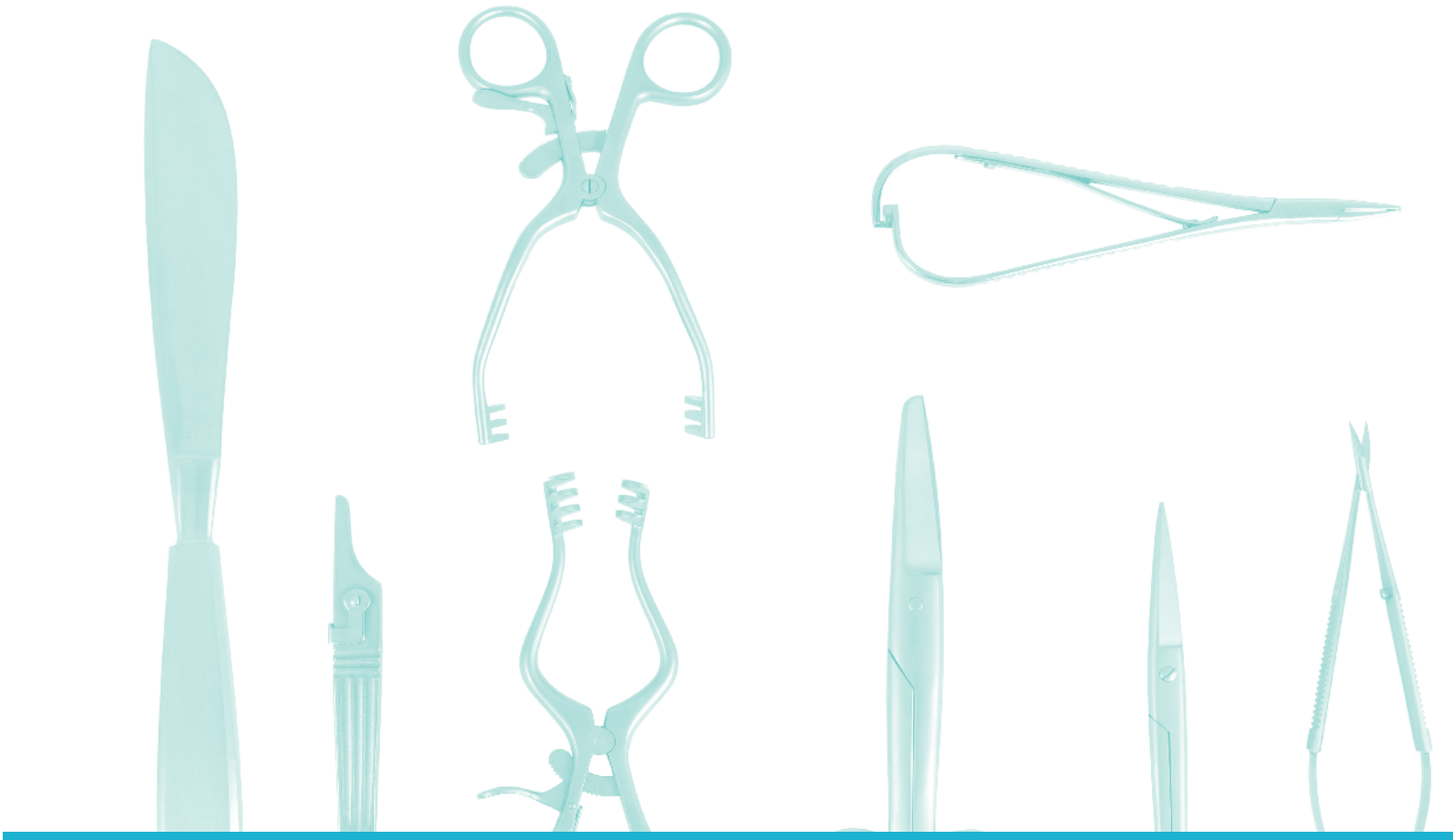
SURGICAL INNOVATION, NEW TECHNIQUES AND TECHNOLOGIES

Royal College of Surgeons
ADVANCING SURGICAL CARE

SURGICAL INNOVATION, NEW TECHNIQUES AND TECHNOLOGIES

A Guide to Good Practice



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RCS Professional Standards

February 2019

inQuisit was commissioned by The Royal College of Surgeons of England to prepare this guide. The RCS would like to thank Sally Williams for drafting the report"

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1. Introduction

Surgeons are innovators. The advancement of surgery is set against a backdrop of continuous development and, in the past 50 years, surgical innovations have transformed the way clinical care is delivered. Procedures that were unthinkable only a few decades ago are now common practice. Surgical innovations have improved patient outcomes, reduced complication rates and length of hospital stay, and have decreased morbidity and mortality.

