RCSI Robotic Surgery

RCSI NATIONAL ROBOTIC SURGERY LEADS GROUP 2024

Robotic Surgery Governance in Ireland: A guide to good practice

Contents

ROBOTIC SURGERY REPRESENTS THE FUTURE OF HIGH-TECH SURGICAL INNOVATION. AT RCSI, WE ARE COMMITTED TO DEMONSTRATING LEADERSHIP BY ENSURING THE HIGHEST STANDARDS OF PATIENT SAFETY AND EQUIPPING SURGEONS WITH THE SKILLS TO USE THIS TECHNOLOGY COMPETENTLY AND RESPONSIBLY.

Foreword

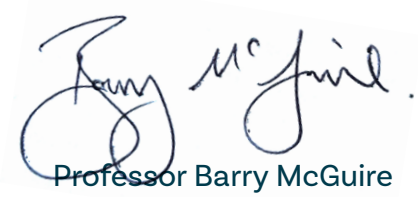
Leading the Future of Robotic Surgery: *Best Practices for Safety and Excellence*

As robotic platforms become a foundational element of modern healthcare, the Royal College of Surgeons in Ireland (RCSI) recognises the growing need for a unified approach to robotic surgery governance across Ireland. In December 2023, RCSI established the National Leads on Robotic Surgery Committee in collaboration with the Irish Surgical Postgraduate Training Committee (ISPTC). This committee, composed of representatives from across surgical specialties, was founded with the mission of ensuring that the adoption of robotic surgery in Ireland is both safe and sustainable, safeguarding patient outcomes while supporting the professional growth of Irish surgeons.

The committee's first major initiative is this national governance document, developed as a comprehensive framework to support robotic surgery at the hospital level. This document sets clear safety standards, structured training pathways, and operational protocols for managing robotic-assisted procedures. By providing these foundational guidelines, RCSI aims to equip surgeons and healthcare institutions with the tools and guidance necessary to integrate robotic technology effectively, confidently and safely to a national standard.

The role of RCSI and the National Leads Committee is not to impose restrictive regulations but to empower and support surgeons in their practice. This governance document reflects RCSI's commitment to help surgeons work autonomously while ensuring best practices are accessible, adaptable, and aligned with the rapid pace of technological advancement in surgery. Drawing from lessons learned in the initial adoption of laparoscopic surgery—which ultimately required the development of programs like the Fundamentals of Laparoscopic Surgery (FLS) to establish safety standards—this framework proactively addresses similar needs in robotic surgery.

This governance document positions Ireland as a leader in robotic surgery, fostering surgical autonomy, enhancing patient safety, and providing surgeons with structured pathways for navigating the complex and dynamic future of healthcare technology. As the landscape of surgery continues to evolve, RCSI's goal is to create a foundation that promotes both innovation and excellence in patient care.



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RCSI National Robotic Surgery Leads Group

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Message *from* RCSI President

A framework for safety, training and practice in this rapidly evolving field

Over its 240-year history, RCSI has been an advocate for the highest standards of surgical care. Our experience, built on the committed work of our Fellows over the generations, provides a unique perspective on how to ensure safe surgical care.

The remarkable advances in surgical practice and technology that have taken place over recent years have radically changed our discipline. The improvement in patient outcomes enabled by the development of minimally invasive surgery and enhanced recovery pathways has delivered enormous benefit to individual patients and to our health service.

At the same time, the introduction of new technologies into daily practice has the potential to fundamentally change the interaction between surgeons and their patients. As the range of minimally invasive and robotic-assisted technologies expands, RCSI recognises that surgical training and practice must remain agile and responsive.

This document, Robotic Surgery Governance in Ireland: A Guide to Good Practice, establishes a framework for safety, training and practice in this rapidly evolving field. Importantly, it recognises that in an age of rapid technologic evolution, clinical governance plays a vital role in creating a culture that supports teamwork, values learning and prioritises safe surgical care.

I commend the members of the National Robotic Surgery Leads Group on their first publication and look forward to their ongoing leadership in this important area.

Deborah McNamara

Professor Deborah McNamara
President, RCSI

Message *from* RCSI Surgical Affairs

Surgery is undergoing a profound transformation.

I am delighted to introduce this important document, which places patient safety at its core while remaining highly practical and surgeon-friendly. Independence among surgeons has always been a driving force for innovation and, ultimately, for delivering better patient care. We owe much of the progress in surgery to the determination and expertise of surgeons, and this document ensures that the surgeon remains central to the Robotic Surgery Governance Committee.

Surgery is undergoing a profound transformation, with technology rapidly reshaping the operating room at an exponential pace. This document represents a foundational step in ensuring that as these advancements unfold, both patients and surgeons remain at the center of progress. It provides clear, practical guidance for experienced robotic surgeons, empowering them to identify and address issues effectively.

I would like to congratulate the RCSI National Robotic Surgery Leads Group for their exceptional work in developing this document, and I extend my gratitude to all contributors whose diverse opinions have shaped its creation. The insights gathered from the national stakeholder survey, which received an outstanding response rate from surgeons, further emphasise the strong endorsement and demand for this type of guidance within the surgical community.

While this may be the first of many such documents as technology continues to evolve, it is a testament to the leadership of surgeons in embracing and shaping these changes to prioritise both safety and innovation. By maintaining the expertise and independence of surgeons at the heart of these advancements, we can ensure the best outcomes for patients and the surgical profession alike.

Congratulations again to everyone involved in this groundbreaking effort.

Mr. Kieran Ryan
Managing Director of Surgical Affairs, RCSI

Introduction

Robotic-assisted surgery represents one of the most significant advancements in modern surgical practice, with its application rapidly expanding across multiple specialties. Robotic platforms offer precision, minimal invasiveness, and the potential for faster recovery times, making them invaluable in the modern surgical era.

The diversity of robotic systems available today reflects this technological evolution. We now have 'soft tissue robots' (commonly used in urology, colorectal, thoracic, hepatobiliary, ENT and gynaecology), as well as 'orthopaedic robots' designed specifically for bone and joint operations. As surgical technology continues to evolve, we can potentially expect even more advanced robotic platforms in the future, such as autonomous robots or innovations involving artificial intelligence.

This guidance document however, focuses specifically on soft tissue robotic surgery, which has become a standard of care in many specialties. Despite the widespread adoption of these systems across Ireland where they are now integral to both routine and complex procedures, the introduction of robotic platforms has occurred without a unified national governance framework.

As robotic systems become more ingrained in healthcare, there is growing recognition of advantages of structured hospital governance best practices to ensure that these technologies are used safely and effectively.

This document serves as a guide to best practices for hospitals looking to develop and manage a robotic-assisted surgery programme. It outlines recommendations for training, credentialing, and governance to help hospitals implement robotic surgery safely and effectively. By following these suggested protocols, Irish hospitals can support high standards of surgeon competency, ensure patient safety, and responsibly incorporate new technologies.

The need for Robotic Surgery Governance

The rapid adoption of robotic-assisted surgery has enabled significant advancements, yet without structured guidance, patient safety can be at risk—especially during the steep learning curve. Surgeons transitioning from traditional or laparoscopic techniques must develop new skills that don't necessarily transfer from these surgical approaches (*Eddib et al., 2013; Pietersen et al., 2023; Schmidt et al., 2024*).

During this initial phase, when surgeons are still mastering robotic techniques, patient risk is highest (*Dyer, 2018; Larcher et al., 2019; Nik-Ahd et al., 2019; Rabinowitz et al., 2024; Thompson et al., 2014*), and there are a number of documented cases where a lack of specific governance has contributed to adverse outcomes (*De Ravin et al., 2023; Dyer, 2018; Pucher et al., 2024*).

A national survey in Ireland, which included the majority of Irish robotic consultant surgeons, highlighted a strong desire for clearer regulation, supervision, and guidance in the use of robotic systems, with 95.2% of respondents endorsing the establishment of a dedicated committee (*Leads, 2024*).

