THE ROYAL COLLEGE OF SURGEONS OF EDINBURGH

Development of new robotic surgical services

A guide to good practice

ROBOTIC SURGERY TASKFORCE, RCSEd

Preface

This guidance document has been developed by the RCSEd Robotic Surgery Taskforce and its guidance writing group.

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1. INTRODUCTION

Robotic-assisted surgery is increasingly being utilised in many surgical specialties in the UK. Robotic urological programmes (especially in robotic-assisted prostatectomy) have been successfully implemented in many centres in the UK and internationally. Such programmes have undergone the iterative improvements of a mature service. However, in many other specialties, robotic-assisted surgery is still limited but increasingly being embraced, with multiple centres putting forward business cases to develop new robotic surgical programmes. For these centres, the surgical teams will be embarking on robotic-assisted surgery in non-urological specialties for the first time within their NHS trusts and health boards. As with introduction of any new surgical procedures, patient safety is of paramount importance, and it is essential that individual hospitals have robust local protocols to enable safe adoption of robotic-assisted surgery. Increasingly, there are also new robotic systems coming into the market which may introduce a further layer of complexity to the development of such services.

The Royal College of Surgeons of Edinburgh (RCSEd) has established a robotic expert advisory group to consider issues around the implementation of robotic-assisted surgery in the UK. This includes the development of this guidance document to provide a practical tool kit for individual hospitals to use when they are setting up a new robotic surgical service. This document aims to provide comprehensive generic recommendations covering areas of training and clinical governance relevant to all surgical specialties in which robotic surgery is being adopted. It aims to help the multidisciplinary robotic surgical team develop safe practices and set-up, before embarking on clinical cases for the first time. It is important to point out that this guidance document highlights areas of best practice. The responsibility for clinical governance lies with individual NHS trusts and health boards.

2. SETUP OF ROBOTIC GOVERNANCE AND PEER REVIEW GROUP

Prior to establishing a new robotic surgical service, a robotic governance and peer review group (RGPG) should be set-up. Membership should consist of established robotic surgeons, surgeons who are new robotic adopters, anaesthetists, surgical care practitioners (SCPs), operating theatre team members (scrub teams, operating department practitioners [ODPs]) and representatives from the hospital management team. The chair of the RGPG should aim to cater to the differing needs of both the established robotic surgeons as well as surgeons who are developing new services for the first time. The remit of the RGPG will include all aspects of the robotic surgical service encompassing business case development, education and training, recommendation regarding robotic surgical privileges, safeguarding of clinical governance and auditing of surgical outcome and cost effectiveness (Figure 1: Roles of RGPG). This will also include approval of proctors, in collaboration with the local surgeon and robotic vendor, when new robotic surgeons start undertaking their first clinical cases. This forum will allow for sharing of best practice and to trouble-shoot problems when they arise. A robotic surgery operational group (RSOG) with representations from IT, medical physics, clinical engineering, sterile services, operating theatre stores and procurement will be essential to deal with the technical implementation of any new robotic system (e.g. IT installation and data management, consumable and tray procurement, sterilization of reusable equipment and maintenance contracts). The lead of the RSOG should report to the RGPG regularly and facilitate the smooth day to day running of all robotic surgical services

