Royal Australasian College of Surgeons

# Training for robot-assisted surgery: A preliminary scoping exercise

## Final Scoping Report

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| Title | Training for robot-assisted surgery: A preliminary scoping exercise |
| Author / Affiliation | Dr Alun Cameron, David Tivey (RACS) |
| Working Group | Dr Adrian Anthony<br>Professor Guy Maddern<br>Professor Henry Woo |

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# 1. Summary

The use of robot-assisted surgery (RAS) has increased significantly since its inception in the early 2000s. However, what constitutes appropriate training is not well understood, and the role of RAS as an appropriate therapeutic modality remains uncertain. This scoping exercise is a preliminary investigation to identify exemplar material related to training and clinical evidence across surgical specialties.

This report aims to inform discussions of the Working Group regarding future targeted formal activity.

**Clinical evidence**

The searches for clinical evidence were targeted and time-limited, and thus the results represent recent research interests. There were many clinical studies across most specialties but with the most commonly reported indications including colon and rectal cancers, pancreatectomy and pancreatoduodenectomy, radical prostatectomy, radical cystectomy, partial nephrectomy and hysterectomy. The vast number of indications in the clinical literature show that RAS continues to evolve and be applied to increasing numbers of procedures. As with other health technologies, RAS is considered safe and effective based on evidence generated through long-term, patient-relevant outcomes reported in appropriately designed studies.

RAS appears to enter clinical practice for specific indications without standardised decisions, and no explicit cross-specialty predictors of safe and effective RAS were identified. Clinical studies are varied in their type, design, focus and conclusions, with the availability of randomised controlled trials and the overall maturity of the evidence base varying from one indication to another. While not comprehensive, these examples provide an insight into the variability of clinical evidence related to RAS and the difficulty in establishing clinical equivalence or superiority for any surgical approach. RAS research is a microcosm of surgical research and faces similar limitations, restrictions and biases. For each new proposed indication of use for RAS, questions to ask before considering it to be usual care may include:

- Is there a clinical rationale and theoretical clinical benefit to using RAS for this indication?
- Is this procedure commonly undertaken internationally?
- Is this procedure commonly undertaken in Australia and Aotearoa New Zealand?
- Is there a standardised surgical technique?
- What is the appropriate trial design, and what are the necessary outcomes?
- What is the evidence base and are there any limitations in the available studies? For example, are there formal trials of safety and efficacy? Is there appropriate study design, follow-up, long-term safety data and evidence on the use in real-world settings?
- Does the evidence show that RAS is superior or equivalent to current best practice?
- Are there concerns about the use of RAS in this population?
- What are the international decisions regarding this use?
- What is the access to RAS systems for surgeons, trainees, and patients?
- What are the costs of care associated with this use of RAS?

**Training material**

In preparing this report, the team did not identify any cross-specialty guidance for RAS use or training in core curricula. However, training material was available for certain specialties with information published for the curriculum, training modules and dedicated robotic training centre requirements. Common themes include the importance of formal, standardised, modular training programs and information regarding validated training methods and assessment tools. Exemplars from Urology and General Surgery showed that training material varied widely between specialties and reflects differing maturity of the use of and clinical evidence for RAS and a reluctance from many specialties in formally adopting the requirement of RAS training for all surgeons. However, existing validated material could be used or adapted to inform the needs of the Royal Australasian College of Surgeons (RACS).

Commonly reported components of published training and credentialing activities include:

- Develop specialty- and procedure-specific programs, with training undertaken to proficiency and according to procedure complexity.
- Consider the required experience of the trainee or surgeon, including the impact on training requirements and at what career-point RAS training should be offered.
- Use a modular program to improve the learning curve, including electronic learning, simulation and laboratory models, and a stepped approach defined according to the complexity of parts of each procedure.
- Each curriculum should be based on an existing, validated educational framework and use validated educational formats (e.g. simulation platforms and other training tools).
- Training centres should be accredited.
- Mentors should be experienced, high-volume surgeons with proven educational skills.
- Each procedure should have evidence-based predefined learning curves (number of cases) and quality indicators (technical, functional, oncological).
- Independent examiners (assessors) are required and should use validated evaluation and assessment tools.
- Lists of surgeons who have been accredited or credentialed to undertake RAS should be published. Consider publishing a list of approved RAS trainers or mentors.
- There should be centralised data collection and publication of outcomes.
- All elements of training and credentialing should be standardised for consistency.
- There should be systematic evaluation of training activities and publication of education outcomes.

**Possible future activities**

- Expand or adapt identified RAS training guidelines to create standardised RACS RAS training materials and requirements. These will allow the creation of specialty-specific guidelines.
- Develop methods to identify procedures for clinically appropriate use of RAS or minimum thresholds for RAS use. Suggestions include surgeons, surgical craft groups or societies to nominate indications for RAS use that they believe have become common practice, and for decisions to be informed using best-practice evidence-based methods in line with existing

RACS guidelines. Methods can be based on existing frameworks and activities of appropriate study design and outcomes reporting.

- Develop a consensus statement to summarise the minimum requirements for RAS and critical aspects of RAS training and credentialing.
- Undertake ongoing monitoring of novel RAS systems and indications to determine whether RAS training guidelines require amending.
- Reviews of clinical evidence are not recommended as these would be time-consuming. However, indication-specific reviews of clinical effectiveness should be considered if significant concerns are raised regarding specific procedures or outcomes (e.g. systematic audit of outcomes).
- Undertake research to identify the current uses of RAS in Australia and Aotearoa New Zealand.
- All the material produced from these activities will be endorsed by RACS as the peak body.

# 2. Introduction

Robot-assisted surgery (RAS) has been available in Australia since 2003 with the use of the da Vinci system (Intuitive Surgical) for prostate cancer.[1] This system is available as a multi-port (da Vinci Xi system) or single-port (SP system). In addition, numerous dedicated machines are available for orthopaedics: for spine surgery (Mazor [Medtronic], ROSA [MedTech Surgical] and Excelsius GPS [Globus Medical])[2] and knee arthroplasty (Mako [Stryker], NAVIO Surgical System [Smith & Nephew], OMNIBot [Corin Group]). Additional machines will soon become available. For example, the Senhance Surgical System, Versius (CMR Surgical), CorPath (Corindus), Hugo RAS (Medtronic), Auris Health and Verb Surgical (a collaboration between Johnson & Johnson and Google). Internationally, the use of RAS is rapidly diffusing across a broad range of common general surgical procedures.[3]

These systems aim to provide a safer and more effective RAS platform for patients and surgeons. Although they are a novel technology, surgical robot systems are tools used to provide existing services, and they have entered clinical practice without an agreed formal framework of adoption. In Australia and Aotearoa New Zealand, there are no established curricula for RAS training, which is mainly overseen by the RAS system manufacturers and vendors.[4] With robotic systems becoming more common, there is a need to consider using these technologies further and to develop appropriate curricula for surgeon training and assessment to minimise the impact of learning curves on patient outcomes.[5 6]

In 2020, RACS participated in a national workshop to review aspects of RAS in Australia, including data collection and characteristics of training and credentialing. These discussions highlighted uncertainties regarding RAS in Australia and Aotearoa New Zealand:

- RAS has entered surgical practice with no standardised training and credentialing, and the satisfactory training and credentialing requirements are unclear.
- RAS can be applied to a wide range of procedures. However, the clinical outcomes of RAS are unclear. As a result, it is uncertain which procedures RAS can be considered an option for standard care.

# 3. Objectives

This scoping exercise is a preliminary investigation to identify exemplar publicly available material related to training and clinical evidence across surgical specialties. This draft report aims to inform discussions of the Working Group regarding future targeted formal activity. The questions considered in this exercise were:

- In recent years, which surgical specialities have adopted RAS and for what indications?
    - What is the clinical evidence for common uses of RAS?
    - What is the clinical evidence for an exemplar of less-common uses of RAS?
    - What are the elements of a mature evidence base for RAS?
- Are training materials available for RAS?
    - What is an exemplar of a validated, high-quality RAS curriculum?

- What is an exemplar of a less-standardised RAS curriculum?
- What are the main components of validated training and credentialing activities for RAS?

A formal investigation of the effectiveness, safety and cost effectiveness[7] of RAS is not within the scope of this report.

# 4. Scoping methods

This report provides an initial overview of RAS summarised by volume and type of publication by surgical specialty. A systematic, iterative, mixed-methods approach was taken with searches targeted to specified websites and defined search terms.

### 4.1. PubMed

Literature searches were date-limited from 1 January 2016 to 26 November 2021. Study identification was iterative, with publications grouped by procedure or indication, as identified from the title and abstract. In addition, systematic reviews, randomised controlled trials (RCTs) and studies related to training and credentialing were categorised in EndNote according to the surgical specialty by training or clinical data by indication or procedure.