Ireland is not alone in recognising this need; other major organisations have also advocated for dedicated robotic governance. Both the Royal College of Surgeons of Edinburgh (*RCSEd*) (*eta ll, RCSEd 2022*), the Royal College of Surgeons of England (*RCSE*) (*Beard et al, RCSE 2023*) and the Association of Upper Gastrointestinal Surgery (*AUGIS*) (*Pucher et al., 2024*) have developed best practice policies to guide robotic surgery programmes.

These frameworks recommend oversight by multidisciplinary governance committees to uphold training and competency standards, providing comprehensive yet flexible policies that promote consistency in training and patient safety.

A RECENT ALL-IRELAND ROBOTIC STAKEHOLDER SURVEY, WHICH ACHIEVED A 76% RESPONSE RATE FROM SURGEONS, REVEALED OVERWHELMING SUPPORT FOR THE ESTABLISHMENT OF DEDICATED ROBOTIC GOVERNANCE COMMITTEES WITHIN HOSPITALS. RESPONDENTS ALSO STRONGLY ENDORSED THE MONITORING OF KEY PERFORMANCE INDICATORS (KPIS) TO ENHANCE PATIENT SAFETY. THESE FINDINGS HIGHLIGHT THE COLLECTIVE COMMITMENT AMONG ROBOTIC SURGEONS TO FOSTERING A STRUCTURED AND SAFETY-FOCUSED APPROACH TO ROBOTIC-ASSISTED SURGERY IN IRELAND.

Croghan S, The RCSI Robotic Surgical leads Group

A guide to establishing a new Robotic Surgery programme

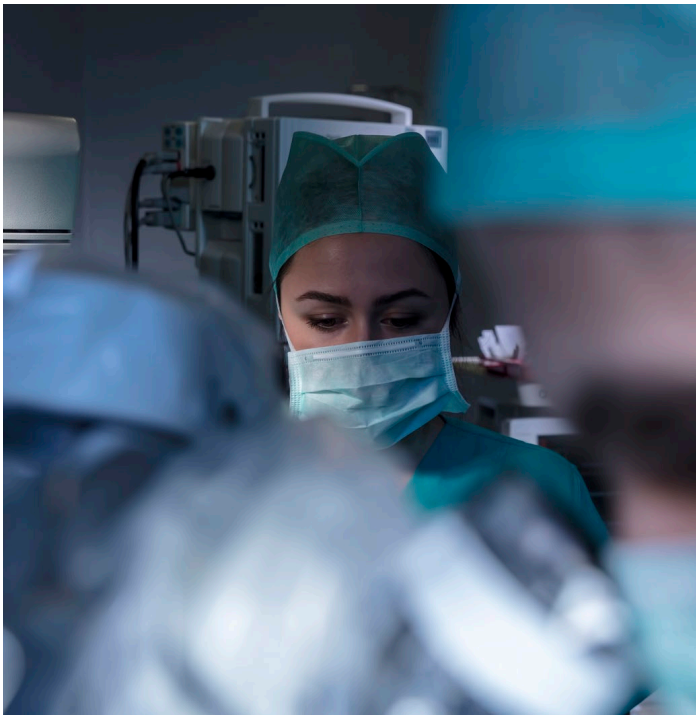
For hospitals starting a robotic surgery programme without existing infrastructure, several foundational steps are crucial. This process includes establishing a governance structure specifically responsible for the safe introduction of the programme. It is important to note that this governance body is distinct from other committees tasked with non-governance aspects of establishing a robotic programme

i. **Establish a Governance Committee**

Hospitals should form a dedicated Robotic Surgery Governance Committee (*see section: 'The Robotic Governance Committee'*). The primary role of this committee is to oversee the development, safety, and operational effectiveness of the robotic programme. In the initial stages, input should come from anaesthesia, nursing, hospital porters, and allied health professionals, all of whom play key roles in delivering safe robotic surgery. Each of these groups requires specific training and planning before the first clinical case.

ii. **Nominate a Robotic Lead Consultant Surgeon**

Appointing a lead consultant robotic surgeon is essential for guiding the development and implementation of the programme. This individual should have extensive experience in robotic surgery and take responsibility for overseeing the programme's early stages. The robotic lead will ensure that appropriate training, credentialing, and safety standards are in place as the first robotic case is prepared and while the governance committee is still establishing itself. In cases where no surgeon with robotic experience is available, an external robotic surgeon may be invited as an advisor during the initial phases until local independence is achieved. This advisor should be selected by the lead surgeon from that institution.



iii. **Implement a Phased Introduction of Robotic Surgery**

A phased approach to introducing robotic surgery ensures controlled and safe implementation. Initially, robotic-assisted surgery should begin within a single specialty, allowing the hospital to focus resources, refine protocols, and address any challenges in a manageable scope. This approach provides an opportunity for the entire surgical team to build experience and troubleshoot the often-encountered, unpredictable bumps along the way. Once the initial specialty demonstrates consistent success, the programme can gradually expand to additional specialties, building on a foundation of safe practices. This phased approach also allows the broader surgical team time to gain experience with the new robotic programme.

iv. **Plan for the First Case**

The hospital should work closely with the selected vendor while planning the first case. This includes assessing compatibility with hospital infrastructure, planning for physical setup (e.g., operating theatre space), sterilisation processes, hospital porters, and ensuring support systems such as IT integration and technical support are in place.

v. **Identify the First Surgeons and Surgical Team**

The governance committee will ensure that the chosen surgeons and the wider surgical teams complete all required training before performing their first case. Preferably, two surgeons from the same specialty should be selected to initiate the robotic programme. This 'buddy' system is a strong recommendation by AUGIS (*Pucher et al., 2024*). These surgeons will follow a structured, vendor-led training pathway prior to the first case (*see section: "Vendor Led Training Pathway"*).

vi. **Rehearsal**

Prior to the first case, the entire surgical team should conduct a 'dry run' simulation. This rehearsal should include docking the robot and practicing emergency scenarios to ensure the team is well-prepared.

vii. **Proctoring and Initial Case Selection**

During the initial phase, experienced proctors should oversee surgeons as they perform their first robotic cases, starting with lower-complexity procedures. This gradual approach allows surgeons to develop competence while maintaining patient safety (*see section: "Novice Robotic Surgeons: A Variety of Training Approaches"*).

viii. **New Applications**

All new applications for robotic surgery privileges should be vetted by the committee. This involves reviewing qualifications and training pathways to ensure that new surgeons meet established standards before beginning robotic practice (*see section: "Applications to the Hospital Robotic Surgical Governance Committee (RSGC)"*).

Existing Robotic Surgery Programmes

For hospitals with an established robotic surgery programme, implementing a standardised best practice model can help elevate programme performance, ensuring consistent quality and safety across all procedures. This document outlines the ideal framework for robotic surgery governance, guiding hospitals as they refine their programmes to meet national standards. Many hospitals already have some structures in place for robotic surgery and governance; however, this model serves to streamline and enhance those efforts, providing a national unified approach to oversight, training, and credentialing.

With independent, proficient robotic surgeons already in place, the primary focus will be on standardising processes for onboarding new surgeons, whether they are newly appointed or experienced surgeons beginning robotic practice. A multidisciplinary governance committee will oversee new applications, facilitating structured pathways for training and credentialing while maintaining rigorous safety standards. By aligning with these best practices, hospitals can ensure their robotic surgery programmes deliver consistent, high-quality care, supporting both patient safety and surgeon development.

Robotic Surgery Training: The various approaches

In robotic-assisted surgery, three primary pathways support a robotic surgeon's progression from initial training to independent practice: vendor-led training, internal mentoring, and modular training. Each has unique advantages, and a blended approach is often most effective.