The introduction of minimally invasive surgery, for example, has transformed patient outcomes across many different surgical specialties. The use of smaller incisions has reduced surgical trauma, improved postoperative pain and shortened recovery times. For surgeons, it has meant a shift in the way they physically operate, with a move away from seeing, feeling and manipulating organs and tissues with their own eyes and hands. The technology has also opened the door to the increasing use of robotics in surgery, allowing increased surgical precision within confined spaces and introducing the prospect of remote operating.[1]

The pace of surgical innovation shows no sign of slowing, from developments in three-dimensional printing, artificial intelligence and nanotechnology to advances in regenerative medicine and the ability to grow organs and tissues in the laboratory. Such innovations will have fundamental consequences for surgical decision making and the way surgeons treat patients.

As exciting as these innovations are in terms of their potential, there are significant risks in allowing innovation to occur in the absence of a clear guiding framework. Surgical innovations can be risky. Without proper evaluation, regulation and training in their use, innovations have the potential to harm patients rather than benefit them.

Historically, the development of new techniques has often taken place in the absence of the rigour associated with the development of new medicines or devices. Surgical innovation is frequently driven by one clinician's desire to improve care for an individual patient. The onus has been on the individual surgeon to use his or her clinical judgement and professionalism to decide on a new technique, identify which patients might benefit and to know and recognise the surgical limitations despite their personal enthusiasm for the innovation. There then arises the need to communicate all of this clearly to the patient so that they are in a position to give informed consent. The recent notorious case of a breast surgeon single-handedly creating and applying a novel surgical procedure, the so-called 'cleavage-sparing mastectomy', outside the parameters of peer review or a strong clinical governance framework, demonstrates the harm that can be done to large numbers of patients without proper oversight of new procedures.

Most surgery now takes place in teams, and effective surgical teamworking results in better outcomes for patient safety.[2,3] Even so, there remain issues about:

- the processes by which a surgeon (and the surgical team) train in a new approach
- the oversight and quality assurance underpinning the training
- how patients are selected
- how consent is obtained
- how the outcomes of the new approach are audited.[4]

Surgeons, clinical leaders in hospitals (including medical and clinical directors), commissioners and health system leaders need to be cognisant of the challenges associated with innovations and not just the opportunities they offer. It is incumbent upon the surgical profession to ensure that surgical innovation takes place with great care, with the consensus of other surgeons and clinicians and is underpinned by rigorous clinical governance processes, appropriate training and close oversight of outcomes.

1.1 ABOUT THIS GUIDE

This guide seeks to provide surgeons with up-to-date thinking on the development, implementation and dissemination of surgical innovation. A strong framework is needed to ensure that the development of new techniques is driven by altruistic motives and that both patient safety and the best interests of patients always come first.

This guide highlights the challenges commonly faced by surgeon innovators and signposts sources of assistance. It is also written for those medical and clinical directors charged with providing oversight of surgical activity within their organisations.

The RCS has launched an independent commission to explore the future of surgery in the next 20 years. For further details see www.rcseng.ac.uk/standards-and-research/future-of-surgery.

2. Developing a new technique

2.1 WHAT IS A NEW TECHNIQUE?

There is no consensus on what constitutes a 'surgical innovation'. Surgical innovation tends to fall somewhere between commonly undertaken variations (or minor modifications) of procedures and surgical research. A surgeon might adapt techniques taken from two or more different procedures to deal with a particular patient situation, without feeling that they have introduced a truly innovative procedure. Surgical research, on the other hand, might develop innovations that need much further research and evaluation before they are suitable to be introduced into patient care.

