023 (forthcoming). Mentoring A Guide to Good Practice.



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