1. Vendor-Led Training Pathway
This traditional pathway provides foundational skills through vendor-facilitated simulation training (typically 30–40 hours) and intensive lab sessions. Following these, an external proctor—a high-volume robotic surgeon selected by the vendor in tandem with the novice surgeon—supervises the first cases to ensure patient safety as the surgeon transitions to live procedures. After a specified number of cases, the proctor evaluates and "signs off" on the surgeon's competency. However, once vendor proctoring ends, the surgeon may face challenges in the early learning curve without adequate support.

2. Internal Mentoring Pathway
The internal mentoring model pairs a novice surgeon with an experienced in-house robotic surgeon from the same specialty, who supervises early cases and provides ongoing support. This mentorship allows the mentor to offer immediate, hands-on assistance when needed, significantly reducing patient risk, especially in complex or unpredictable cases. One of the key advantages of this model is that it helps prevent excessively long surgeries, which are sometimes seen in early cases due to inexperience. An experienced surgeon can quickly resolve situations where there is stalling or lack of progression, ensuring that cases do not extend beyond reasonable timeframes due to the learning curve.

In the modern era, surgeries that run significantly over expected durations due to inexperience are not acceptable, and an internal mentoring system provides an effective solution. Over time, the mentor's presence may shift from direct supervision to an "on-call" role, allowing the mentor to assist the novice surgeon if challenges arise. In this setup, the mentor should remain available and be able to attend the operating room within a reasonable timeframe.

While internal mentoring avoids the cost of vendor proctors, it does require adjustments to the mentor's schedule, potentially impacting their own clinical duties. However, the benefits—consistent guidance, improved safety, and skill development—outweigh these logistical challenges. This system fosters a collegial environment and a unified focus on patient safety. If hospitals lack sufficient experienced surgeons for this pathway, they should consider investing in telementoring or securing ongoing proctoring support as additional resources.

3. Modular Training Pathway/Parallel Component Training
The modular training/parallel component training pathway structures the learning curve by breaking down robotic procedures into specific components, enabling the novice to progressively handle more complex aspects under direct supervision. This approach allows the surgeon to begin with simpler tasks, such as dissection in non-critical areas, and gradually take on advanced manoeuvres like suturing or precise dissection. The mentor can step in as needed, allowing the novice to build competence without taking on the entire procedure too soon. Modular training is highly effective for developing skills incrementally and maintaining patient safety through each learning stage (*Ryan et al., 2022*). It is particularly suitable to the novice surgeon, to a surgeon who has passed through the early learning curve and wishes to take on more challenging components of complex operations, and to surgeons on a training scheme. It is mostly used in fellowship style training.

4. Telementoring
Telementoring adds an innovative and flexible dimension to robotic surgery training. Through real-time remote observation, an experienced surgeon can provide live guidance during the procedure, assisting with technique, troubleshooting, and ensuring the case progresses smoothly. Telementoring is particularly valuable when an in-house mentor is unavailable, offering continued support

after vendor-led proctoring ends. This approach enables surgeons to manage complex cases with added confidence and minimises risks, especially for hospitals in the early stages of building a robotic programme. Telementoring has become a good solution for ensuring safe progression without the constant need for an onsite expert. It is particularly useful in surgeons who have progressed through the early learning curve, and also to those who may be taking on a more challenging or complex case with a mentor present.

Training Pathways – Which to Choose?

There are several pathways to support robotic surgeons' development, each with unique strengths. Vendor-led training with external proctors for the first cases provides a solid foundation, while internal mentoring and modular training offer ongoing support to help surgeons manage the complexities of robotic surgery after external proctors leave.

These methods are not mutually exclusive; a combination of approaches can be tailored to fit the hospital's and surgeon's needs, always prioritising patient safety. A hybrid system blending vendor-led training, internal mentoring, and modular approaches can offer comprehensive support, allowing surgeons to develop skills safely and effectively. The Irish National Stakeholder Survey(NSS) (*Leads, 2024*) highlights strong support for these methods, suggesting that a mix of approaches is likely most effective. Ultimately, the goal is to minimise patient risk, particularly by reducing complications or negative outcomes during the surgeon's learning curve, while ensuring ongoing mentoring and support from experienced colleagues within the institution. This flexible framework fosters both skill development and patient safety.

Establishing a Robotic Surgery Governance Committee (RSGC)

Given the distinct requirements of robotic surgery, a dedicated RSGC is essential for supporting the safe and effective integration of this technology in hospitals. The committee's primary role lies in fostering safety, training, and continuous improvement rather than exercising the formal authority of other investigative hospital committees. While the RSGC may be called upon to provide expert input or analysis in cases requiring robotic expertise, its focus remains on making training and safety recommendations, not conducting formal investigations.

A national structure for RSGCs ensures consistency in oversight, training, and governance across all hospitals, addressing the variability seen in current institutional practices. This standardised framework holds all surgeons and hospitals to the same high standards, fostering uniformity in patient safety and surgeon development.

The RSGC establishes safeguards, protocols, and training structures to proactively address risks and support surgeons through their learning curve. This includes mentorship, training, and structured oversight as surgeons progress from lower-risk cases to more complex procedures. The committee's role balances surgeon support with patient safety and creating an environment of continuous improvement.

By aligning institutions under a national framework, the RSGC promotes fairness, consistency, and excellence in robotic surgery governance. In rare instances requiring review, the committee's expertise can provide critical insights, reinforcing its constructive and supportive role within the hospital system.

KEY RESPONSIBILITIES OF THE ROBOTIC SURGERY GOVERNANCE COMMITTEE

1. Authorisation for Novice Robotic Surgeons

The Robotic Surgery Governance Committee (RSGC) is responsible for evaluating applications for robotic surgery privileges. Recognising that surgeons have varying levels of experience and training, the RSGC tailors its assessment and recommendations based on each applicant's background. There are multiple types of applications the committee may receive, each requiring a unique approach to ensure surgeons are appropriately supported and patient safety is upheld.

The RSGC can make several recommendations, from approving independent practice to requiring additional supervision or targeted mentoring (*figure 01*). These recommendations are designed to provide a supportive pathway for surgeons as they integrate robotic techniques into their practice, ensuring a safe and gradual progression of skills.

Figure 01 **Potential Governance Committee Recommendations**

- **Approval for Independent Practice**
- **Limited Supervision for Initial Cases**
- **Assessment with a view to immediate sign off**
- **Vendor-Led Training**
- **Internal Mentoring**
- **Modular Training**
- **Telementoring**

2. Reviewing Training Needs

The field of robotic surgery is constantly evolving, with new technologies, techniques, and systems being introduced. To ensure surgeons and their teams remain at the forefront of this high-tech discipline, the RSGC is tasked with continuously evaluating training needs. This is not a one-time process but an ongoing effort to identify areas where additional skills or updates may be required.

A key part of this responsibility is recognising that robotic surgery demands both technical and non-technical competencies. Beyond mastering the equipment itself, surgeons must refine skills in communication, decision-making, and teamwork, particularly in the context of complex robotic systems. The committee ensures that surgeons receive regular opportunities to enhance these competencies, whether through simulation-based training, advanced courses, or exposure to new robotic platforms.

For all members of the operating theatre team (nurses, dedicated bedside assistants, anaesthetic team, physician associates), the RSGC ensures that training aligns with the demands of the robotic environment. This might include refreshers on emergency protocols, system troubleshooting, site visits to other high volume centres, or the specifics of supporting increasingly complex procedures. By fostering a culture of continuous learning, the committee ensures that both surgeons and teams remain competent, confident, and ready to adapt to advancements in robotic surgery.

3. Reviewing Serious Outcomes Related to Training or Learning Curve

The RSGC is responsible for reviewing serious outcomes where training or the learning curve may have been a contributing factor. These reviews are aimed at identifying areas for improvement and ensuring patient safety while maintaining a constructive, non-punitive environment. While such outcomes are most likely to occur during a surgeon's early robotic cases, the committee's remit extends to any incident where training-related factors may play a role.