A narrative, thematic approach was taken to summarise the evidence. There was no formal evidence appraisal, data extraction or interpretation.

### 4.2. Website searches of colleges, societies and associations

The Google advanced search engine was used to search selected college and specialty society websites.

A description of the methods is provided in Appendix A.

# 5. Results

From a total of 10,004 references identified in PubMed since 2016, 1,298 studies were identified related to RAS for training or clinical evidence across all surgical specialties (Appendix C, Table 3):

- 996 clinical studies (systematic review, RCT, other comparative or other clinical study types [case series/observational or case report])
- 302 studies on a variety of topics related to training and credentialing

# 6. Results: Clinical studies

The largest number of clinical studies was from Urology (300 studies), followed by General Surgery (291) (Table 4, Table 8). There were no reported clinical studies for Plastic and Reconstructive Surgery or Ophthalmology. The da Vinci machine was the most common RAS system. These results are further described in Appendix C.

Across all specialties, there were 78 indications or procedures for which published evidence for RAS was identified (see Appendix C). RAS was used across the greatest number of procedures for General Surgery (23 procedures or indications). Common indications were colon and rectal cancers, pancreatectomy and pancreatoduodenectomy. Other commonly reported procedures for RAS were radical prostatectomy and hysterectomy.

Systematic reviews and RCTs were available for most specialties. RAS was variously compared with alternative procedures, including open or laparoscopic approaches. However, the utility of these higher levels of evidence is limited. Systematic reviews commonly included a range of publication types (that were not restricted to RCTs), limiting their conclusions' certainty. In addition, the scope of many studies was technical, with analyses of different approaches such as comparisons of varying RAS techniques, comparisons of various analgesia and reviews of short-term outcomes such as intraoperative complications. For more established RAS procedures such as radical prostatectomy and knee and hip arthroplasty, few studies compared RAS with alternative surgical approaches as such evidence was likely published before 2016.

Due to a large number of indications, robot-assisted radical prostatectomy and robot-assisted gastric surgery were selected as exemplars to indicate the available evidence related to RAS.

### 6.1. Clinical study focus: Urology | radical prostatectomy

The most common use of RAS in Australia is in the specialty of Urology, with 65% of all radical prostatectomies performed in 2019 with the assistance of the da Vinci robot system[8]. There is a significant clinical body of evidence for the use of RAS in this surgical specialty, particularly for radical prostatectomy, with 153 studies identified in total, including 41 systematic reviews and 62 RCTs (Table 4).

NICE has recognised robotic-assisted radical prostatectomy (RARP) as an option for treating localised prostate cancer.[9] Several systematic reviews, including three recent Cochrane reviews, investigated a range of aspects of RAS for radical prostatectomy. The results and methods of these reviews varied widely.

A 2017 Cochrane review found that RAS or laparoscopic surgery was similar to open surgery for quality of life, complications and pain.[10] Evidence was from two RCTs for short-term outcomes. Long-term prostate-cancer-specific survival data were not available. Another review compared RALP with (open) retropubic radical prostatectomy in the same year. This review included 78 articles and concluded that RALP was safe and effective.[11] A 2018 network-meta-analysis of 45 studies concluded that open, laparoscopic and RALP had similar outcomes.[12] Pooled outcomes of 20 observational studies undertaken in 2017 showed satisfactory biochemical recurrence-free survival for RALP at 5 and 10 years.[13] A 2017 systematic review of 18 comparative studies concluded that RARP was superior to laparoscopic prostatectomy, including biochemical recurrence.[14]

Different RAS techniques have been analysed. The Retzius-sparing technique was compared with standard RALP to treat clinically localised prostate cancer in a separate Cochrane review.[15] The results were similar or improved for the Retzius-sparing approach from five trials, although there may be higher positive margin rates. There were no long-term outcomes. A Cochrane review of posterior musculofascial reconstruction RALP found that compared with standard RALP, early continence, but not later outcomes, were improved across eight RCTs.[16] Adverse events and surgical margins were similar.

Recent RCTs provide evidence on longer-term outcomes of RAS compared with open or laparoscopic approaches.[17-19]

Systematic reviews also investigated:

- outcomes of the single-port RAS compared to the standard multi-port da Vinci system, with similar outcomes shown[20]
- use of intraoperative fluorescence[21]
- impact of the Trendelenburg position[22]
- costs and economic impact[23 24]
- impact of various postoperative urine drainage[25 26]
- anatomical reconstruction[27]
- postoperative management techniques[28 29]
- analgesia[30].

### 6.2. Clinical study focus: General Surgery | gastric surgery

The relatively large evidence base for General Surgery (291 studies) is spread across many indications (Table 8). For gastric surgery as an exemplar, there were 36 studies including 20 systematic reviews and four RCTs.

The European Association of Endoscopic Surgeons states that '*robotic gastric resection has comparable clinical outcomes to standard laparoscopic gastrectomy for cancer. It may reduce intraoperative blood loss and postoperative length of stay as compared with laparoscopic gastrectomy, but is associated with longer operative time and higher cost*'.[31] In terms of cost effectiveness, the authors state that robotic General Surgery is more expensive than conventional laparoscopic surgery with comparable clinical outcomes.

Twenty systematic reviews were identified for gastrectomy, most of which compared RAS with laparoscopic or open surgery. The most recent examples are briefly summarised below.

Compared with laparoscopy, RAS has increased operative time and lower blood loss. Other reported short-term outcomes (e.g. adverse events, retrieved lymph nodes, proximal resection margin and distal resection margin) are similar.[32-35] Cancer recurrence is not commonly reported, although a small number of studies conclude that there is no difference in recurrence-free survival.[36 37] The length of follow-up time was not reported. Therefore, this statement's adequacy is unclear.[36 37] A recent systematic review concluded that the quality of studies was low,[33], with all 15 included studies from the most recent review being of a non-randomised design.[35]

Compared with open surgery, RAS was reported to be associated with longer operation time, lower blood loss and shorter hospital stay.[38] Other reported outcomes including cancer outcomes were similar.

Recent RCTs report short-term outcomes of RAS compared to laparoscopic or open approaches.[39-41] One RCT compared different types of analgesia.[42]

Compared to radical prostatectomy, the evidence base for RAS in gastrectomy is less mature. There are few RCTs, and long-term cancer-relevant outcomes are rarely reported. Clinical trials are still focused on the feasibility and absolute safety and effectiveness of RAS for this indication.

### 6.3. Summary of clinical evidence

Based on this high-level overview of identified studies, the clinical evidence related to RAS is highly varied:

- Most published clinical evidence is for the da Vinci surgical system.
- Clinical trials address many questions. For example, many RCTs and systematic reviews compare different RAS techniques.
- Most key RCTs for recognised uses of RAS were published before 2016.
- Observational studies or retrospective database analyses are more likely to report long-term outcomes.
- Rare conditions or less mature uses of RAS are less likely to have RCT evidence available.
- Systematic reviews commonly include studies other than RCT design.
- The scope of studies is varied. For example, across the PICO (Population, Intervention, Comparator, Outcomes):
    - Population: Broad or focused
    - Intervention: Different systems, more than one RAS approach
    - Comparator: Open, laparoscopic or an alternative RAS approach. Defining the current surgical standard of care in Australia and Aotearoa New Zealand would need to be confirmed
    - The reported outcomes vary and may be short-term (e.g. perioperative complications) or long-term cancer markers.
- The quality of the systematic reviews varies; this would impact study selection, quality assessment of the included studies and data synthesis.

As a result of the above, the interpretation and conclusions of systematic reviews vary widely. Therefore, a formal approach for each procedure is recommended to frame questions in line with local surgical activities and provide explicit findings on the clinical safety and effectiveness of RAS.