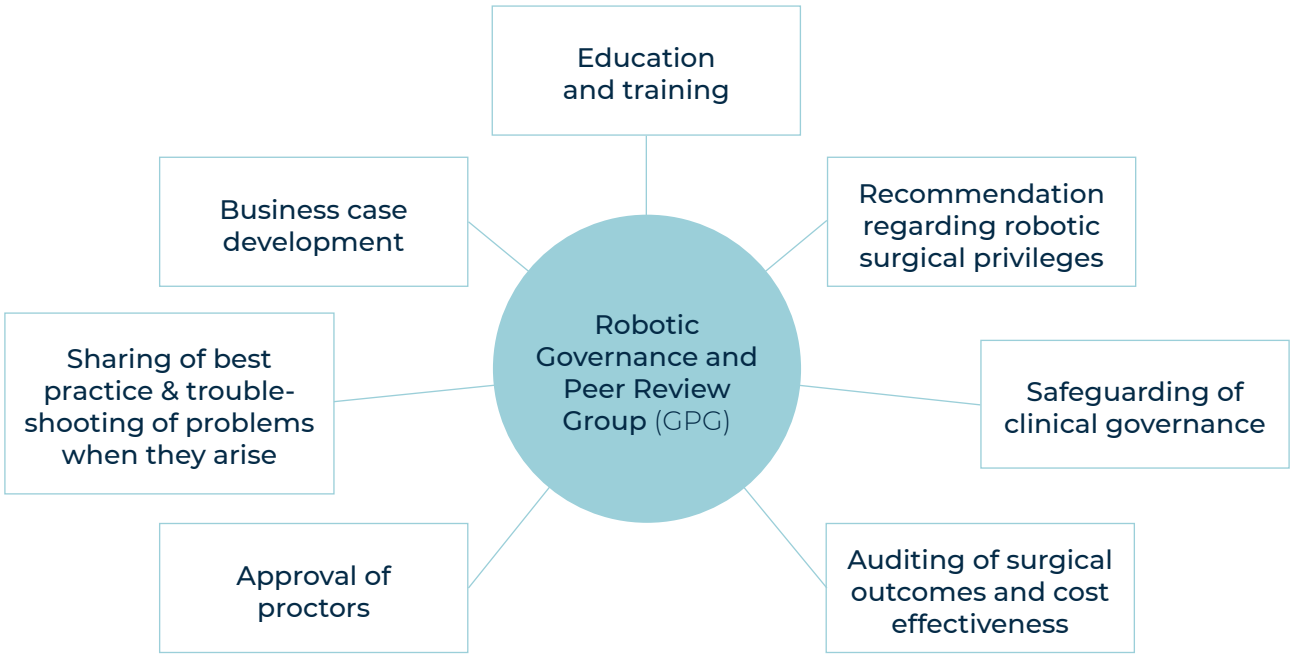

Figure 1. Roles of RGPG

3. MODEL FOR ROBOTIC SURGICAL TRAINING

Before embarking on clinical cases, it is recommended that each surgical team enroll their robotic surgical team members into a graduated training programme. Robotic-assisted surgery is currently not part of regulated surgical training curricula in the UK. Therefore, a series of graduated training steps are recommended to allow surgeons and their teams to incorporate robotic-assisted surgery into their practice. In line with current surgical training curricula, both technical and non-technical skills are important components of robotic surgical team training.

With increasing number of robotic systems in the market, several principles to the training model which will remain consistent across robotic vendors are proposed. Currently, components of training are catered for by each robotic vendor upon agreement to purchase individual systems. In the UK, there are also training opportunities provided by a few Specialty Associations and local training centres.