This guide uses the definition for surgical innovation offered by the IDEAL (idea, development, exploration, assessment, long-term follow-up, improving the quality of research in surgery) framework: 'surgical innovations comprise new techniques, modified strategies, or innovative instruments'.[5] Under this definition, new techniques are one type of surgical innovation, although it remains unclear how and when a variation is distinguished from an innovation.

Researchers at Macquarie University in Australia distinguish between two types of innovation: those that involve new techniques and those that involve a new device (see Appendix 1). Each of these may be new in three different ways. They may be altogether new, new to an anatomical location or new to a certain patient group.[6] This distinction does not include considerations such as 'new to the hospital' or 'new in the hands of the surgeon', which can equally apply to long-established and new procedures and are features of introduction rather than innovation.

In practice, new techniques are often introduced in conjunction with new devices. The Macquarie researchers identified three key questions that seek to clarify the degree of change and the potential risks:

1. Are the likely outcomes of the change unknown or have they been described previously?
2. Are the outcomes likely to be publishable or suitable for uptake more generally?
3. Should special preparation be undertaken by the surgeon and/or the surgical team?

Designed to be used alongside these questions is the Macquarie Surgical Innovation Identification Tool (Appendix 2). The tool is a checklist designed as a practical tool for hospitals to identify planned surgical innovations.[7] It asks whether the techniques, instruments or devices have been used before, either in the hospital or by the surgeon. Hospitals may want to provide the same level of support for the local introduction of established techniques or technologies as they do for truly innovative procedures.

2.2 WHAT TO CONSIDER WHEN DEVELOPING A NEW TECHNIQUE

Surgeons working in the NHS are encouraged to innovate.[8] Technological change has been identified as the most important determinant of improvements in health care and hospital productivity.[9] These benefits are only likely to be realised if surgical innovation happens in a structured way that has evaluation at its centre.

The Medical Research Council (MRC) recommends that those planning to develop a complex intervention should ask themselves the following questions:[10]

1. Are you clear about what you are trying to do? What outcome are you aiming for and how will you bring about change?
2. Does your intervention have a coherent theoretical basis? Have you used this theory systematically to develop the intervention?
3. Can you describe the intervention fully, so that it can be implemented properly for the purposes of your evaluation and replicated by others?
4. Does the existing evidence (ideally collated in a systematic review) suggest that it is likely to be effective or cost effective?
5. Can it be implemented in a research setting and is it likely to be widely implementable if the results are favourable?

If there is uncertainty about the answers to these questions, further development work is needed before an evaluation can begin. The MRC further distinguishes between five stages of investigation in the evaluation of a complex intervention, with objectives to be met at each stage before moving to the next (see Appendix 3).

The IDEAL framework describes the stages of innovation in surgery as: idea, development, exploration, assessment and long-term study. Proponents of this framework argue that surgery has a specific combination of attributes that create additional problems.[11] These attributes add complexity

because they include dependence of the outcome on the operator, the surgical team, the setting and other quality variations. The IDEAL framework therefore takes the MRC recommendations and tailors them to the surgical setting to avoid hindering surgical innovation with overly-demanding requirements. There are still five stages of progression, but at the heart of the IDEAL framework is a conviction that surgical innovation and evaluation should evolve together in an ordered manner from concept, through exploration, to validation by randomised trials. The different stages of the IDEAL framework are shown in Table 1.

Traditionally, research into surgery and new surgical techniques has been poorly funded in comparison with research into basic medical sciences and new medicines. The Royal College of Surgeons of England (RCS) has worked with the National Institute of Health Research and others, to establish a national network of surgical trial centres to develop and expand clinical trials in surgery, raise surgical standards and transform the quality of patient care across a number of conditions.[12] This initiative has significantly increased funding for clinical research in surgery, with many more patients being entered into well-designed and properly supervised clinical trials across the UK.

2.3 THE COST IMPLICATIONS OF DEVELOPING A NEW TECHNIQUE

Surgeon innovators should assess the cost implications of a new procedure before embarking upon its development. The assessment will often require an understanding of the costs before data are available on safety and efficacy or long-term outcomes. This understanding is necessary to establish whether the investment costs in equipment and/or personnel needed to support introduction of the procedure are justified and to understand the financial implications of rolling out the procedure within the organisation.