It should be noted that significant heterogeneity between surgeons remains in functional and oncological outcomes for RAS, with some differences in outcomes explained by differences in surgeon volume.[43] However, high-volume surgeries are associated with improved patient radical prostatectomy outcomes, including RARP.[44]

In the literature, the quality use of RAS is determined with long-term retrospective observational studies or database reviews of relevant clinical outcomes for specific indications.[45 46] No formal predictor of or threshold for safe and effective RAS use was identified in this scoping exercise. The conclusions of recent systematic reviews for RARP, a common use of RAS, were varied, suggesting that the interpretation of the evidence base is inconsistent, and the uptake of RAS is likely informed by a range of factors beyond the evidence of clinical superiority. At present, surgeons can largely use robotic surgery for any procedure at their professional discretion.[3] In the United Kingdom, NHS England has recommended RAS for radical prostatectomies and treatment of early-stage kidney cancer.[47]

RAS appears to enter clinical practice for specific indications without standardised decisions. There is no published information regarding the indications for which RAS is commonly used in Australia and Aotearoa New Zealand. These decisions are likely made at the hospital or local health network level, in line with usual practice. Factors involved in these decisions may include the availability of the robot system, the experience and enthusiasm of surgeons, and patient and hospital interest. These decisions likely try to balance surgical innovation with evidence-based medicine.[48]

The use of RAS should be considered in line with the adoption of any other new technology for use in a novel indication or patient population and should show that its application is equivalent or superior to existing best practice for any given use. General guidelines for assessing, approving and introducing new surgical procedures into a hospital or health service are published by RACS and could be further developed for RAS.[49] From a health technology assessment perspective, formal thresholds are rarely applied, but decision-making includes the consideration and availability of appropriately designed studies with:

- well-defined populations and sufficient number of patients recruited to show evidence of an effect
- a standardised technique for RAS, established through observational trials
- if possible, a prospective comparator that represents current best practice in the absence of RAS (e.g. open or laparoscopic surgery)
- patient-relevant outcomes (e.g. oncological), with appropriate long-term follow-up in line with disease progression
- equivalence (at a minimum) to current best practice and ideally identifying a material benefit of RAS compared to current best practice.

The relevance of the evidence to local practice should be clearly articulated. In the absence of a clinical benefit, the costs of providing RAS should be considered.[48]

The appropriate design and reporting of studies for RAS can be informed by existing research, including the framework provided by the Idea, Development, Exploration, Assessment and Long-term follow-up (IDEAL) Collaboration.[50]

In order to avoid bias, the evidence should be assessed using best-practice health technology assessment. Based on the variability in the clinical use of RAS across the surgical specialties internationally and across Australia and Aotearoa New Zealand, specific thresholds for the accepted use of RAS in each specialty and for each procedure should be determined based on an understanding of the broader evidence base for best practice. RACS could provide guidance on relevant outcomes across all procedures and specialties, based on existing activities such as the standardised core outcome sets that have been developed by the Core Outcome Measures in Effectiveness Trials (COMET) Initiative.[51-55]

In the absence of high-quality evidence, some jurisdictions approve certain technologies on an interim basis. Local data collection is then able to inform a long-term decision. This process may be relevant for some uses of RAS where evidence is uncertain.

For each new proposed indication of use for RAS, questions to ask before considering it to be usual care may include:[3]

- Is there a clinical rationale and theoretical clinical benefit to using RAS for this indication?[3]
- Is this procedure commonly undertaken internationally?
- Is this procedure commonly undertaken in Australia and Aotearoa New Zealand?
- Is there a standardised surgical technique?
- What is the appropriate trial design, and what are the necessary outcomes?
- What is the evidence base and are there any limitations in the available studies? For example, are there formal trials of safety and efficacy? Is there appropriate study design, follow-up, long-term safety data and evidence on the use in real-world settings?
- Does the evidence show that RAS is superior or equivalent to current best practice?
- Are there concerns about the use of RAS in this population (e.g. breast cancer)?[56]
- What are the international decisions regarding this use?
- What is the access to RAS systems for surgeons, trainees, and patients?
- What are the costs of care associated with this use of RAS?

If required, the development of methods to determine predictors of the safe and effective use of RAS could be undertaken as part of the next steps.

# 7. Results: Training and credentialing

In the PubMed searches, there were 302 studies on a variety of topics related to training and credentialing, with most publications in the specialties of General Surgery (61) and Urology (56) (Table 3).

A range of materials were identified on surgical websites (Appendix B). In Australia and Aotearoa New Zealand, while RAS is widely acknowledged in conference programs, advertisements for Fellowship positions and Morbidity Audit and Logbook Tool (MALT) procedure codes,[57] information on RAS use in Australia and Aotearoa New Zealand is limited. Workgroups are established for RAS and related broader future issues, but their activities are not publicised.[58 59] The Royal Australian and New Zealand College of Obstetricians and Gynaecologists provides some information on RAS, including a position statement (Appendix B).[60-62]

There is relatively little cross-specialty information on RAS from international colleges and societies. The available information appears conflicting, as RAS is considered an example of innovative technology[63-66] and included in curriculum programs.[67 68] There is concern that much of the formal training to date is provided directly by the manufacturer and product vendor.[4 31]

For this scoping exercise, 5 surgical specialties were investigated in more detail. A summary of the information identified for obstetrics and gynaecology, Otolaryngology Head and Neck Surgery, and Orthopaedic Surgery is provided in Appendix B. Urology and General Surgery are used as exemplars and described below.

### 7.1. Validated RAS training: Urology

Sixteen publications were identified through web searches relating to training and credentialing for RAS in Urology, and an additional 56 studies were identified through PubMed (Table 3).

With the growing use of RAS in Urology, there has also been an increase in training options, modules and curricula.[69] The appropriate balance between training for open and RAS techniques is not understood.[70] Current approaches to RAS training appear *ad hoc*, and a standardised curriculum to train surgeons has been advocated.[5 71]

**European Association of Urology Robotic Urology Section curriculum**

The Robotic Urology Section (ERUS) is responsible for all robotic urological surgery in the European Association of Urology (EAU)[72] and has published its structured curriculum for RAS.[5 73] As taken from its website, this '*curriculum includes theoretical sessions, skills training (dry and wet laboratories), real-case observation in a training centre, bedside assistance, and mentored training at the console. Participants will follow a modular training program at a recognised host centre under the expert guidance of a local mentor.*'[73]. ERUS publishes a list of certified host centres, including two in Australia.[74]

Focus groups at EAU and ERUS conferences participated in discussions to develop the content and implementation of a standardised curriculum (Figure 1).

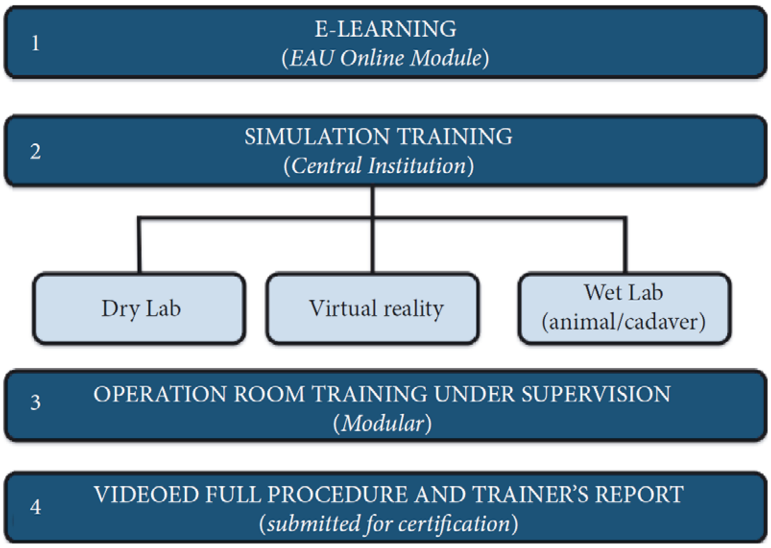


**Figure 1 Proposed curriculum of the European Association of Urology Robotic Urology Section, taken from Ahmed et al 2015[5]**

Key components of the curriculum include:[5]

- technical and non-technical skills; non-technical skills include knowledge of the robot, decision-making and clinical judgement, patient selection and preoperative preparation, teamwork and communication
- online theoretical training and examination to ensure a sound knowledge of console and procedure theory, such as the Intuitive Surgical online training system or the urology-specific online modules from the EAU, eBRUS[75]
- 'discovery course' simulation training and case observations (3 days); a range of simulators are available, the most common being the dVSS simulator, which can be attached to the back of the da Vinci console;[75-79] validated simulators should be used in the training curriculum[76]
- a formal training course (five days) with dry and wet laboratory sessions and live surgery observation, acknowledging that live animal training is not available in all countries[75]
- a structured fellowship program (six months) that includes the transition from observation to assistance in the surgical procedure to performing segments of a procedure before undertaking a whole procedure using modular training and a dual console; modular training pathways require the trainee to progressively develop skills for each procedure segment before attempting the entire procedure;[75] modular training refers to progression through surgical steps of increasing difficulty, moving onto more advanced steps once competence has been attained in more straightforward ones[80]
- training centres and fellowship schemes at high-volume centres; these may require accreditation to ensure minimum standards are met;[75 81] in addition, a team approach should be used for training purposes [75]
- assessment of trainee performance using standardised methods, procedure-specific checklists, videos and anonymous experts, after which the trainee is approved through appropriate governing bodies; certification should be from accredited, regional training centres; it is good practice for trainees to log all stages of the training pathway.[75]

The learning curve to proficiency is recognised.[82] Theoretical and practical courses[83 84] are available to support this curriculum. Centres can apply to become an EAU Robotic Training Centre.[85]

This standardised Urology curriculum has been adopted for specific societies and procedures.