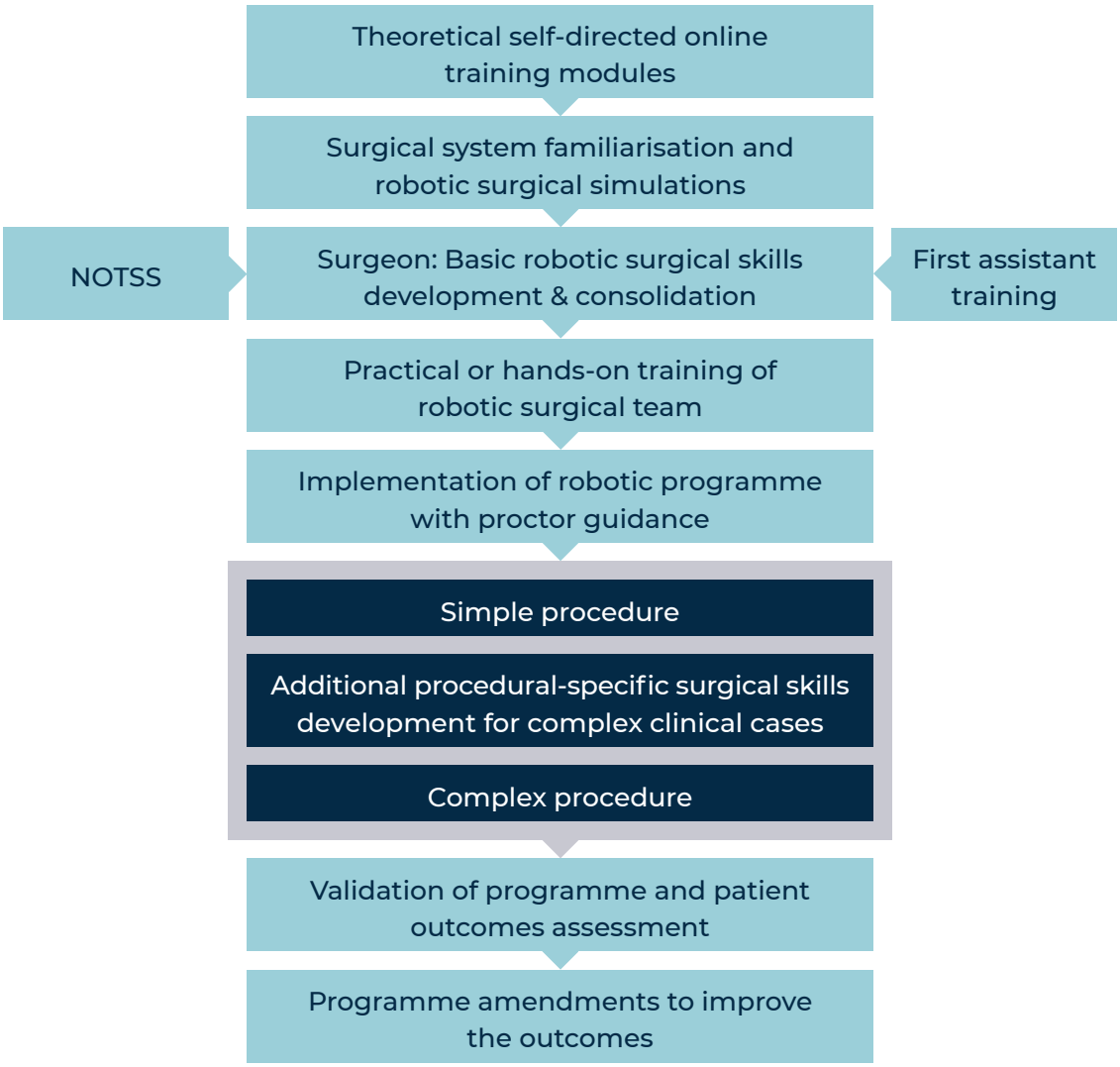

Figure 2. Journey of Robotic Training Programme

3.1 Competency in the procedures to be performed

It is anticipated that the surgical team wishing to perform robotic-assisted surgery will have substantial experience with conventional approaches for that procedure with good patient outcomes. This ensures that the surgical team will be well-versed in the intraoperative steps of the procedure as well as the peri-operative care of the patient. Importantly, the surgeon should be proficient with the proposed procedure and be familiar with the indications, pre-operative case selection, intra-operative steps and post-operative care (including management of complications). Implementation of a new robotic-assisted procedure out with the usual clinical practice of the surgeon should be approved by the local RGPG. This will ensure that all necessary steps are taken to protect patient safety.

3.2 Structured and graduated step-wise programme of training

Each of the team members should be encouraged to undergo training that is relevant to their role within the robotic surgical team. Surgeons and their multidisciplinary robotic surgical team should train using a structured programme that includes the following components (Table 1).

3.2.1 Theoretical self-directed online training modules

Each member of the robotic team should undergo training to understand the basic functions of the robotic system to be used. This usually entails a series of self-directed online modules produced by the robotic system vendor, and other organisations involved in robotic surgical training (e.g. Robotic Training Network[1]). The online modules should cover the basic robotic set-up (including patient preparation and operating room set-up) for the specific type of robotic system that the surgeon intends to use (i.e. vendor and model of robot). For the surgeon, all basic modules including psychomotor skills in robotic-assisted surgery should be completed. For other members of the robotic surgical team, it is expected that the modules relevant to the basic understanding of the robotic system as well as content pertaining to robotic team training and communication skills should be completed. At the end of this component of the training, the desired outcome is that the robotic surgical teams will be conversant with the basic functioning of the robotic system, and surgeons will understand the theoretical aspects of the skills required for robotic-assisted surgery.