The focus of the RSGC's review is on understanding whether the outcome was linked to gaps in training, system familiarity, or procedural challenges. Based on its findings, the committee may recommend additional mentorship, further training sessions, or adjustments in case selection. The goal is to provide actionable guidance to support surgeon development and reduce the likelihood of recurrence.

For incidents unrelated to training or the learning curve, these are referred to the hospital's standard investigative pathways, as the RSGC is not tasked with reviewing general clinical incidents. This delineation allows the committee to remain focused on its primary objective: supporting surgeon growth and ensuring safety within the context of robotic surgery training.

By addressing serious outcomes constructively and transparently, the RSGC fosters professional development while safeguarding patients. This approach reinforces a culture of learning and improvement without undermining trust or creating unnecessary apprehension.

4. Monitoring Safety Key Performance Indicators (KPIs)

1. **Annual Case Volume**
2. **Prolonged Console Time**
3. **Assessment with a view to immediate sign off**
4. **Intra-operative Transfusions**
5. **Unexpected emergency conversions**
6. **Unexpected Returns to theatre**
7. **Unexpected ICU admissions**
8. **Morbidity and Mortality**

The RSGC is responsible for monitoring performance using Key Performance Indicators (KPIs), a best-practice approach that allows the committee to identify outliers and support safe, effective practice. Based on the Irish National Stakeholder Survey (NSS), 95.2% of respondents emphasised the importance of KPI monitoring at both the surgeon and unit level to support quality care. Regular reviews help the committee to recommend appropriate actions, whether by suggesting mentoring, retraining, or other supportive measures.

KPIS TO MONITOR:

1. Annual Case Volume: Maintaining a minimum volume of cases is essential for surgeons to retain proficiency. The committee's subspecialty lead is best positioned to provide guidance on appropriate case volumes, considering the specific needs and practices of surgeons within each specialty at the hospital. Although case numbers alone are insufficient to assess competency, as a general guideline, the Irish National Stakeholder Survey (NSS) suggests performing at least one case per month to maintain skill levels. The Royal College of Surgeons of Edinburgh (RCSEd) advises an "adequate volume" annually, while the Royal College of Surgeons of England (RCSE) recommends a minimum of 20 procedures per year, with simulator retraining and proctor guidance if the surgeon has been inactive for over 90 days.

2. Prolonged Console Time: While complex procedures may naturally take longer, excessively prolonged durations should be reviewed, especially for novice surgeons. If patterns emerge, the committee may recommend additional guidance from an experienced mentor or adjustments to case selection. The specialty lead should oversee this review, as they can often readily interpret whether extended times are expected for specific operations. In cases where prolonged durations clearly result from the learning curve or training deficiencies, the committee can exercise discretion to recommend necessary changes, supporting the surgeon's development while prioritising patient safety.

3. Intraoperative Transfusions: Monitoring the frequency of intraoperative transfusions can reveal potential issues with surgical technique or case suitability. Cases with higher transfusion rates should be reviewed by the specialty lead, as they can often readily interpret whether the transfusion requirements are expected for certain procedures. This targeted review helps focus on whether there is a genuine issue or if the transfusion requirement is within the expected range, rather than relying solely on an arbitrary KPI datapoint.

4. Unexpected Emergency Conversions: While conversions to open surgery are sometimes necessary and may be more common in certain specialties, frequent unexpected conversions may indicate a need for further review. The RSGC will monitor these patterns carefully. It is essential, however, to approach conversions with caution—ensuring that surgeons do not feel pressured to prolong operations or avoid conversions out of concern for metrics, as this could negatively impact decision-making and patient outcomes. Conversion rates naturally vary by specialty, and the subspecialty lead on the committee is best positioned to assess these cases.

This KPI is not intended to penalise surgeons but rather to identify repeated conversions that clearly stem from training deficiencies. When these patterns are observed, the RSGC may recommend additional support, such as mentorship or adjusted case selection, to align case complexity with the surgeon's skill level. The subspecialty lead will oversee this review, providing guidance to ensure that case selection and procedural decisions remain supportive of both patient safety and surgeon development

5. Unexpected Returns to Theatre: A high rate of postoperative returns to the operating room may suggest underlying technical or case-selection issues. The committee's role is to monitor these patterns and make recommendations for additional supervision or adjustments to case mix if deemed necessary. The specialty lead, in conjunction with the committee, can assess whether any intervention is warranted, and any recommendations are made at the committee's discretion.

6. Unexpected ICU Admissions: While ICU admissions are sometimes appropriate for complex cases, a pattern of unexpected admissions may prompt the committee to evaluate whether case complexity is suitable for the surgeon's experience level. The specialty lead, in collaboration with the committee, can determine if adjustments or additional support are needed, with recommendations provided at the committee's discretion.

7. Morbidity and Mortality: Any cases of significant morbidity or mortality are assessed by the committee, not as formal investigations, but to identify gaps in training or procedural knowledge. Hospitals typically have established mechanisms for reviewing morbidity and mortality, and serious incidents are usually addressed through these pathways. However, in cases where such mechanisms have not been engaged, the committee may need to highlight these incidents to the appropriate hospital committees. It is important to note that the committee itself does not take on the role of conducting these formal investigations.

Additionally, the surgeon and the surgical team should be fully aware of their legal obligations under the Open Disclosure framework, ensuring transparent communication with patients and families following adverse events. Familiarity with and adherence to these processes are critical for fostering trust and maintaining professional and legal standards. Recommendations from the committee may include safety enhancements, proctoring, or adjustments to emergency rehearsal protocols to prevent recurrence and improve overall procedural outcomes.

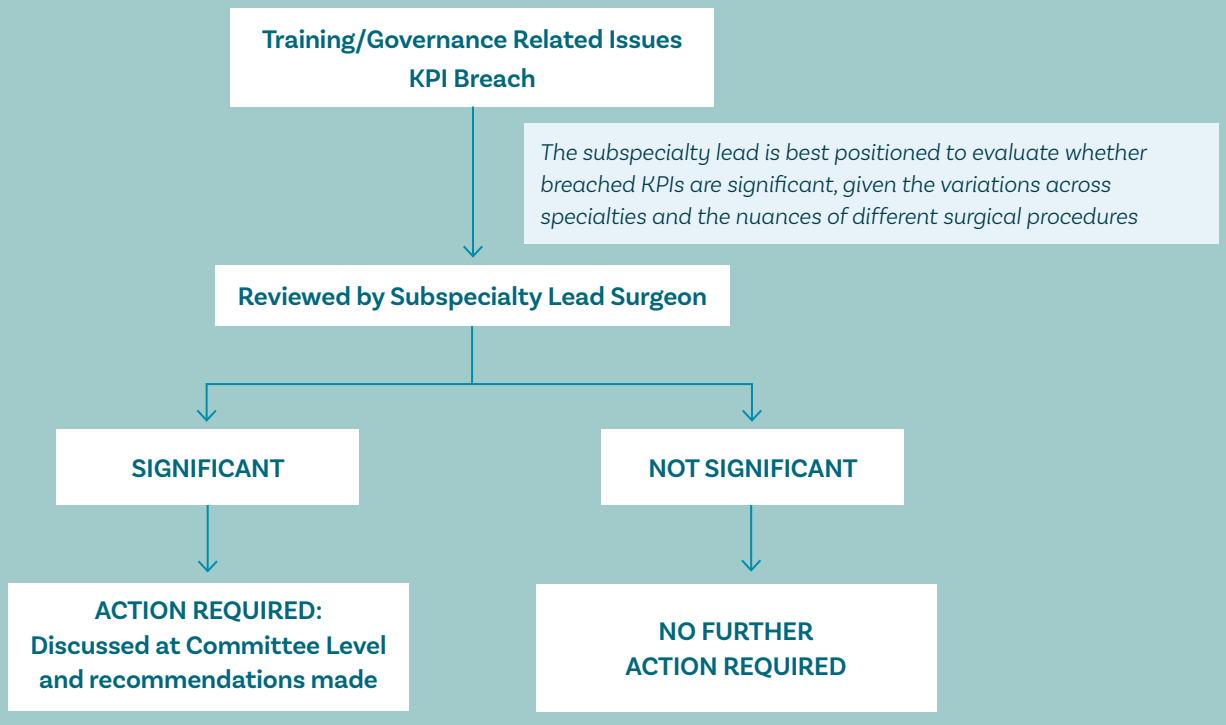
INCIDENT INVESTIGATION PROCESS

All incidents that breach a KPI should first be assessed by the subspecialty lead for the specialty in question.