**British Association of Urological Surgeons curriculum**

A detailed example of a Urology curriculum based on the ERUS program is provided by the British Association of Urological Surgeons (BAUS).[75]

While the General Medical Council Urology curriculum[67] mentions that knowledge is required of robot-assisted surgery skills, BAUS has developed a recommended curriculum for RAS training[75]. A five-stage curriculum for robotic training is proposed based mainly on the content validated model proposed by the EAU Robotic Urology Section, ERUS. This curriculum describes the skills required, discusses current training methods for robotic surgery, and establishes procedures for modular training and centralised clinical data collection. BAUS also provides system advice regarding developing robotic-assisted radical prostatectomy[86], including the current and future need for robotic prostatectomy, and poses questions that should be considered before implementation. It notes that while RAS for localised prostate cancer is an established therapy, there may be benefits to concentrating the service in fewer centres and in the hands of fewer surgeons. A detailed patient information leaflet is available[87].

An overview of the curriculum is shown in Figure 2.


**Figure 2 Outline of the British Association of Urological Surgeons (BAUS) standardised training pathway, taken from the BAUS robotic surgery curriculum – Guidelines for Training[75]**

In line with a modular approach based on the complexity or technical demand, BAUS recommends a stepped approach to training. For example, the steps for pelvic urological surgery are:

- robot-assisted radical prostatectomy (RARP)
- robot-assisted radical cystectomy (RARC) with extracorporeal diversion
- robot-assisted radical cystectomy (RARC) with intracorporal diversion or neo-bladder.

Modular pathways are provided for each procedure, divided into separate segments for training purposes, based on the complexity of each task. The curriculum notes that the training requirements will vary depending on the surgeon's previous experience with open or laparoscopic techniques. BAUS recognises that the training is '*is highly dependent on a competent mentor who is required to be skilled and experienced in the procedure and must be able to teach these skills effectively*'.

In line with the varying complexity and differences in learning curves, BAUS recommends specific metrics for sign-off for defined procedures. For example, for RARP the learning curve is 50–200 cases; quality indicators are operating time <240 minutes; estimated blood loss <200 ml, prostate-specific antigen >95%; positive surgical margin <25%; complication rate <15%.

The curriculum acknowledges that the RAS training pathway will differ between specialists with extensive previous experience of open and/or laparoscopic surgery, and trainees who are new to any form of urological procedures including open, laparoscopic and robotic surgery. However, explicit differences in training are not provided.

BAUS recommends the national coordination of data collection related to robotic surgery to proactively audit patient outcomes, inform surgeons and maintain services.

**ERUS robot-assisted radical prostatectomy curriculum**

A specific curriculum has been designed for RARP, with a target audience of fellows with minimal or no previous experience of simulation-based training.[88]

The key components of the curriculum are shown in Figure 3 and include: (1) e-learning and observed and assisted in live surgery for three weeks, (2) an intensive week of structured, simulation-based training (virtual reality synthetic, animal and cadaveric platforms, and (3) supervised modular training in RARP, with each distinct surgical step described in terms of complexity. The full RARP procedure was assessed by mentors and video-recorded for evaluation by blind assessors. The critical steps to RARP training for the modular pathway and the associated RARP Assessment Score have been separately validated.[80] The design of the modular training and sequence of procedural steps is based on technical complexity and was established through an observational study.[89]

The curriculum was validated (10 participants) using a range of metrics. Technical skills were assessed by the da Vinci surgical system for moving the camera and clutching, manipulating the EndoWrist, use of energy and dissection, and needle driving. The surgical performance was graded and scored using the validated Global Evaluative Assessment of Robotic Skills (GEARS) score and a RARP procedure-specific scoring scale.

During the validation, participants observed and assisted in at least 12 cases during the first three weeks and were involved in a median of 18 RARPs as console surgeons during the modular training. At the end of the curriculum, eight out of 10 Fellows were deemed able by their mentors to perform a RARP independently, safely and effectively. Average procedure scores of experts familiar with RARP were higher than course participants (mean score for all steps 13.6 vs 11).

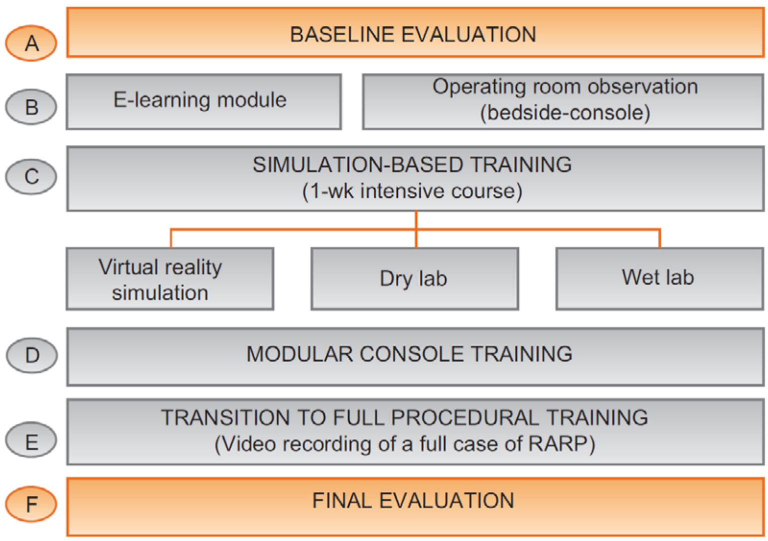


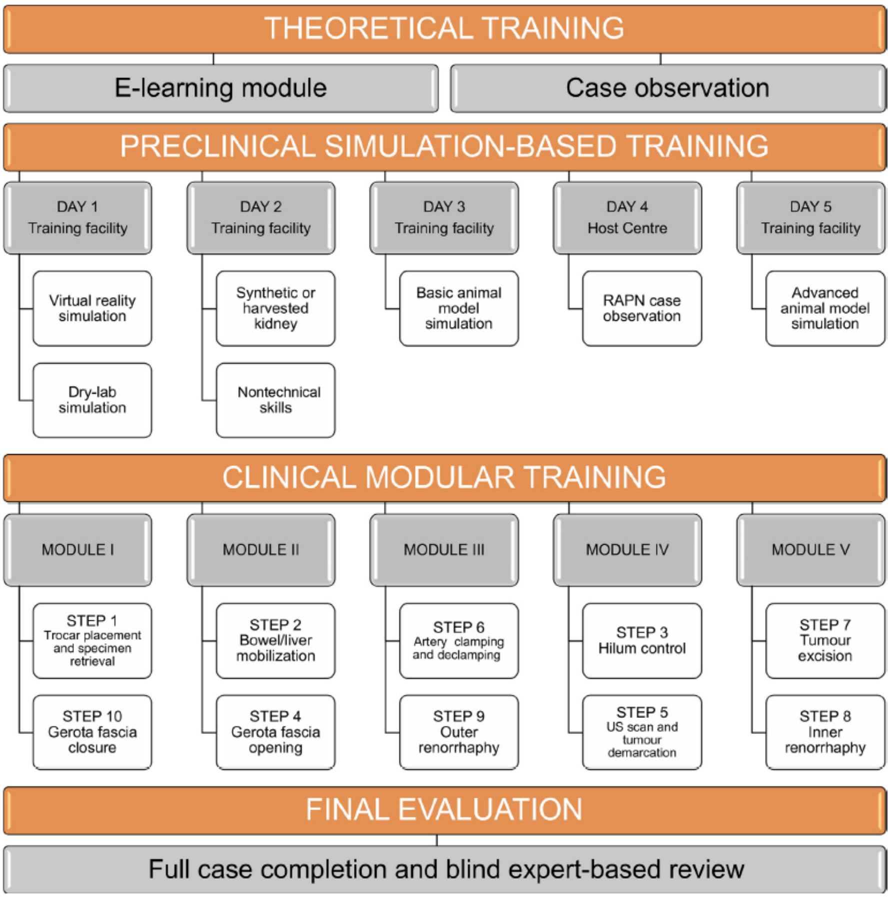

**Figure 3 Structure of the European Association of Urology Robotic Training Curriculum, taken from Volpe et al 2015[88]**

Initial results of the application of the ERUS RARP curriculum have been reported.[90 91] Although single-surgeon retrospective analyses, these studies show that the curriculum is a safe and effective training program with early oncological and functional outcomes consistent with published standards. Reported outcomes included complications, positive surgical margin and continence rates.