Currently available online training modules:

- **Fundamentals of robotic surgery** [2,3]
  Modules available: (i) Introduction to surgical robotic systems, (ii) Didactic instructions to surgical robotic systems, (iii) Psychomotor skills curriculum and (iv) Team training and communication skills.
- **American Urologic Association Robotic Surgery Online Course** [4]
  Modules available: 9 modules covering fundamentals, basic and advanced urologic procedures.
- **Da Vinci technology training pathway** [5]
  Modules available: (i) Phase 1: Introduction to Da Vinci Surgery, (ii) Phase 2: Da Vinci technology training.
- **Versius training pathway** [6]
  Module: Versius e-learning online modules

3.2.2 Robotic surgical simulations

Surgeons should gain access to a robotic simulator to train on the basic robotic surgical skills as well as robotic procedural skills. Increasingly, virtual reality (VR)-based exercises enhance the learning experience, especially in procedural skills. Simulators are helpful training tools that allow surgeons to spend time on the consoles to improve their robotic techniques with exercises that cater to both basic and advanced levels. It is recommended that surgeons complete the recommended programme of simulations provided by the robotic system vendor before starting clinical cases. This can be supplemented by simulator access during a hands-on course, as well as by the regular use of an available simulator at a local training centre. Regular use of a simulator is useful during the implementation phase of initial clinical cases as well as an ongoing training tool.

Currently available robotic simulators

- Intuitive Da Vinci Sims Now [7]
- Robotic Surgery Simulator – RoSS, Simulated Surgical Systems [8]
- dV-trainer – Mimic Simulation [9]
- Simbionix RobotiX mentor – 3D systems [10]
- Versius trainer [6]

3.2.3 Basic robotic surgical skills development

Surgeons embarking on robotic-assisted surgery should undertake dedicated training to practise skills using the robotic system on inanimate models, cadaveric or animal-based models. The emphasis should be to develop the psychomotor skills required for robotic-assisted surgery to achieve safe and competent manoeuvring of the robotic endowrist, safe dissection techniques, instrument transfer, energy device application, needle driving/suturing and surgical knot tying. Cadaveric and animal-based models have the additional benefit of allowing practice of robotic system positioning. The cadaveric and animal models will also allow confirmation of the appropriate level of skills before moving to clinical cases. This should include both generic as well as procedure-specific skills development (e.g. vascular dissection and control, luminal anastomosis).

Available on-site hands-on courses covering basic robotic surgical skills

- Fundamental skills of robotic-assisted surgery (FSRS) course (USA) [11]
- Association of Laparoscopic Surgery of Great Britain and Ireland (ALSGBI) basic robotic surgical skills course [12]
- Essentials in robotic surgery (RCSEd)
- Robotics: basic surgical course, Advent Health (USA) [13]

3.2.4 Practical or hands-on training of the robotic surgical team

Once the theoretical and didactic training has been completed, the robotic surgical team should proceed to small group hands-on training. This is usually completed in the resource centre set-up by the robotic system vendor. The practical training will allow each team member to gain hands-on familiarity with the basic and advanced functions of the robotic system. This training should cover settings, functions and instruments relating to the specific robotic system to be used. This training episode should also allow the robotic surgical team to familiarise themselves with advanced technologies such as electrosurgical devices and other robotic instrumentation (e.g. stapling devices) used during robotic surgery. This is followed by robot positioning in relation to a patient, practical steps of docking/undocking depending on the robotic system, troubleshooting steps and more importantly, procedures in the event of a surgical or medical emergency. In addition to the generic set-up, the surgical team should also learn the robotic set-up that is specific to the procedures to be performed.