New techniques often rely on new technology, which is almost always more expensive than traditional techniques.[13] Other costs include the operating time (new procedures often take longer, at least while the surgeon is getting familiar with the technique) and the costs associated with training in the new technique for the surgeon or the surgical team.[14] These costs will influence which and how many patients may be able to receive the new procedure.

Not all surgical innovations have to be costly. The Royal Academy of Engineering highlights the potential of 'frugal innovation' in medical technologies. Re-engineering devices, such as adapting a mobile phone to incorporate diagnostic sensors, is one example.[15] Some innovations can reduce costs if resources are fully released from displacing older technologies and, as innovations mature, their cost effectiveness often improves.[9]

Surgeons who innovate need to be prepared to pitch for investment to support the development of their innovation, as do surgeons who wish to introduce more costly new technologies to their hospital in the face of organisational financial constraint. This is an area where surgeons may need to gain specific skills to win support within their organisation or externally with financiers, such as how to create a credible business plan.

Securing early-stage investment can be a challenge. Key factors to be taken into account are:

- a well-designed early stage surgical innovation or technology
- clear and transparent evidence of clinical benefit
- adequate scientific evaluation and peer review
- well-designed surgical databases, registries and reporting systems.

Good Surgical Practice expects surgeons to be open and transparent about the sources of funding for the development of any new technique.[2]

2.4 REGULATORY REQUIREMENTS

There are few regulatory requirements for surgery in terms of introducing innovative surgical techniques. The General Medical Council reminds doctors to take account of the clinical guidelines published by the National Institute for Health and Care Excellence (NICE) and equivalent bodies, in addition to the medical royal colleges.[16] *Good Surgical Practice* also advises surgeons to contact the interventional procedures programme at NICE to learn the status of the procedure and/or register it and liaise with the relevant surgical specialty association.[2] Surgeons are reminded to ensure that any new device complies with European standards and is certified by the competent body, such as the Medicines and Healthcare Products Regulatory Agency in the UK.

The NHS is legally obliged to fund and resource medicines and treatments recommended by NICE's technology appraisals (see Appendix 4) and the NHS Constitution gives patients the right to drugs and treatments that have been recommended by NICE for use in the NHS, if their doctor believes that they are clinically appropriate.[17] In practice, many surgical interventions are not subject to NICE guidance as the evidence available is often sparse.[18] Guidance on surgical interventions tends to be more advisory in nature, offering advice on safety and efficacy rather than cost effectiveness.

NICE states that where it has not published interventional procedures guidance for the procedure, a surgeon's organisation can still approve it as long as the clinician has appropriate training and experience, patients are made aware and give their consent and arrangements are made for data collection and audit (all addressed in other sections of this guidance).