**ERUS robot-assisted partial nephrectomy curriculum**

A ERUS partial nephrectomy curriculum has been developed based on the structure of the RARP curriculum. Thirty experts in robotic-assisted partial nephrectomy (RAPN) were involved in its production using a modified Delphi consensus methodology.[71]

The structure of the curriculum is described in Figure 4. Clinical training was provided at an ERUS host centre for 18 months under the mentorship of an experienced RAPN surgeon. As for the RARP curriculum, the module was divided into a number of steps based on the complexity of each part of the surgery.




<u>**Abbreviations**</u>
**RAPN** = robot-assisted partial nephrectomy, **US** = ultrasound

**Figure 4 Structure of the European Association of Urology Robotic Urology Section curriculum for robot-assisted partial nephrectomy, taken from Larcher et al 2019[71]**

Validated with one course participant, the results of 40 patients following curriculum training were compared to 160 patients from an expert surgeon. Safety outcomes included complications, estimated blood loss, operative time, estimated glomerular filtration rate and positive surgical margins. There were no differences between the trainee and the expert regarding safety outcomes. Curriculum efficacy was investigated using descriptive analysis of steps and modules attempted and completed by the trainee.

**Other training and credentialing programs**

Other activities related to training in RAS were identified, although there were no published programs or curricula.

The American Urological Association (AUA) has a dedicated Laparoscopic, Robotic and New Surgical Technologies Education Council Subcommittee whose mission is to evaluate, analyse and disseminate skills, surgical simulation and skills assessment to the urological community.[92] In addition, the minimal requirements for granting RAS privileges for Urology surgery is published in the Robotic Surgery (Urologic) Surgery Standard Operating Procedure (SOP) SOP[93], and guidance on the use of robotics in Urology is provided.[94 95]

The Royal College of Physicians and Surgeons of Canada has high-level information related to training, including logbook requirements,[96] Urology competencies and a list of procedures where RAS or laparoscopic surgery are applied,[97] as well as a suggestion for online training in RAS as an optional part of the core discipline.[98]

Individual components of these training programs for RAS in urologic surgery have been assessed and validated separately.[99]

**Peer-reviewed literature**

Other themes identified in the peer-reviewed literature for Urology training include:

- validated, procedure-specific metrics for assessment, grading and evaluation of surgical performance,[100-105] including the use of machine learning[106]
- benefits of a structured or modular curriculum[89 107 108]
- impact of surgeon heterogeneity[43]
- ergonomics[109]
- standardised criteria for reporting adverse events [110]
- development of validated mentoring programs to formalise technical aspects of clinical training[111]
- variability in structure, requirements and availability of training programs and certification[112 113]
- training and checklist for conversion from RAS to open surgery[114]
- development and validation of simulation, laboratory, cadaver or virtual-reality training models for specific procedures or techniques, including skills transfer.[71 79 115-122]

The components identified from the described training materials are summarised in Table 2.

### 7.2. Other examples of training: General Surgery and gastric surgery

General Surgery is used as an alternative example, as it is distinct in its training needs compared with Urology.[4] Compared to Urology, the uptake of RAS in General Surgery has been slower and less structured.[31]

No training material was identified for gastric surgery.

Examples of locally-developed Australian structured training programs for General Surgery and colorectal surgery are summarised in Table 1.[4 123] High-level examples of other international curricula are also available for General Surgery which include themes similar to the above, although little detail is provided.[124-128]

It should be noted that these training materials do not appear to be validated or adopted for formal accreditation in any jurisdiction.

No formal training curricula were identified from specialty societies. However, there were many examples of robot surgery as part of conference proceedings, workshops or training courses and advertisements for fellowship positions. The UK General Medical Council Intercollegiate Surgical Curriculum for General Surgery (updated in 2018) does not mention robot-assisted surgery.[129]

The European Association for Endoscopic Surgery recognises that there have been delays in developing certified training for RAS. It has a consensus statement on the use of RAS in General Surgery, which includes discussion regarding RAS training and curriculum[31]. The Fundamentals of Robotic Surgery (FRS) program is used as an example. The authors provide statements on a range of clinical applications but note that most reported clinical evidence does not include data about the level of proficiency of the surgeons reporting their experience with robot-assisted surgery.

The European Society of Surgical Oncology mentions RAS in its core curriculum, but no detail is provided[130]. RAS is included only as a treatment for prostate cancer. In a 2020 report, RAS is mentioned as a surgical innovation rather than as part of standard care[131].

Other themes investigated in peer-reviewed publications related to RAS training and credentialing include:

- training for trainers[132 133]
- benefits of a modular approach[134-136]
- assessment and evaluation[137-141]
- different training methods, including dual consoles and models[142-146]
- transferability of skills from laparoscopy to RAS[147]
- ergonomics[148 149]
- learning curve.[150-152]

**Summary of training and credentialing**

In summary, although the searches for this exercise were not comprehensive, it is clear from the identified material that Urology training is mature compared with General Surgery. However, there were no identified validated programs for General Surgery, which may reflect a reluctance from General Surgery subspecialties to embrace RAS as a required component of surgical training for all trainees and fellows, or that RAS in General Surgery is not universally regarded as an alternative standard of care.

An outline of the main steps and components of the curricula described above is shown in Table 1. This is based on the BAUS urological surgeons' curriculum,[75] supplemented with other references.

**Table 1 Components of identified training curricula**

| Step | Comment | Urology | General Surgery |
|---|---|---|---|
| **Determine procedure complexity** | Procedures should be trained for and assessed in order of increasing technical demands | 75 97 | |
| **Baseline evaluation** | | 88 | |
| **Online theoretical training** | To develop a sound knowledge of console and procedure theory. These are generic and specialty-specific | 5 71 75 88 | 4 123 |
| Assessment | | 5 75 | 4 |
| **Simulation and observation** | | 5 71 75 88 | 4 |
| Dry laboratory, simulation | Use of validated simulation platforms | 5 71 75 88 | 4 123 |
| Observation | In high-volume centres | 71 75 88 | 123 |
| Procedure-specific theoretical training | | 75 88 | |
| Non-technical skills | Decision-making and emergency scenario | 71 | |
| Wet laboratory | Live animal or cadaver training | 5 71 75 88 | 4 123 |
| Assessment and certification | Of technical and non-technical skills (e.g. GEARS and NOTSS, theoretical examination) | 5 75 80 88 | 123 |
| **Fellowship and mentorship** | At high-volume centres | 5 71 75 | 4 123 |
| Observation | | 75 | 4 123 |
| Assistance in the surgical procedure | | 75 | 4 123 |
| Performing part of the procedure with dual console and monitor | | 75 | |
| Performing full procedure with dual console and monitor | | 75 | 4 |
| Establish appropriate learning curve (number of cases) and quality indicators (technical, functional, oncological) for each procedure | | 75 82 | 4 |
| Establish modular pathways, with components of each procedure defined according to complexity | To progressively develop skills | 71 75 80 88 | |
| Assessment and sign-off | Using independent examiners | 5 71 75 80 88 | 4 123 |
| **Certification** | | 5 75 | |
| **Independent surgery** | | 75 | |

**Abbreviations**
**GEARS =** Global Evaluative Assessment of Robotic Skills, **NOTSS =** Non-Technical Skills for Surgeons

The themes identified in this scoping report are summarised in Table 2. Individual components of training, or trainee characteristics that predict improved outcomes from undertaking the RAS curricula, were not identified. Not all participants who complete these courses will be considered to have passed[88].

A small number of curricula and components of these courses have been validated. Commonly reported components of published training and credentialing activities include:

- All elements of training and credentialing should be standardised for consistency.
- Develop specialty- and procedure-specific programs, with training undertaken to proficiency and according to procedure complexity.
- Consider the required experience of the trainee or surgeon, including the impact on training requirements and at what career-point RAS training should be offered.
- Use a modular program to improve the learning curve, including electronic learning, simulation and laboratory models, and a stepped approach defined according to the complexity of parts of each procedure.
- Each curriculum should be based on an existing, validated educational framework and use validated components (e.g. simulation platforms and other training tools).
- Training centres should be accredited.
- Mentors should be experienced, high-volume surgeons with proven educational skills.
- Each procedure should have evidence-based predefined learning curves (number of cases) and quality indicators (technical, functional, oncological).
- Validated evaluation and assessment tools and independent examiners should be used.
- Lists of surgeons who have been accredited or credentialed to undertake RAS should be published. Consider publishing a list of approved RAS trainers or mentors.
- There should be centralised data collection and publication of outcomes.
- There should be systematic evaluation of training activities and publication of educational outcomes.