Currently available team training

- Da Vinci technology training pathway [5]
- Versius technical training and hospital dry run [6]

3.2.5 First assistant training

All surgeons, surgical trainees and surgical care practitioners (SCPs) should undergo first assistant training. It is anticipated that surgeons and surgical trainees should assist during the initial phase of their training, either as first assistants before moving on to become the console surgeon, or assisting other colleagues in advanced robotic procedures. SCPs will likely have a dominant role as bedside assistants in most robotic cases, and will need to acquire full competency as first assistants as part of their essential training. Such skills include robotic system positioning (including docking and undocking depending on the robotic system being used), instrument insertion, camera arm navigation and maintenance, irrigation/suction and use of additional laparoscopic instruments as required (e.g. for tissue retraction or exposure).

Available on-site hands-on courses for first assistants

- Intuitive Da Vinci first assistant training [5]
- Essentials in robotic surgery (RCSEd)
- Robotics: basic surgical course, Advent Health (USA) [13]

3.2.6 Procedure specific robotic surgical skills development

Having achieved competency in basic robotic surgical skills, the surgeon will progress to procedure-specific skills development. Typically, this may involve reviewing surgical videos of robotic procedures to be performed, case observation visits to a centre of excellence and completion of both basic and advanced robotic courses relevant to the specialty and robotic system being used. This will allow surgeons to master the robotic surgical skills required which can be deployed upon embarking on clinical cases. For advanced surgical procedures, each surgeon should adopt a graduated approach and practise the specific skills and steps required for such procedures. This training will be specialty-specific and is outwith the remit of this guidance.

Currently available procedure-specific robotic surgical skill course

- Advanced courses in Colorectal, Head and Neck, Pancreatic, Thoracic, Upper Gastrointestinal Surgery and Urology (IRCAD, France) [14]
- Colorectal robotic surgery cadaveric course [15]
- Intuitive Da Vinci advanced procedure training (TR200-300) [5]
- Newcastle Surgical Training Centre Robotic HPB Surgery and Trans-oral Robotic Surgery (TORS) courses [16]

3.2.7 Non-technical skills in the robotic surgical team

Training should also focus on non-technical aspects of robotic surgical team performance. This includes teamwork and communication between robotic surgical team members. The dynamics within the surgical team are different between robotic-assisted surgery and conventional surgery due to the operating surgeon being separated from the patient on a console. Using a valid non-technical skills framework to structure training in interpersonal communication, teamwork and situational awareness will be critical to enhance team coordination, prevent ambiguous communications and ensure seamless progression through robotic-assisted cases. A formal task analysis detailing robotic surgical team roles, responsibilities and norms of behaviour should be conducted in every site and made available to all team members. The use of additional technology to enhance communication between the robotic surgical team members should also be considered (e.g. use of headsets to allow good communication, operating theatre screens to allow all staff to have a good view of the surgery and to follow its progress).

It is recommended that teams follow high quality human factors guidelines (such as those in development from IDEAL) to ensure safety for every patient. In addition, the robotic team should be trained on basic and advanced strategies for troubleshooting and contingency planning in the event of robotic equipment failure or non-routine emergent situations. The latter could occur in simulated or non-clinical spaces to ensure that teams have experience of the non-technical skills required in high acuity, low frequency robotic surgical situations in order to ensure patient safety.

Table 1. Components of training for the robotic multidisciplinary surgical team

Robotic surgical team member / Training component	**Consultant surgeon**	**Surgical trainee**	**Robotic surgical care practitioner** (SCP)	**Theatre nurse** (scrub nurse and circulator)	**Anaesthetist***	**Anaesthetic operation department practitioner** (ODP)
Theoretical, didactic online modules on robotic system	Essential	Essential	Essential	Essential	Desirable	Desirable
Hands-on basic training of robotic system - Settings and features of robotic system (including devices & instruments) - Positioning of robot - Trouble shooting of robotic system - Emergency procedures	Essential	Essential	Essential	Essential	Essential*	Essential*
Basic robotic surgical skills - Simulation - Inanimate model - Cadaveric model	Essential	Essential	N/A	N/A	N/A	N/A
First assistant skills (bedside)	Essential	Essential	Essential	Desirable	N/A	N/A
Advanced prodecdure-specific surgical skills - Inanimate model - Cadaveric model - Simulation	Essential	Desirable	N/A	N/A	N/A	N/A
Safety protocol training & rehearsal	Essential	Essential	Essential	Essential	Essential	Essential
Robotic non-technical skills	Essential	Essential	Essential	Essential	Essential	Essential