Subspecialty leads are best positioned to determine the significance of a KPI breach, as variations across specialties and operations must be considered. For instance, some procedures naturally have higher blood transfusion rates, while others may have higher conversion-to-open rates.

The subspecialty lead evaluates these incidents in context and decides whether further review by the committee is warranted or if the breach can be deemed non-critical.

Figure 03 **Process for managing training/governance-related issue or KPI breach**



5. Evaluating New Robotic Platforms

Robotic surgery technology evolves rapidly, with new platforms offering varied features such as open versus closed consoles, different hand controls, and other operational nuances. Anticipating further advancements, it is crucial that each new system is carefully evaluated to ensure it meets the highest standards of safety and operational readiness.

The RSGC plays a key role in reviewing new robotic platforms, ensuring that they are thoroughly assessed before being introduced into clinical practice. This evaluation includes examining the platform's safety profile, training requirements, compatibility with existing workflows, and its overall impact on patient care. By overseeing these considerations, the RSGC ensures a smooth and safe transition when adopting new technology.

This process establishes a consistent approach to integrating innovative systems while safeguarding patient safety. With the pace of advancements in robotic surgery, the RSGC's oversight ensures that hospitals remain equipped to adopt cutting-edge technology responsibly, supporting both surgeons and patients in this rapidly evolving field.

As robotics advances, alongside developments in information technology and Artificial Intelligence, the RSGC will need to adapt to emerging technologies and their implications for surgical practice. The committee should remain flexible and responsive, ensuring it continues to guide safe, efficient, and innovative robotic surgery practices into the future.

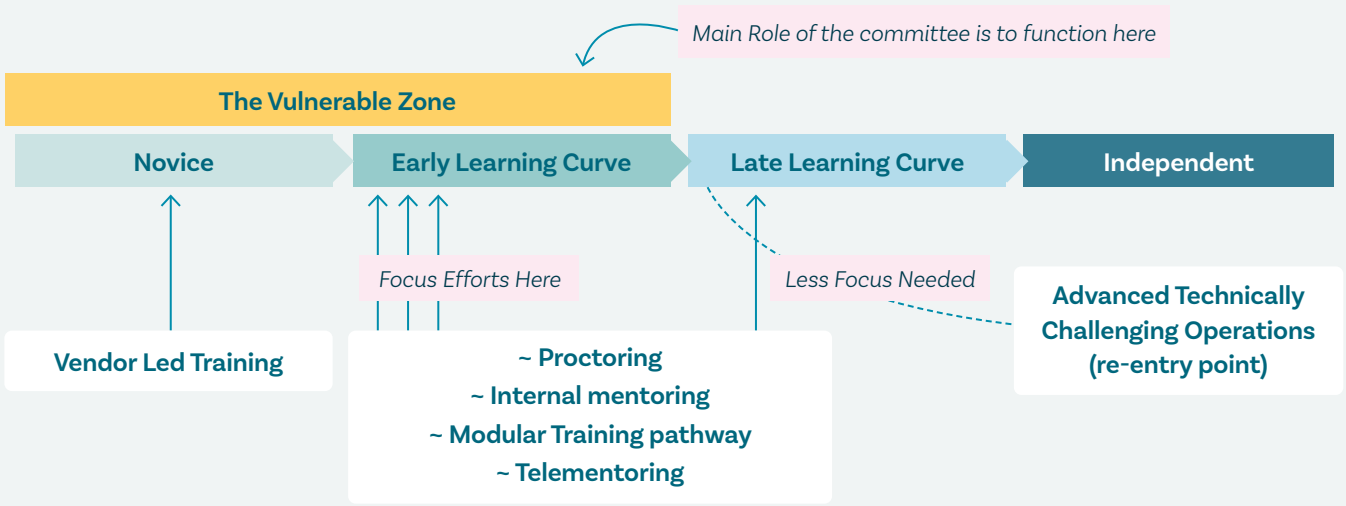
GUIDANCE ON COMMITTEE COMPOSITION

The ideal hospital RSGC would consist of:

- **Clinical Director:** Chairperson of the committee, ensuring governance standards are met and protocols are followed. Reports to the CEO.
- **Consultant Surgeons (from each specialty using robotic systems):** Provide specialty-specific insights, lead on advising regarding the training and support of surgeons within their specialty, and contribute to the committee's general duties, including oversight of safety protocols and standards in robotic surgery. Ideally this surgeon has been nominated by peers, and the position is rotated. It is important that the representative is a robotic surgeon who is independently practising robotic surgery, who has passed the learning curve. In situations where this is not possible, a temporary advisory position can be sought from peers in an outside institution chosen by the surgeons in that specialty.
- **Clinical Nurse Manager (CNM) for Robotic Surgery:** Oversees nursing staff readiness for robotic procedures and addresses operational issues within the theatre.
- **Assistant Director of Nursing (ADON):** Coordinates the needs of nursing and support staff to align with surgical requirements.
- **IT and Finance Representatives:** Evaluate the technological and financial viability of implementing and maintaining robotic systems. This can be particularly helpful in robotic programmes that are being established.
- **Trainee Surgeons:** Represents the trainee perspective, offering insights on training needs and challenges. Including a senior trainee actively learning robotic surgery provides a valuable, first hand view of the programme and supports professional development.

This multidisciplinary team helps balance patient safety, operational efficiency, and continuous improvement in robotic surgical practices. Hospital group structures provide an ideal framework for fostering collaborative support during the early adoption phase of robotic surgery. Surgeons from a different hospital within the same group can lend their expertise, offering mentorship, proctoring, or guidance to those navigating the initial learning curve.

Figure 03 **How the Committee Functions**



How the Committee Functions

The primary role of the committee is to ensure safety, provide guidance, and offer robust support to surgeons during the novice and early learning curve stages of robotic surgery.

This phase, referred to as the vulnerable zone, carries the greatest potential for risk, and the committee's energy, focus, and resources should be allocated here. Effective supervision, proctoring, and mentoring are key strategies to mitigate these risks and support surgeon development during this critical period.

For surgeons who have completed their learning curve and practice independently, the committee's involvement is minimal, maintaining a hands-off approach unless specific circumstances arise.