**Table 2 Broad themes**

| Theme | Example supporting references |
|---|---|
| **High-level advice** | |
| Have a dedicated RAS association or committee | 72 92 |
| Provide advice for which procedures RAS is an established therapy | 31 86 |
| Provide clarity on the patients, indications and procedures for which RAS is appropriate | 31 75 |
| Consider the demand for therapy | 86 |
| Consider future models of care for all types of surgery | 86 |
| Publish a consensus statement on the use of RAS as a guidance document | 31 |
| **Availability of training curricula** | |
| Define the minimum requirements for credentialing | 93 |
| Ensure that all training is standardised and validated | 5 75 88 |
| Ensure that all components of the training program are validated | 75 123 |
| Provide a basic surgical training curriculum for RAS fundamentals | 4 31 67 97 |
| Provide a specialty-specific training curriculum specifically for RAS including a formal curriculum for specific procedures (see Table 1) | 4 5 31 73 75 93 94 |
| Provide structured, modular courses to support the curriculum requirements based on each procedure and technical complexity (see Table 1) | 4 5 31 75 83 84 |
| Train to a proficiency curriculum, not a time-based curriculum | 31 |

| Theme | Example supporting references |
|---|---|
| Consider training requirements for novice (no experience in any form of surgical procedure) and experienced (familiar with specialty-specific open and/or laparoscopic procedures) surgeons | 75 |
| Ensure that training includes technical and non-technical skills | 5 31 75 |
| Provide a proctoring/clinical monitoring period | 31 |
| **Training centres** | |
| Dedicated training/host centres | 75 85 86 |
| Mentoring and training in high-volume centres | 71 75 |
| Accreditation of training centres to ensure minimal standards are met | 75 |
| Ensure that training centres have access to the required training facilities and expert trainers with proven educational skills | 75 |
| Ensure the use of appropriate training methods (e.g. simulation-based training) | 75 98 153 |
| Team training for all assistants | 75 |
| **Evaluation and assessment** | |
| Ensure the use of validated tools for evaluation and assessment | 31 75 |
| Ensure that training activities are appropriately logged | 75 96 |
| Certification | 31 |
| **Ongoing activities** | |
| Centralise RAS activities to high-volume centres | 75 |
| Be explicit on the learning curve, volume-outcome relationships | 75 82 |
| Publish the names of surgeons who have been accredited to use RAS | 154 |
| Maintain and support skills, continuing education (e.g. describe the surgical technique) | 93-95 153 |
| Ensure equitable patient access to RAS | 86 |
| Inform the patient of RAS | 87 |
| Have criteria for selecting patients suitable for RAS | 86 |
| Inform surgeons of changes to RAS (software, artificial intelligence, updates to hardware, new systems, changes in regulation, new indications for use) | |
| Collect and publish centralised administrative and defined clinical data to ensure that RAS use is as expected and to ensure good patient outcomes | 75 86 |
| Consider surgeon heterogeneity | 43 |

# 8. Discussion

Internationally, there is currently no cross-specialty guidance for RAS use or training or credentialing. While international colleges recognise RAS as an innovative technology, training for RAS is included in curricula for many surgical specialties worldwide, although few training programs were identified. In addition, there are specialty societies, associations and working groups with a specific focus on RAS, but their activities are often uncertain. Practical aspects of RAS include access to machines for training or practice and concerns regarding novel predicate systems that are available for use with little peer-reviewed clinical evidence.

The searches for clinical evidence were time-limited and results likely represent recent research interests and should not be taken as a qualitative summary of RAS activity. Nevertheless, there were many clinical studies across most specialties. The vast number of indications in the clinical literature show that while the use of RAS for some procedures is more mature, RAS continues to evolve and be applied to increasing types of surgeries. A detailed analysis of the clinical data supporting these uses was beyond the scope of this report, and any formal review should initially define the necessary PICO. The evidence-base varies widely between some indications, reflecting differences in the maturity of the use of RAS. However, it seems that long-term clinical evidence is lacking.

Clinical studies are varied in their type, design, focus and conclusions. While not comprehensive, these examples provide an insight into the variability of clinical evidence related to RAS and the difficulty in establishing clinical equivalence or superiority for any surgical approach. RAS research is a microcosm of surgical research and faces similar limitations and restrictions. For more novel uses of RAS, clinical data may be from surgeons who are still on their learning curve in using this technology.

Training material was available for certain specialties with information published for the curriculum, training modules and dedicated robotic training centre requirements. These materials are explicit regarding which procedures are appropriate for RAS, and curricula are based on standardised, modular training programs with validated training methods and assessment tools. The programs are structured according to skills acquisition and learning curves. Patient information is also available, and technical and non-technical skills are recognised. Ongoing activities such as evaluation of training, centralised data collection and publication of this data are noted.

This material could be used or adapted to inform the needs of RACS.

# 9. Conclusion

This scoping review has identified that training resources for RAS are focused on a limited number of surgical specialities. There is a lack of general guidelines to inform overall training and credentialing requirements for surgeons wishing to adopt robotic-assisted techniques. It is deemed feasible to review current guidelines to develop a generalised framework for RAS training and accreditation that can be adopted or adapted to be speciality specific.

The scoping exercise has also identified that a generalised review of the clinical effectiveness and safety of RAS will be of limited utility. Instead, monitoring of the literature for new robotic systems and indications should be considered. The review of clinical data should be considered if significant concerns are voiced about the appropriateness of RAS for a given surgical approach or if there are questions about surgical outcomes. No minimum thresholds defining the safe and effective use of RAS were identified.

The next steps and proposed future activities are provided in the summary section of this report.

# 10. Appendices

### Appendix A: Search methods

Searches were undertaken in the last week of November and first week of December 2021.

#### Literature review

A literature search was undertaken on PubMed (26 November 2021) using the MeSH heading ‘Robotic Surgical Procedures Descriptor’. This term includes Robot Surgery, RAS, Robot-Enhanced Procedures, Robot-Enhanced Surgery, Robotic-Assisted Surgery and Surgical Procedures, Robotic.

Searches were date limited to 2016, and references were uploaded to an EndNote library. In total, 10,004 references were identified.

The EndNote library was searched for publications related to systematic reviews, RCTs and training and credentialing (any field: random OR randomised OR randomized OR RCT; Notes: Systematic Review OR Meta-Analysis; Title contains: train OR training OR credentialing).

Identified studies were sorted by specialty, procedure or indication, and study type (systematic review RCT, comp, observational, case report). Studies were excluded if they contained non-clinical data, were non-systematic reviews, were not written in English, were not robotic, or were opinion (e.g. letter, editorial). Due to restrictions of this initial scoping exercises, refinement of these categories is needed as certain categories should be grouped together or further divided.

#### Website searches

The following websites from Australia and Aotearoa New Zealand were searched in Google using the term 'robot' (e.g. site:https://anzscts.org/ robot).

- RACS https://www.surgeons.org/en
- Australian & New Zealand Society of Cardiac & Thoracic Surgeons https://anzscts.org/
- General Surgeons Australia https://www.generalsurgeons.com.au
- New Zealand Association of General Surgeons https://www.nzags.co.nz
- Neurosurgical Society of Australasia https://www.nsa.org.au
- Australian Orthopaedic Association https://www.aoa.org.au
- Australian Society of Otolaryngology Head and Neck Surgery https://asohns.org.au
- Australian and New Zealand Association of Paediatric Surgeons https://www.anzaps.org/
- Australian Society of Plastic Surgeons https://plasticsurgery.org.au/
- Urological Society of Australia and New Zealand https://www.usanz.org.au
- Australian and New Zealand Society for Vascular Surgery https://www.anzsvs.org.au
- Royal Australian and New Zealand College of Obstetricians and Gynaecologists https://ranzcog.edu.au/
- Royal Australian and New Zealand College of Ophthalmologists https://ranzco.edu/

The following websites from Great Britain were searched in Google using the term 'robot' (e.g. site:https://www.rcseng.ac.uk robot)

- Royal College of Surgeons England https://www.rcseng.ac.uk

- UK General Medical Council https://www.gmc-uk.org

The following websites from Great Britain were searched in Google using the term 'robot training' (e.g. site:https://scts.org/ robot training)

- Society for Cardiothoracic Surgery https://scts.org/
- Association of Surgeons of Great Britain and Ireland https://www.asgbi.org.uk/
- Society of British Neurological Surgeons https://www.sbns.org.uk/
- British Orthopaedic Association https://www.boa.ac.uk/
- ENT UK https://www.entuk.org/about/who_we_are.aspx
- British Association of Paediatric Surgeons https://www.baps.org.uk/
- British Association of Plastic, Reconstructive and Aesthetic Surgeons https://www.bapras.org.uk/
- British Association of Urological Surgeons https://www.baus.org.uk/
- Royal College of Obstetricians and Gynaecologists https://www.rcog.org.uk/
- https://www.rcog.org.uk/en/about-us/specialist-societies/british-association-of-robotic-gynaecological-surgeons-biargs/
- Royal College of Ophthalmologists https://www.rcophth.ac.uk/