2.5 WHERE TO START?

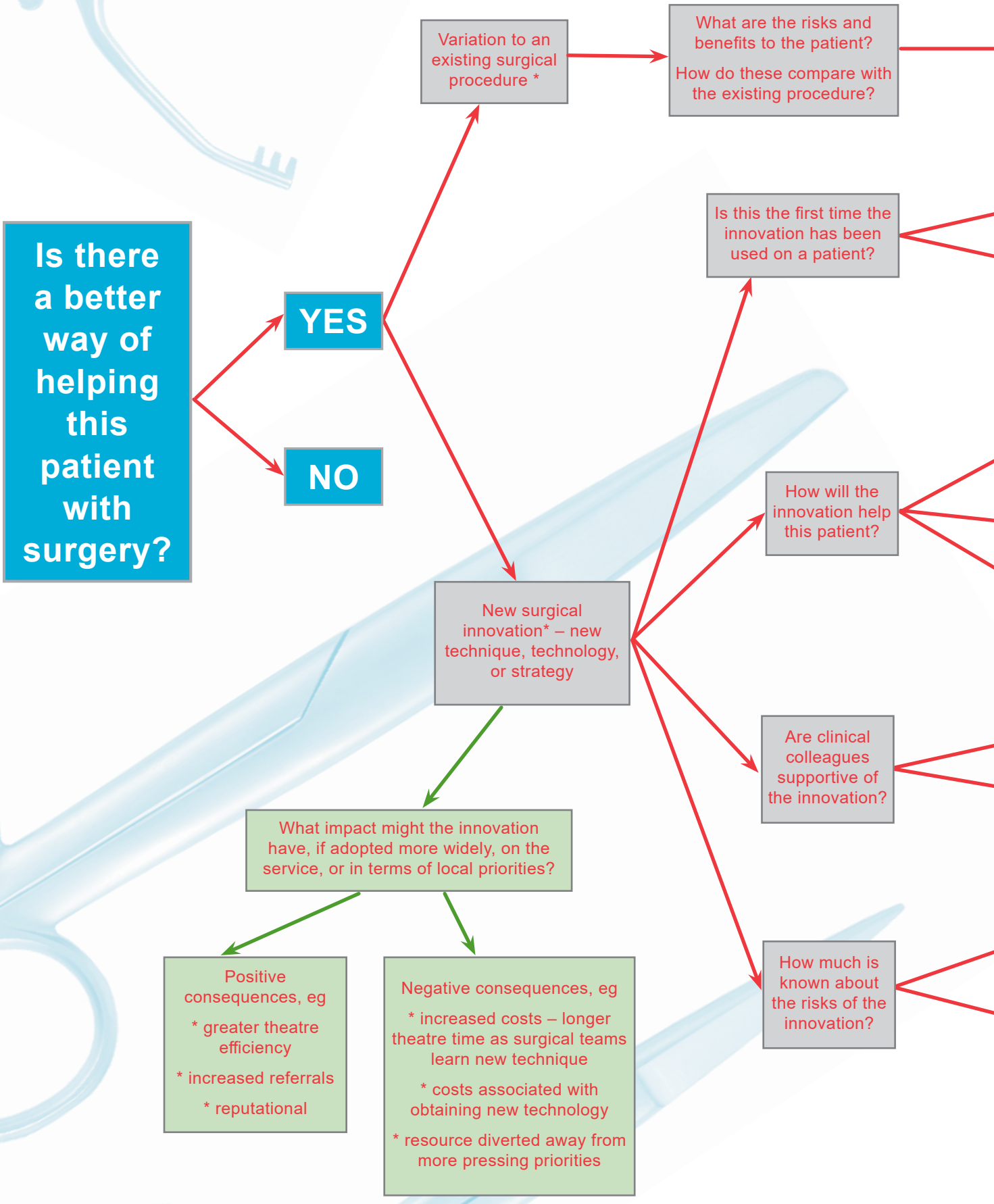
The decision tree shown in Figure 1 seeks to help surgeons at the stage of inception of an idea to innovate. The emphasis throughout this decision tree is on involving and discussing the innovation with other surgeons and agreeing appropriate mechanisms for oversight and reporting of outcomes.

Table 1: Stages of surgical innovation (source: McCulloch *et al*. *Lancet* 2009; **374**: 1,105–1,112)