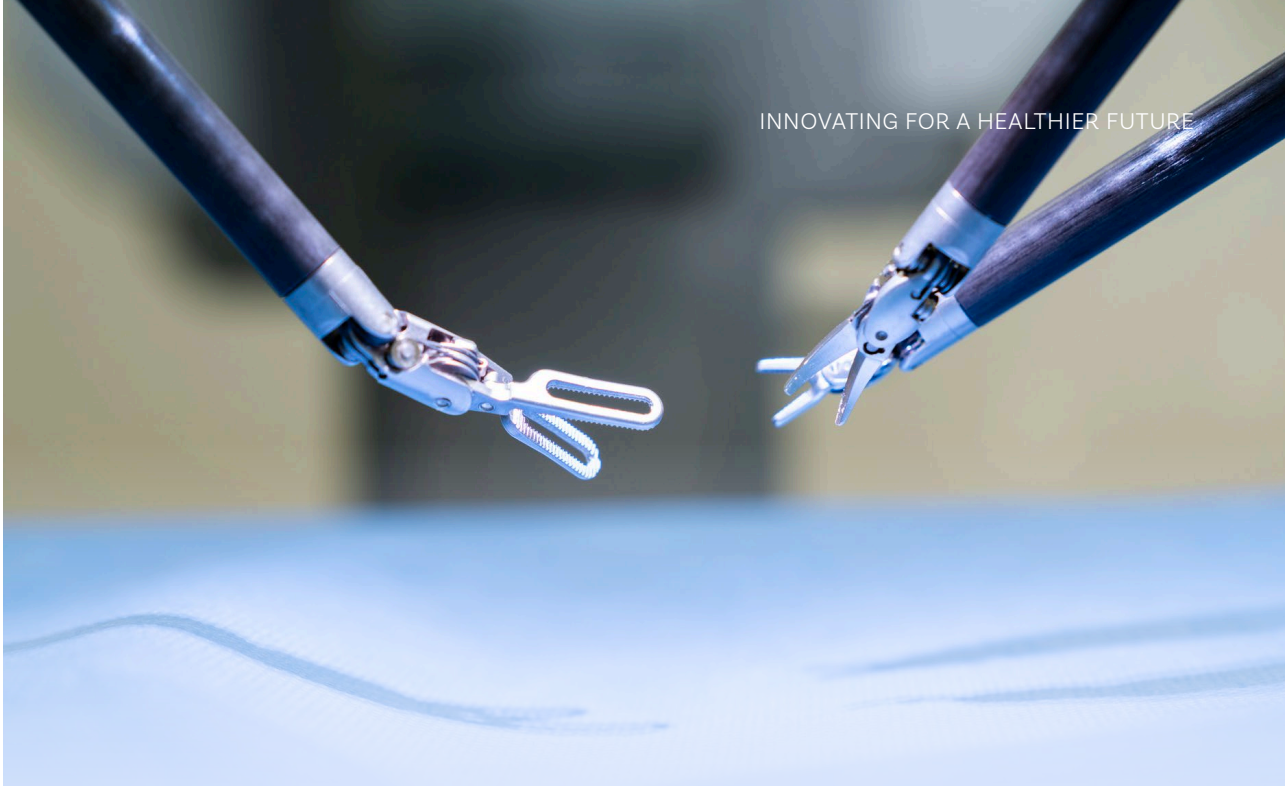
However, even experienced surgeons may re-enter what could be described as a late learning curve when they take on new, highly complex operations or unfamiliar techniques. In such instances, the committee may recommend additional support, such as buddying up with a peer surgeon, engaging external expert proctoring, or offering targeted mentorship.

This flexible approach ensures that even experienced surgeons can access support when tackling advanced challenges, while maintaining the committee's focus on safety and growth.

Roles and specific responsibilities within the **Robotic Surgery Governance Committee (RSGC) structure**:

Role/Stakeholder	Responsibilities
CEO	- **Reviews Committee Decisions:** Ensures the RSGC recommendations align with institutional goals and priorities. - **Resource Allocation:** Approves and allocates financial, operational, and technological resources necessary for robotic surgery programs. - **Final Decision-Maker:** Provides final approval for major strategic decisions and initiatives.
Surgical Clinical Director	- **Chairperson of the Committee**: Leads and facilitates RSGC meetings, ensuring a focused agenda and actionable outcomes. - **Governance Alignment:** Ensures robotic surgery initiatives align with hospital-wide clinical governance structures. - **Reporting:** Reports committee progress and significant findings to the CEO. - **Compliance Oversight:** Monitors adherence to safety protocols and governance frameworks - **KPI Integration:** Oversees the incorporation of robotic-specific KPIs into broader hospital performance metrics.
Subspecialty Lead	- **Training Assessment:** Evaluates training requirements and deficiencies within their subspecialty. - **Incident Review:** Assesses KPI breaches or adverse events for their subspecialty and determines whether further action or investigation is necessary. - **Liaison Role:** Acts as a bridge between the practicing surgeons in their specialty and the RSGC, ensuring two-way communication of concerns and updates. - **Specialty Advocacy:** Represents subspecialty-specific needs and challenges during RSGC deliberations.
Nursing Clinical Nurse Manager (CNM)	- **Training Oversight:** Ensures nursing staff are appropriately trained to meet the operational needs of robotic surgery. - **Theatre Operations:** Addresses operational issues within the operating room, ensuring efficiency and preparedness. - **Emergency Protocols:** Collaborates on the development and rehearsal of emergency response protocols, including undocking drills. - **KPI Collection:** Oversees the collection of KPI data relevant to robotic surgery and submits findings to the Surgical Clinical Director.
Data/IT Manager	- **Data Collection Support:** Assists the Nursing CNM in gathering and managing KPI data. - **IT Support:** Resolves general and robot-specific IT issues that impact data collection and surgical operations. - **Benchmarking:** Supports performance benchmarking by ensuring accurate and timely data submission. - **Quality Improvement:** Works collaboratively to identify trends and implement improvements based on KPI analysis.

The Clinical Director has been designated as Chairperson of the RSGC. However, in the event that this person is not robotically trained or does not have sufficient expertise in robotic surgery, they may nominate another senior subspecialty surgeon as Chairperson. This individual would ideally be one of the robotic leads, ensuring they possess the necessary understanding of robotic surgery and its complexities. To promote good governance and broad engagement, the Chairperson role should rotate periodically among the subspecialty leads. The robotic leads may also nominate an appropriate individual for the Chairperson role. This approach ensures wide buy-in, avoids disputes, and supports the evolving demands of robotic surgery governance. The Clinical Director would continue to participate in the committee, focusing on hospital safety standards and strategic oversight. The Chairperson would report to the Clinical Director, who, in turn, would liaise with the CEO to maintain alignment with institutional priorities.