The following websites from Ireland were searched in Google using the term 'robot training' (e.g. site:https://www.rcsi.com/ robot training)

- Royal College of Surgeons in Ireland https://www.rcsi.com/
- Irish Orthopaedic Association http://ioa.ie/index.html
- Irish Institute of Otorhinolaryngology / Head and Neck Surgery http://www.iiohns.org/
- Irish Association of Plastic Surgeons https://www.plasticsurgery.ie
- Irish Society of Urology https://irishsocietyofurology.ie/
- Institute of Obstetricians and Gynaecology https://www.rcpi.ie/faculties/obstetricians-and-gynaecologists/

The following websites from America were searched in Google using the term 'robot training' (e.g. site:https://www.facs.org/ robot training):

- American College of Surgeons https://www.facs.org
- American Urological Association https://www.auanet.org
- American College of Obstetricians and Gynecologists https://www.acog.org/
- American Association of Orthopaedic Surgeons https://www.aaos.org/
- American Academy of Otolaryngology – Head and Neck Surgery https://www.entnet.org/
- American Head and Neck Society https://www.ahns.info/
- American Society of General Surgeons https://theasgs.org/

The following websites from Canada were searched in Google using the term 'robot training':

- The Royal College of Physicians and Surgeons Canada https://www.royalcollege.ca/
- Canadian Urological Association https://www.cua.org/

- The Society of Obstetricians and Gynecologists of Canada https://sogc.org/
- Canadian Orthopaedic Association https://coa-aco.org/
- Canadian Society of Otolaryngology – Head and Neck Surgery https://www.entcanada.org/
- Canadian Association of General Surgeons https://cags-accg.ca/

The following websites from Europe were searched in Google using the term 'robot training':

- European Association of Urology https://uroweb.org/
- European Society of Gynaecological Oncology https://www.esgo.org/
- European Society for Sports Traumatology, Knee Surgery and Arthroscopy https://www.esska.org/
- European Federation of National Associations of Orthopaedics and Traumatology https://www.efort.org/
- Confederation of European Otorhinolaryngology – Head and Neck Surgery https://www.ceorlhns.org/
- European Head and Neck Society https://www.ehns.org/site/
- European Society of Surgery https://essurg.org/
- European Association for Endoscopic Surgery https://eaes.eu/
- European Society of Surgical Oncology https://www.essoweb.org/
- European Society of Gastrointestinal Endoscopy https://www.esge.com/

## Appendix B: Summary of website information

### Training materials from Australia and Aotearoa New Zealand

RAS has been included in conference programs and advertised surgical positions and Fellowships for many years. RAS is recognised in many procedure codes in the Morbidity Audit and Logbook Tool (MALT)[57] and in a Pickard Robotic Training Grant.[155] In addition, there are a number of RAS-specific books and manuals in the RACS member-only library. However, information on RAS use in Australia and Aotearoa New Zealand for RAS is limited.

The Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) has a position statement on using RAS,[60] noting the minimum standards for training, practice and skill acquisition and the understanding of the appropriate equipment. It states that individual hospitals undertake credentialing of RAS surgeons. Further information on the use of RAS is provided in general guidelines for gynaecologic procedures[61] and a draft scope of practice[156] and is mentioned in the Training Program Handbook for certification in gynaecological oncology.[62] Workgroups are established for robot surgery and broader future issues, but their activities are not publicised.[58 59]

Existing Surgical Education and Training (SET) information and Australian Orthopaedic Association National Joint Replacement Registry (AOANJRR) records[157] were not investigated as part of this initial scoping exercise.

### Training materials from international sources

There is relatively little cross-specialty information on RAS based on public information from international colleges and societies. In England, the Royal College of Surgeons of England (RCSE) recognises that advances in minimally invasive surgery, including RAS and artificial intelligence, will continue to progress and notes that there will be challenges and benefits.[65] In its ‘Surgical Innovation, New Techniques and Technologies: A Guide to Good Practice’, RCSE considers RAS an example of innovative technology.[66] Notably, the RCSE is working with the Department of Health and Social Care and the General Medical Council on robotic-surgery guidelines.[64] This work followed the death of a patient who suffered multiple organ failure after robot-assisted heart valve surgery; further information was not identified.

The UK General Medical Council has published several specialty-specific intercollegiate surgical curriculum programs (e.g. Urology and Otolaryngology).[67 68] These curricula include comments on the level when robotic surgery training should be included but no detail about how these are provided.

In North America, The Royal College of Physicians and Surgeons of Canada recognises RAS in its Task Force Report on Artificial Intelligence and Emerging Digital Technologies.[63] In addition, the limitations in RAS training is considered in a presentation on ‘Evidence-based benchmarking in surgical performance: Leveraging the skill-outcome relationship in procedural assessment’.[158]

In the peer-reviewed literature, themes included:

- reviews of training programs and courses[159-161]
- initial experience of structured programs[162 163]
- importance of formal training programs[164-167]

- training the trainer[168 169]
- learning curves[170-173]
- ergonomics[174-176]
- use of stimulators and use of other different training methods[177 178]
- skills acquisition and transfer[179-181]
- skills assessment and evaluation.[171 182-185]

**Training materials from international specialty societies and associations**

Four specialties were assessed for RAS training material for this initial scoping exercise. These were selected based on material identified from UK societies, the volume of evidence from the PubMed searches and an understanding of the use of RAS:

**Obstetrics and gynaecology**

The British and Irish Association of Robotic Gynaecological Surgeons (BIARGS) has a curriculum,[186], a range of training modules,[187] requirements for robotic training centres[188] and advice to surgeons regarding how to certify as a robotics-specialised surgeon.[189] They also provide a list of Gynaecology Robotic surgeons.[154] The syllabus has been defined based on evidence after pilot work and Delphi projects in robotic training, including some Society of European Robotic Gynaecological Surgery (SERGS) training frameworks. However, from a presentation on the Royal College of Obstetricians and Gynaecologists (RCOG) website, it appears as if RAS for gynae-oncology is restricted to tertiary cancer centres.[190]

The Royal College of Physicians and Surgeons of Canada in its 'Objectives of Training in the Subspecialty of Gynecologic Oncology' includes training and competency in robotic-assisted vaginal radical hysterectomy, robotic-assisted radical hysterectomy and robotic-assisted lymphadenectomy as part of the required skills.[191] No detail is available on the training. The American College of Obstetricians and Gynecologists provides training for RAS as part of a non-boarded subspecialty for Minimally Invasive Gynecologic Surgery.[192] Further detail is not provided. The use of RAS for several conditions is discussed in a range of committee opinions.[193-196] In Europe, the European Society of Gynaecological Oncology publishes clinical guidelines on various conditions;[197] these were not reviewed as part of this scoping activity.

**Otolaryngology Head and Neck Surgery**

The American Head and Neck Society has published a Transoral Robotic Training Curriculum.[198 199] The components were from a previously published consensus.[200] Curricula are also described in the peer-reviewed literature.[201-205]

In the UK, RAS is part of the Otolaryngology curriculum,[68] although no detail is provided on training. The role of RAS in ENT is highlighted by a range of guidelines published by the UK National Multidisciplinary Guidelines and the American Academy of Otolaryngology Head and Neck Surgery.[206-209]

**Orthopaedic Surgery**

Orthopaedic specialty sites (UK, Ireland, US, Canada, Europe) were also searched for training material. The American Academy of Orthopaedic Surgeons (AAOS) published a Position Statement on Innovation and Novel Technologies in Orthopaedic Surgery, which mentions robotics and the lack of clinical data for certain predicate technologies[210]. Some member-only video material was available to train fellows in specific knee and spine procedures[211 212], but no training programs or curricula were identified.

**Urology**

Sixteen publications were identified through web searches relating to training and credentialing for RAS in Urology and an additional 56 studies through PubMed. This is described in greater detail in the body of this report.

**General Surgery**

Through web searches, 4 publications were identified relating to training and credentialing for RAS in General Surgery and an additional 61 studies through PubMed. This is described in greater detail in the body of this report.

## Appendix C: Summary of PubMed results

The clinical studies are presented according to level of evidence and indication (Table 4 to Table 12). Please note that, due to restrictions of this initial scoping exercise, refinement of these categories may be needed to ensure that indications are grouped appropriately.