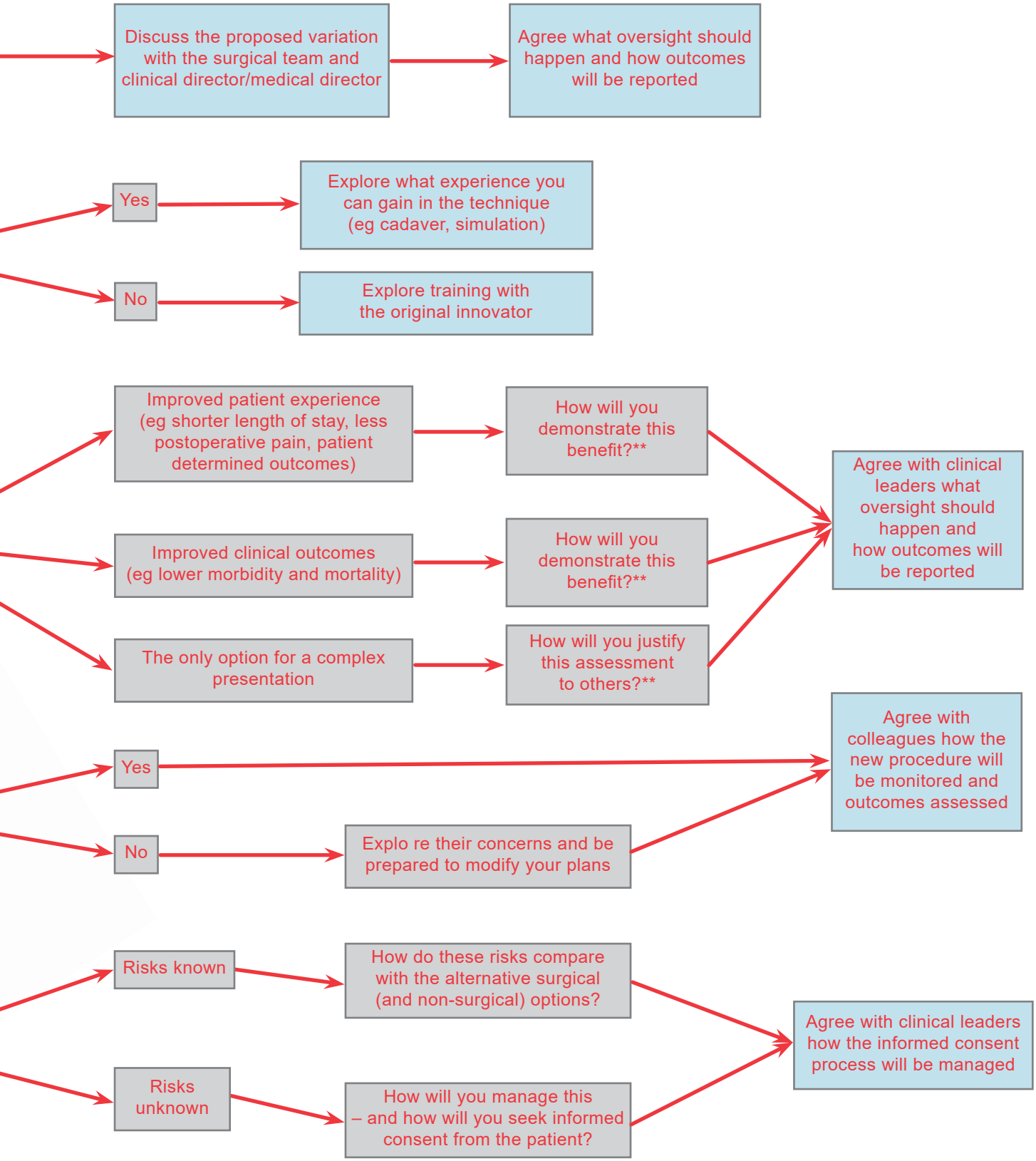
	1a Proof of concept	2a Development	2b Learning	3 Assessment	4 Long-term study
Purpose	Proof of concept	Development	Learning	Assessment	Surveillance
Number and types of patients	Very few; innovators	Few; selected	Many; may expand to mixed; broadening indication	Many; expanded indications (well defined)	All eligible
Number and types of surgeons	Very few; innovators	Few; innovators and some early adopters	Many; innovators, early adopters, early majority	Many; early majority	All eligible
Output	Description	Description	Measurement, comparison	Comparison; complete information for non-RCT participants	Description; audit, regional variation; quality assurance; risk adjustment
Intervention	Evolving; procedure inception	Evolving; procedure development	Evolving; procedure refinement; community learning	Stable	Stable
Method	Structured case reports	Prospective development studies	Research database; explanatory or feasibility RCT (efficacy trial); disease based (diagnostic)	RCT with or without additions/ modifications; alternative designs	Registry; routine database (eg SCOAP, STS, NSQIP); rare-case reports
Outcomes	Proof of concept; technical achievement; disasters; dramatic successes	Mainly safety; technical and procedural success	Safety; clinical outcomes (specific and graded); short-term outcomes; patient-centred (reported) outcomes; feasibility outcomes	Clinical outcomes (specific and graded); middle- and long-term outcomes; patient-centred (reported) outcomes; cost effectiveness	Rare events; long-term outcomes; quality assurance
Ethical approval	Sometimes	Yes	Yes	Yes	No
Examples	NOTES video[6]	Tissue engineered vessels[7]	Italian D2 gastrectomy study[8]	Swedish obesity study[9]	UK national adult cardiac surgical database[10]

NSQIP, National Surgical Quality Improvement Programme; NOTES, natural orifice translumenal endoscopic surgery; RCT, randomised controlled trial; SCOAP, Surgical Clinical Outcomes Assessment Programme; STS, Society of Thoracic Surgeons.