A GUIDE TO THE TYPES OF APPLICATIONS THAT A RSGC MAY RECEIVE

Types of Applications

1. Novice Surgeons with No Robotic Experience

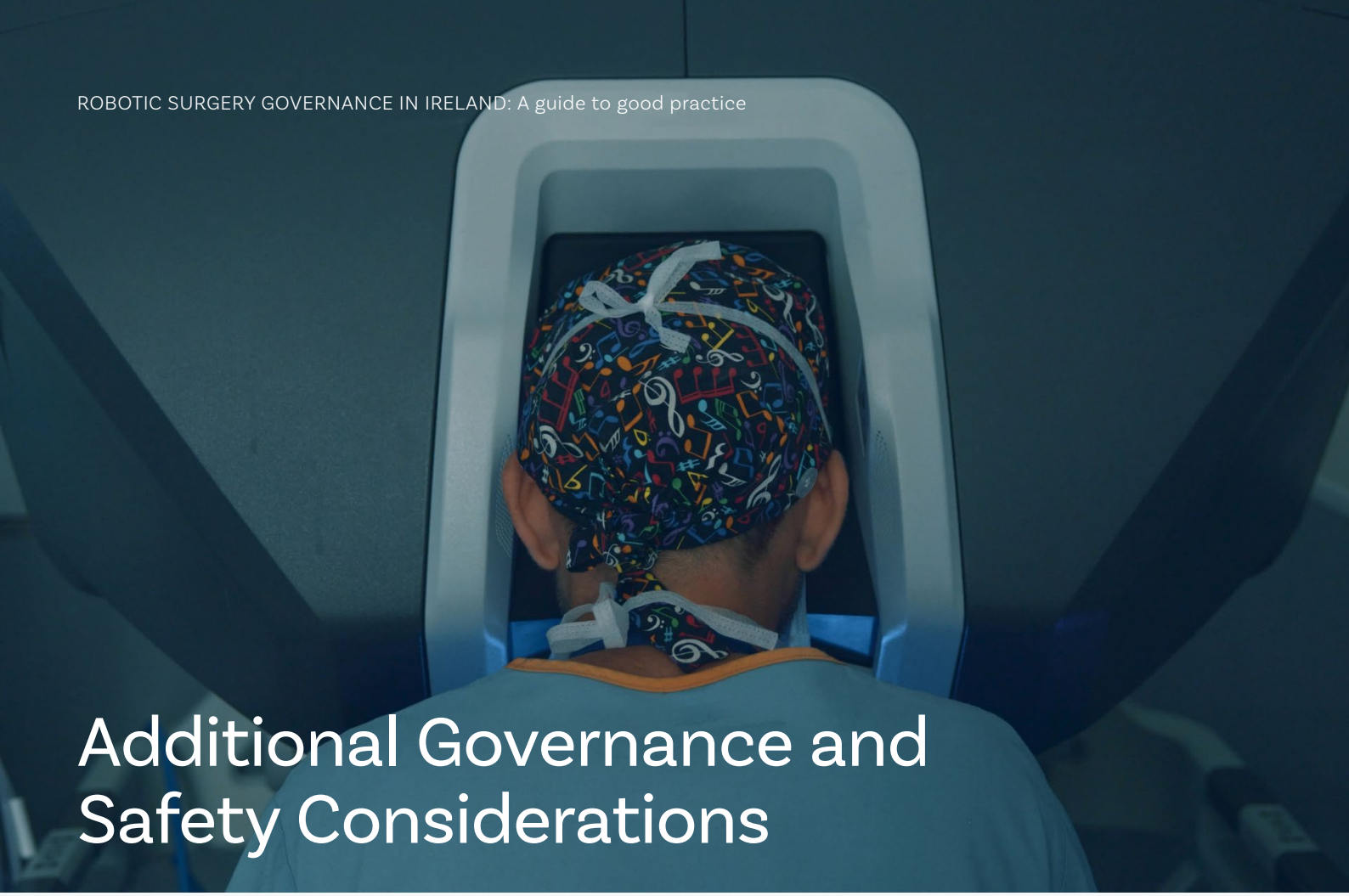
Surgeons new to robotic-assisted surgery are typically brought through vendor-led training, covering comprehensive simulation steps from basic to complex, followed by immersive dry and wet lab training. Before the surgeon's first clinical case, the RSGC reviews this pathway to ensure all simulator steps are completed and that an appropriate proctor has been chosen in partnership with the surgeon. Additionally, the RSGC verifies that the operating theatre team is adequately prepared for the first case. During this period, lower-complexity cases are recommended to help the surgeon build confidence and experience gradually. The committee will receive written feedback from the proctor upon the surgeon's initial training completion, with a recommendation for either sign-off or further mentoring (e.g., internal mentoring, modular training, or telementoring). It would be preferable to employ an internal mentoring system at this point after proctor sign off (*see* '*Internal Mentoring Pathway*').

2. Surgeons with Prior Robotic Training

For surgeons with previous robotic experience (such as through fellowships or practice at another institution), the RSGC may recommend limited initial supervision by an established in-house robotic surgeon. This supervising surgeon assesses the applicant's proficiency and sends a sign-off correspondence to the RSGC if they deem the surgeon fully proficient. In cases where an in-house robotic surgeon is unavailable, a vendor-led proctor can be assigned to observe initial cases and report back to the committee. Experienced surgeons currently practicing robotic surgery elsewhere who can demonstrate adequate case volume and skill may be eligible for immediate independent practice.

3. Experienced Surgeons Starting on a New Robotic Platform

Surgeons proficient on one robotic system who are transitioning to a new platform may require targeted training specific to the new system. In these cases, the RSGC may arrange guidance from a consultant familiar with both platforms, ensuring a smooth adaptation process for the surgeon as they learn to navigate the new system.



Additional Governance and Safety Considerations

1. Multiple Robotic Systems in the Same Hospital

As the field of robotic surgery continues to evolve and competition increases, it is likely that hospitals will adopt and operate more than one type of robotic platform. This raises important questions about safety and the transferability of skills across different robotic systems.

In Ireland, surgeons often operate in more than one hospital, and as such they will potentially be frequently switching from one robotic platform to another depending on the institution. There will also be challenges to hospital governance committees to ensure safety when faced with introducing a new robotic platform design.

There will also be challenges to training bodies to manage the trainee experience as they learn robotic surgery across multiple different platforms. There are limited data on transferability of skills across multiple platforms, however a scoping review on this topic demonstrated that experts transfer many domains of technical skill but still have a learning curve on the new system (*Devine et al., 2024*).

Interestingly novices appear to operate at a similar performance level between platforms. In the case of an established proficient robotic surgeon starting out on a new robotic platform, these data would suggest some caution in terms of case-mix at the start of the programme, and a standard approach for novices starting out their robotic journey.

In future kinetic data such as efficiency of hand movement to measure skill or learning curve, may potentially be used to guide training, or competency-based assessment.

2. Casemix: Managing Complexity and Risk in the Early Phase

In practice, surgeons are encouraged to begin their robotic surgery journey with lower-risk cases that involve fewer variables and complications. As they gain proficiency, they can gradually take on more technically demanding operations that require complex tissue manipulation and advanced suturing skills.

RSGC role is not to police individual cases but to provide oversight, guidance, and support to ensure that surgeons are progressing appropriately. Surgeons are expected to take responsibility for selecting lower-risk cases during the early stages of their learning curve and gradually increasing complexity over time. This progression should be done under supervision, whether through proctoring, internal mentoring, or modular training pathways, with patient safety at the core of every decision.

The RSGC, along with subspecialty leads, ensures that the surgeon's progression aligns with their evolving skill set, but the responsibility is shared. This approach fosters a culture of good practice, where patient safety is prioritised while ensuring that surgeons are supported as they advance in their training. While the committee offers oversight and guidance, it is ultimately up to the surgeon and their mentors to ensure that learning is conducted safely and progressively.

3. Emergency Scenario Preparedness in Robotic Surgery

Robotic surgery introduces unique challenges in emergencies due to the setup: surgeons operate remotely from the patient using a console, requiring the robotic arms to be undocked before life-saving interventions, such as CPR, can occur. While emergencies are rare, high safety standards recommend regular emergency rehearsals to prepare the team for these situations. Practicing undocking, patient repositioning, and team communication helps ensure fast, coordinated responses when seconds matter.

Key Components of Emergency Rehearsals:

1. **Undocking:** Each team member rehearses their role, enabling efficient and safe undocking.
2. **Patient Repositioning:** Teams practice repositioning from specialised surgical positions to ensure swift access during emergencies.
3. **Communication:** Strong protocols improve coordination between the surgeon at the console and the bedside team.

REHEARSALS

Integrating short, regular emergency rehearsals, even annually, enhanced team readiness, ensuring rapid, confident responses when needed. A study highlights the effectiveness of such rehearsals: teams that regularly practice emergency undocking can reduce response times significantly, with undocking times improved from over two minutes to under 30 seconds (*Kalipershad & Peristerakis, 2022*), and this should be the goal. This preparation supports patient safety in robotic surgery, minimising delays and enhancing outcomes in time-critical events.

Figure 04 **An example of an emergency undocking safety protocol**

Robotic Emergency Safety Protocol

ROBOTIC EMERGENCY SAFETY PROTOCOL: ESSENTIAL STAFF REQUIRED AT ALL TIMES

- Surgeon
- Anaesthetist
- Surgical Bedside Assistant
- Scrub Nurse
- Circulating Nurse

PRE-OPERATIVE SETUP

- At team brief, all staff to confirm familiarity with the protocol
- A gown and gloves placed on a trolley next to the console
- Arrangements for suction to be set up from the beginning of the case
- The robotic console, patient-side cart, vision cart and diathermy generator should be connected to UPS system

TRIGGER PHASE

"Emergency Undocking"

To be initiated by surgeon only. In anaesthetic emergencies, the anaesthetist informs the surgeon.