**Table 3 PubMed results from 2016 | per specialty**

| | Number of identified studies (total N = 1,298) | | |
|---|---|---|---|
| **Specialty** | **Training (n = 302)** | **Clinical evidence (n = 996)** | **Estimated number of indications or procedures** |
| Non specialty-specific | 138 | 33 | - |
| Cardiothoracic Surgery | 7 | 62 | 8 |
| General Surgery | 61 | 291 | 23 |
| Neurosurgery | 1 | 11 | 5 |
| Orthopaedic Surgery | 6 | 84 | 6 |
| Otolaryngology Head and Neck Surgery | 12 | 87 | 7 |
| Paediatric Surgery | 4 | 10 | 3 |
| Plastic and Reconstructive Surgery | 0 | 0 | 0 |
| Urology | 56 | 300 | 14 |
| Vascular Surgery | 1 | 2 | 1 |
| Obstetrics and Gynaecology | 13 | 116 | 12 |
| Ophthalmology | 3 | 0 | 0 |

**Table 4 PubMed results from 2016 | Clinical studies | Urology**

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 14)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Radical prostatectomy | 153 | 41 | 62 | 27 | 23 |
| Radical cystectomy | 49 | 28 | 10 | 5 | 6 |
| Partial nephrectomy | 40 | 24 | 9 | 1 | 6 |
| Kidney transplant | 8 | 5 | 0 | 1 | 2 |
| Adrenalectomy | 6 | 3 | 1 | 1 | 1 |
| Pyeloplasty | 5 | 4 | 1 | 0 | 0 |
| Prostate biopsy | 4 | 1 | 0 | 0 | 3 |
| Radical nephroureterectomy | 3 | 2 | 0 | 0 | 1 |
| Brachytherapy | 1 | 0 | 0 | 0 | 1 |
| Colovesical fistula | 1 | 0 | 0 | 0 | 1 |
| Renal artery aneurysm | 1 | 0 | 0 | 0 | 1 |

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 14)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Renal stones | 1 | 0 | 1 | 0 | 0 |
| Renal tumours | 3 | 2 | 0 | 1 | 0 |
| Ureteral injury | 1 | 1 | 0 | 0 | 0 |
| Broad or multiple indications | 23 | 8 | 2 | | 13 |

**Table 5 PubMed results from 2016 | Clinical studies | Obstetrics and Gynaecology**

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 12)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Hysterectomy | 38 | 13 | 11 | 6 | 8 |
| Endometrial cancer | 11 | 4 | 5 | 1 | 1 |
| Sacrocolpopexy | 10 | 2 | 8 | 0 | 0 |
| Endometriosis | 9 | 3 | 3 | 0 | 3 |
| Cervical cancer | 7 | 3 | 1 | 1 | 2 |
| Myomectomy | 6 | 3 | 0 | 2 | 1 |
| Rectopexy | 6 | 3 | 3 | 0 | 0 |
| Ovarian cancer | 4 | 2 | 1 | 0 | 1 |
| Colpopexy | 1 | 0 | 0 | 0 | 1 |
| Sacrohysteropexy | 1 | 0 | 0 | 1 | 0 |
| Uterine cancer | 1 | 0 | 0 | 0 | 1 |
| Vestigovaginal fistula | 1 | 1 | 0 | 0 | |
| Broad or multiple indications | 20 | 12 | 6 | 0 | 2 |

**Table 6 PubMed results from 2016 | Clinical studies | Otolaryngology Head and Neck Surgery**

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 7)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Thyroidectomy | 20 | 9 | 8 | 3 | 0 |
| Oesophagectomy | 11 | 2 | 2 | 1 | 6 |
| Obstructive sleep apnoea | 11 | 7 | 1 | 3 | 0 |
| Oropharyngeal cancer | 9 | 7 | 1 | 1 | 0 |
| Laryngectomy | 3 | 1 | 0 | 0 | 2 |

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 7)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Myotomy | 3 | 2 | 0 | 1 | 0 |
| Craniomaxillofacial | 1 | 0 | 0 | 0 | 1 |
| Broad or multiple indications | 39 | 29 | 1 | 1 | 8 |

### Table 7 PubMed results from 2016 | Clinical studies | Orthopaedic Surgery

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 6)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Pedicle screw | 27 | 17 | 5 | 2 | 3 |
| Unicompartmental knee arthroplasty | 19 | 14 | 4 | 0 | 1 |
| Total knee arthroplasty | 16 | 6 | 8 | 1 | 1 |
| Total hip arthroplasty | 11 | 4 | 4 | 1 | 2 |
| Lumbar fusion | 6 | 0 | 3 | 3 | 0 |
| Vertebroplasty | 1 | 0 | 0 | 0 | 1 |
| Broad or multiple indications | 5 | 4 | 1 | 0 | 0 |

### Table 8 PubMed results from 2016 | Clinical studies | General Surgery

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 23)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Rectal cancer | 63 | 41 | 5 | 4 | 13 |
| Gastrectomy | 36 | 20 | 4 | 3 | 9 |
| Pancreatectomy | 33 | 18 | 2 | 5 | 8 |
| Hepatectomy | 28 | 23 | 0 | 2 | 3 |
| Colectomy | 27 | 12 | 1 | 11 | 3 |
| Pancreatoduodenectomy | 26 | 14 | 1 | 6 | 5 |
| Cholecystectomy | 17 | 8 | 4 | 5 | 0 |
| Bariatric | 13 | 7 | 0 | 5 | 1 |
| Inguinal hernia | 9 | 5 | 1 | 3 | 0 |
| Colorectal | 3 | 4 | 0 | 0 | 0 |
| Hilar cholangiocarcinoma | 3 | 3 | 0 | 0 | 0 |
| Splenectomy | 3 | 2 | 0 | 0 | 1 |

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 23)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Colorectal natural orifice transluminal endoscopic surgery | 2 | 0 | 0 | 0 | 2 |
| Mastectomy | 2 | 2 | 0 | 0 | 0 |
| Pancreastosplenectomy | 2 | 0 | 0 | 0 | 2 |
| Pelvic exenteration | 2 | 0 | 0 | 0 | 2 |
| Ventral hernia | 2 | 0 | 2 | 0 | 0 |
| Breast | 1 | 0 | 1 | 0 | 0 |
| Lymph node dissection | 1 | 1 | 0 | 0 | 0 |
| Neuroendocrine tumours | 1 | 0 | 0 | 0 | 1 |
| Neurostimulator | 1 | 0 | 0 | 0 | 1 |
| Paraoesophageal hernia | 1 | 1 | 0 | 0 | 0 |
| Protectomy | 1 | 1 | 0 | 0 | 0 |
| Broad or multiple indications | 17 | 12 | 3 | 0 | 2 |

## Table 9 PubMed results from 2016 | Clinical studies | Cardiothoracic surgery

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 8)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Coronary artery bypass graft | 20 | 4 | 0 | 7 | 9 |
| Thoracic surgery | 18 | 12 | 0 | 2 | 4 |
| Percutaneous coronary intervention | 6 | 2 | 0 | 0 | 4 |
| Thymectomy | 4 | 4 | 0 | 0 | 0 |
| Atrial fibrillation | 3 | 0 | 3 | 0 | 0 |
| Bronchoscopy | 1 | 0 | 1 | 0 | 0 |
| Catheter ablation | 1 | 0 | 0 | 0 | 1 |
| Valve surgery | 1 | 1 | 0 | 0 | 0 |
| Broad or multiple indications | 8 | 3 | 2 | 1 | 2 |

**Table 10 PubMed results from 2016 | Clinical studies | Neurosurgery**

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 5)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Brain biopsy | 1 | 1 | 0 | 0 | 0 |
| Electrode implant | 1 | 0 | 1 | 0 | 0 |
| Hemispherotomy | 1 | 0 | 0 | 1 | 0 |
| Intracerebral haemorrhage | 1 | 1 | 0 | 0 | 0 |
| Peripheral nerve | 1 | 1 | 0 | 0 | 0 |
| Broad or multiple indications | 6 | 4 | 0 | 0 | 2 |

**Table 11 PubMed results from 2016 | Clinical studies | Paediatric surgery**

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 3)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Urological | 5 | 1 | 0 | 1 | 3 |
| Pyeloplasty | 4 | 3 | 1 | 0 | 0 |
| Cholecystectomy | 1 | 0 | 0 | 0 | 1 |
| Broad or multiple indications | 0 | 0 | 0 | 0 | 0 |

**Table 12 PubMed results from 2016 | Clinical studies | Vascular surgery**

| | | Study design | | | |
|---|---|---|---|---|---|
| **Procedure or indication (Total: 1)** | **All clinical studies** | **Systematic reviews** | **Randomised controlled trials** | **Other comparative** | **Other** |
| Broad or multiple indications | 2 | 1 | 0 | 0 | 1 |

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