* Anaesthetists will require tailored training in patient positioning in relation to robotic system and emergency procedures

4. EMBARKING ON FIRST CLINICAL CASES

4.1 General considerations upon completion of training for the multidisciplinary robotic surgical team

New robotic surgical services should consider limiting the initial clinical caseload to a few consultant surgeons in each specialty to allow more focused training and proctoring as required. The surgeon should be supported by a dedicated robotic surgical team (which does not change) to ensure consistency. This can then be followed by expansion of the pool of surgeons, using the internally trained robotic surgeons as proctors in due course. A generic pathway for embarking on initial clinical cases is illustrated in Figure 3.

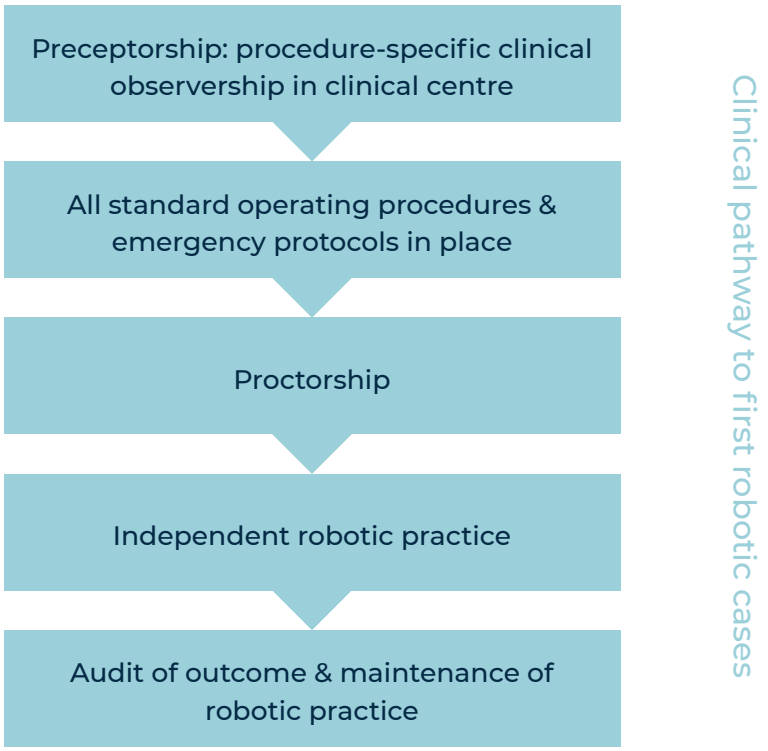

Figure 3. Clinical pathway to embarking on the initial cases of robotic-assisted surgery

4.2 Preceptorship and clinical case observation-based training

Surgeons are encouraged to visit an experienced robotic surgical team who perform the procedures that they wish to embark on. A host surgeon will act as a preceptor, and the visiting surgical team should observe the robotic procedure performed by the preceptor's team. Consideration should be given to visit the trainer surgeon who will be acting as proctor for the initial clinical cases. This will be a good opportunity for the surgical team to observe the other aspects of robotic surgery (e.g. robotic set-up, positioning specific to a procedure, equipment needs). Such experience will be valuable for the surgical team to interact with the preceptor's multidisciplinary team, discuss and learn from potential pitfalls, and consider critical safety set-ups specific to the procedure being undertaken that the experienced team may have evolved.

4.3 Emergency safety protocols and standard operating procedures

Just prior to embarking on the first clinical cases, the robotic surgical team should devise safety protocols to cover emergency medical or surgical situations. In situations where the robotic system used requires emergency undocking, each member of the robotic surgical team should understand their respective roles and the steps to be taken in the event of such an emergency. It will be important to rehearse these scenarios with the robotic surgical team prior to starting the clinical cases. In addition, there will be a need for regular simulation of the emergency protocols to ensure the teams are regularly updated. Local safety protocols should be shared widely with the multidisciplinary robotic team and verified competency should be checked periodically depending on local guidance. Safety protocols should also be in place for robotic equipment failure and steps to be taken in the event of such failure to protect patient safety.