ACTIONS

1. Circulating nurse activates emergency buzzer and positions themselves at the patient-side cart.
2. The surgical bedside assistant assists in controlling the operative field and does not participate in undocking.
3. The scrub nurse, once instructed by the surgeon, removes all robotic instruments and release the ports.
4. Once ports are released, the scrub-nurse asks the circulating nurse to move the patient-side cart away from the patient.
5. The circulating nurse returns the operating table to neutral position.
6. The surgeon is gowned and positioned at the operating table.
7. The scrub nurse has a scalpel ready if required.
8. The circulating nurse initiates the major haemorrhage protocol if necessary.
9. Members of staff arriving in theatre will be instructed on actions needed by the operating or anaesthetic team.

Source: The introduction of an emergency safety protocol. Sujala N.R. Kalipershad and Ioannis Peristerakis.

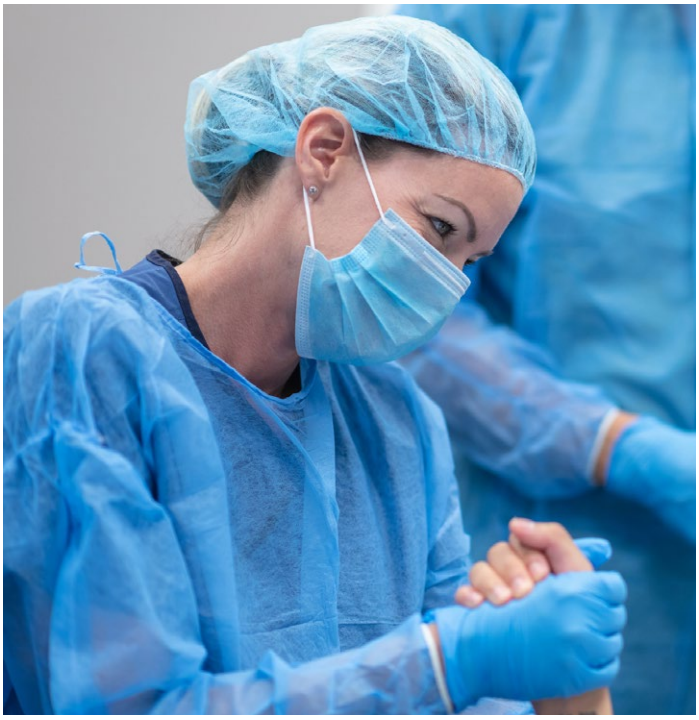
4. Well Leg Compartment Syndrome (WLCS)

Well Leg Compartment Syndrome (WLCS) is an uncommon but critical complication associated with prolonged robotic-assisted pelvic surgeries, particularly in positions involving hip and knee flexion, such as the reverse Trendelenberg position.

During robotic procedures, sustained elevation of the lower limbs can lead to reduced perfusion, causing ischemia and potential reperfusion injury when the legs are lowered. This complication, although rare (incidence around 0.01-0.03%) (*Halliwill et al., 1998; Simms & Terry, 2005; Warner et al., 2001*), can have severe outcomes including permanent nerve damage or limb loss.

To mitigate these risks, the combined WLCS guidelines (on behalf of the Association of Coloproctology of Great Britain and Ireland, the Society of Great Britain and Ireland, the British Orthopaedic Association and the British Association of Urological Surgeons) recommend that all surgeons who undertake pelvic operations on patients maintained in reverse Trendelenburg should be aware of well leg compartment syndrome and where elevation of legs to facilitate surgery is required the patients legs should be lowered to the level of the heart for a minimum of 15 minutes after each 4 hour interval (*Gill et al., 2019*).

Heightened awareness, preoperative team discussions, and intraoperative monitoring are critical to reduce the incidence of WLCS, safeguarding patient outcomes during prolonged procedures



5. Consent in Robotic Surgery

For novice robotic surgeons, specific consent guidelines align with international standards of care, as recommended by the RCSE (*Beard et al, RCSE 2023*) and AUGIS (*Pucher et al., 2024*). While robotic systems are standard in many procedures, surgeons new to the technology require a learning phase.

It is the responsibility of the novice surgeon to ensure patients are fully informed of their experience level, the learning curve, and any potential implications during the consenting process. There is no need for a specific consent form, but the discussion should ensure patients understand these aspects clearly.

Structured mentoring systems, such as internal mentoring or continued proctoring, help mitigate risks by providing experienced support during procedures (*Ryan et al., 2022*). These safeguards ensure that any challenges can be addressed promptly, maintaining patient safety. While governance systems and hospitals support these frameworks, it is the surgeon's responsibility to explain this setup to the patient as part of the consent process. This approach reassures patients that the learning curve risks are mitigated, offering confidence in their care. By addressing these details transparently, novice surgeons demonstrate professionalism and uphold the highest standards of patient safety while advancing their skills.

6. External Proctors in Robotic Surgery

External proctors provide critical oversight and support in robotic surgery, particularly for surgeons requiring additional guidance during challenging cases or early in their training. Registration with the Irish Medical Council (IMC) is particularly important for proctors involved in supporting surgeons in the early stages of their learning curve. This ensures that the proctor can take over the case if required, prioritising patient safety during these high-risk phases.

Registration Requirements

Every effort should be made to ensure that proctors are appropriately registered with the IMC, as this enhances safety and compliance with regulatory standards. In certain situations, such as when a proctor provides advice or tips to an independently practicing surgeon who is beyond their learning curve, formal registration may not be necessary. However, this should be carefully evaluated, keeping patient safety as the central priority.

Proctor Selection and Hospital Responsibility

Surgeons, in collaboration with the vendor, select a proctor who best fits their needs based on expertise and experience. The hospital must ensure that the proctor meets registration requirements where necessary and has appropriate insurance or indemnity coverage. This ensures that the proctor is prepared to take on a more active role if the situation demands, particularly during the surgeon's early learning phase.

Role of the RSGC

The RSGC plays a key role in ensuring that proctors are integrated seamlessly into robotic programs. This includes verifying their credentials, assessing the need for registration based on the specific context, and ensuring adequate insurance or indemnity coverage. By coordinating with the robotic lead or clinical director, the committee facilitates a structured and safe approach to proctoring, tailored to the needs of the surgeon and the complexity of the case. This ensures patient safety and supports consistent quality standards across all robotic procedures.

Patient safety remains the central priority, and registration or other safeguards should align with the specific context of the proctor's involvement.

Conclusion

This guide to good practice outlines an ideal framework for fostering the safe and supportive growth of robotic-assisted surgery in Ireland. Central to this approach is the Robotic Surgery Governance Committee (RSGC), which prioritises a safety-first ethos, particularly during the early surgical learning curve, with an emphasis on constructive and tailored support for surgeons.

The RSGC includes surgeons from all represented specialties, ensuring peer review supervision of Key Performance Indicators (KPIs). These KPIs are designed to identify outliers and address training deficiencies without adopting a punitive or investigative stance. This approach avoids creating a culture of fear or altering surgeon decision-making in ways that could compromise patient care. Instead, the committee's role is to guide surgeons constructively, ensuring patient safety while building surgeon confidence and skills.

The measures within this governance model are intentionally simple yet effective, focusing on protecting patients and supporting surgeons as they navigate the complexities of robotic surgery. By incorporating diverse perspectives and fostering a culture of trust and teamwork, the RSGC ensures that patient care remains at the forefront while encouraging surgical innovation.

As robotic technology continues to evolve, this governance model strikes a balance between embracing innovation and maintaining consistent, high-quality care. With a commitment to continuous improvement and collaboration, this framework provides the foundation for developing surgical expertise within a supportive and safety-focused environment.

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