4.4 Proctorship

The proctoring episode should start with the proctor and the training surgical team reviewing indications and cases before embarking on the proposed robotic procedure. It will be essential for the surgical team to undergo a detailed review and discussion with the proctor on the suitability of the patients (i.e. indication, case complexity, imaging review) for their first robotic procedures. Discussion should also occur on the anticipated decision-making process when intraoperative difficulty is encountered, and the necessary steps needed with each scenario. It is recommended that the proctor should be onsite at least for the initial cases to observe the robotic procedure and provide advice and assessment. Proctoring should continue until both the operating surgeon and proctor are satisfied that the procedure can be performed independently at a safe level. Once the teams are more conversant with their robotic practice, telementoring can be useful to provide ongoing training and support.

4.5 Robotic surgical checklist: multi-disciplinary considerations

The WHO surgical safety checklist must be followed for robotic-assisted surgery. In addition, consideration should be given to additional elements specific to robotic-assisted surgery (i.e. specific robotic positioning, equipment, safety protocols). Further consideration should be given to an intraoperative multidisciplinary checklist designed to detect any adverse intraoperative events (e.g. checking patient position-related complications if prolonged robotic surgery) and allow rapid communication to the robotic surgical team members. The timing of this additional component should be designated by the surgical team based on the type of procedure and its duration. This may address any issues that arise from the console surgeon being separated from the on-table patient. Debrief of the surgical team upon completion of the case will be critical to highlight any potential lessons learnt during each robotic-assisted case and allow reinforcement of good practice. Any adverse event or incident should undergo root cause analysis in accordance to local governance procedures.

4.6 Graduated approach: simple cases first

The surgical team should focus their initial cases on simple indications for surgery and on least comorbid patients (e.g. low BMI). This will ensure that the initial cases have a high chance of being completed robotically and safely in a timely fashion. Consideration should be given to performing a less complex procedure with robotic assistance as a training procedure before progressing onto more complex operations. Furthermore, careful planning of the operating theatre schedule will allow sufficient time for completion of the initial cases without rushing and in a controlled fashion. This should form part of the structured development plan for the robotic surgical teams with the recognition that the initial training and implementation phase will entail additional time and costs.

4.7 Progressing to complex procedures: revisit the training

Following the completion of a series of simple procedures, the surgical team should revisit their training prior to starting complex cases to ensure they have developed all the necessary skills. Considerations should be given to re-starting the training pathway; for instance, this can include a further case observation visit to an experienced surgical team, participation in a procedure-specific cadaveric or animal model-based course and further proctoring for complex procedures. Surgeons will also need to complete advanced procedure-specific courses provided by the robotic vendor before embarking on more complex cases. To facilitate collaborative working and learning, it will be useful for another consultant surgeon who has undergone robotic training to act as a bedside assistant in the initial complex cases. A proctor should be present for the initial complex case(s) to ensure safety and maximise the chance of successful robotic-assisted completion of the case(s). When available, the use of a dual console system can also facilitate collaborative learning.

Currently available advanced procedure-specific robotic surgical skill course

- Advanced courses in Colorectal, Pancreatic, Thoracic, Upper Gastrointestinal Surgery and Urology (IRCAD, France) [14]
- Intuitive Da Vinci advanced and masters procedure training (TR400-500) [5]

4.8 Technical support provided by the robotic system vendor

Technical support from the robotic system vendor should be on-site for the initial case series to support the robotic team in the event of equipment malfunction. They should be present until the surgical team is comfortable using the robotic system.

5. CONSENTING PATIENTS AS INITIAL CLINICAL CASES: CONSIDERATIONS

Patients for whom robotic assisted surgery is being considered as an option will need to be counselled appropriately with a full informed consent process. The initial consent discussion should occur in the outpatient setting prior to the patient being admitted for surgery. This should be with the surgeon who will be performing the robotic-assisted procedure and should be undertaken by someone who is competent to perform the procedure using a conventional approach. This task should never be delegated. The patient should be provided with verbal, written and web-based information resources if relevant. Shared decision making is a key aspect of informed consent. The focus is on the patient, and should start by eliciting their views, priorities, preferences and attitudes to being 'one of the first'.

The surgeon having responsibility for the consent discussion with the patient must undertake full disclosure and provide clear communication to the patients that if they opt for robotic-assisted surgery, it will be scheduled during the learning curve of the surgical team. This must include a clear explanation of where the surgical team is on their learning curve and the experience of the team with the conventional approach, highlighting the need to convert to a conventional approach if there is a clinical concern. The surgeon must have a detailed and honest discussion with the patient on the benefits and risks of the procedure using conventional and robotic-assisted approaches, as well as other potential risks to the patient by being part of the learning curve. The advent of complications should be framed as outcomes or lived scenarios – not mere names of conditions which may convey little to patients. Rare but catastrophic sequelae must not be omitted – especially if they relate to an area of individual patient priority. The option of not intervening surgically – including medical alternatives if any, simple observation or symptom management should be considered and explained to the patient.

Information provided to patients must be in an appropriate medium, remembering that health literacy may be poor. Patients should be involved in generating new materials specific to the novel intervention. Surgeons should use plain English checkers[17] if a hospital patient reference panel is not available. A video-recording of a Q&A conversation sharing information on robotic-assisted surgery alongside printed material may facilitate understanding – particularly as there will also be a wealth of disease specific information to assimilate. Patients recall information better if it is personalised and so key points should be highlighted where written materials are being used, in the light of their previously elicited preferences and values.

Inevitably with a novel intervention, the credentials of the treating team will be at the forefront of the surgical team's consciousness. If the consent journey is openly and plainly shared, patients may place greater trust in the judgement of their surgeon than the specifics of their technical training credentials. Information on the multidisciplinary robotic surgical team's systematic training and experience to date, its preparation and patient safety protocols prior to embarking on their first clinical robotic cases will supplement confidence of those undergoing robotic surgery as part of the learning curve of the surgical team.

The consent process should also highlight the presence of a proctor and provide a detailed explanation of the roles of a proctor. The full responsibility for the patient lies with the surgical team treating the patient, whilst the proctor will be there with advisory, coaching and assessment roles.

Documentation of the consent discussions is vital and must be recorded either in (a) the clinical notes, (b) a letter addressed to the patient, or preferably both[18,19]. The documentation should include a reference to a cooling off period, clear pointer to contact options for further questions and second discussion,[20] prior to written consent being given.

6. SELECTION OF PROCTOR: CONSIDERATIONS & RESPONSIBILITIES

Proctors should be experienced robotic surgeons in the specific procedure to be performed by the new robotic surgical team. Prior to the initial cases, proctors will require the local NHS trust or health board to provide indemnity. There will need to be a contractual agreement between the NHS trust or health board and the proctor, stating the proctor's roles and responsibilities. The legal liability of the proctor should be minimised in consultation with the local trust or health board legal team. The responsibility for the patient rests on the surgical team, especially in the context of complications. The local NHS trust or health board will usually need to consider granting temporary privileges (e.g. honorary contract) to the proctor to be involved in direct surgical care and assist during the case if the need arises.

7. MAINTENANCE OF ROBOTIC SURGICAL PRACTICE & AUDIT OF CLINICAL OUTCOME

For a trained robotic surgeon to maintain good clinical outcomes, the surgeon will need to maintain an adequate volume of robotic-assisted cases annually with audit of activity and outcomes. The number of cases to maintain skills will be specialty dependent. Prospective audit of the robotic surgical cases and their outcomes should be used to highlight any potential learning points, and as a dashboard to detect any potential adverse trends which may require correction. This should be reviewed by the RGPG and take into account national or international guidelines where available and the published literature. Furthermore, such a strategy will ensure an efficient workflow of robotic surgical cases, and lead to a more cost-effective robotic surgical programme.

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