Figure 1 Decision tree for surgeons at the



stage of inception of an idea to innovate



* The Macquarie Surgical Innovation tool is designed to help identify new procedures

** The IDEAL framework supports the assessment and reporting of new surgical innovations

3 Demonstrating safety and effectiveness

The risks faced by patients from innovative new techniques can be substantial and surgeon innovators and their organisations cannot understand these risks without conducting an evaluation of the innovation in terms of clinical outcomes and other effects. Gathering an evidence base should not only help to establish safety and effectiveness but may also change the way in which the surgical innovation is undertaken and widen the pool of patients who could benefit.

The RCS has identified the enablers necessary to create a virtuous circle, which in turn leads to greater uptake and the development of stronger evidence, as set out in Figure 2.

3.1 CHALLENGES IN SURGICAL RESEARCH

Historically, surgical innovations have often been adopted without adequate supporting evidence of efficacy and safety. The RCS has found that undertaking surgical research in the area of new surgical techniques and technologies has been 'somewhat limited in extent, scope and ambition when compared with other forms of research'.[18] While randomised controlled trials (RCTs) are considered the gold standard for establishing safety and efficacy of an intervention, high quality RCTs have often proved difficult to undertake in surgery. Challenges include a perceived lack of equipoise, problems with double-blinded design, 'surgical exceptionalism' and the unique nature of surgery and the difficulties of gaining statistical significance from often small patient populations.[19] Other factors that may make surgical trials more difficult include a lesser tolerance (than physicians) of uncertainty about the effectiveness of alternative treatments and issues with timing the randomisation close to the intervention.[20]

The following questions may assist surgeon-innovators during the design of surgical RCTs, as suggested by Hirst *et al*:[21]

1. Does the RCT involved a surgical intervention?
2. What is/are the surgical intervention(s) under evaluation?
3. What is/are the co-interventions accompanying the surgical intervention?
4. How will the intervention(s) be standardised in the RCT?
5. How will delivery of the intervention(s) be monitored?
6. Who will deliver the intervention(s)?
7. Where will the intervention(s) be delivered?

It is not in keeping with modern surgical practice to adopt surgical innovations without evidence of safety and effectiveness, and there is reason for optimism that the challenges associated with providing a robust evidence-base are being overcome. Pinkney and Morton report that:[22]

- Clinical research activity in surgery in the UK is at a record high, supported by engagement between the National Institute of Health Research, RCS and major charitable funders to develop multicentre clinical trials.
- There are now national research leads in all major surgical specialties and dedicated surgical clinical trials units have been created nationally.
- Trainee-led collaboratives exist across the country in both general and subspecialist branches of surgery.
- Multi-arm, multi-stage trials are starting to emerge in surgery, which allow for multiple similar interventions to be evaluated in tandem.

3.2 THE IDEAL FRAMEWORK

The IDEAL framework provides a pathway for the assessment and reporting of surgical innovations. It is based on the assumption that surgical innovation and evaluation can and should evolve together in an ordered manner from concept through exploration to validation by randomised trials.[5] It places emphasis on improving transparency in reporting surgical research, including mandatory registration of procedures thought to be first in-man and confidential reporting of adverse outcomes and registries for surveillance.[23]

Two summary tables have been developed by the IDEAL Collaboration to help surgeon innovators identify the stage their own surgical research sits and to help guide the design of the study (Appendix V).

Figure 2 The cycle of innovation

4. Clinical governance and oversight

The interests of patients must always be paramount in introducing new techniques. *Good Surgical Practice* is clear that any new clinical interventions or surgical techniques (including equipment) that deviate significantly from established practice and are not part of an NHS local ethics committee research programme, must be underpinned by rigorous clinical governance processes.[2]

Surgeons must:

- discuss the technique with colleagues who have relevant specialist experience
- seek formal approval from their hospital's medical director
- follow local protocols for obtaining approval by the local ethics committee or the local clinical governance committee.

Local arrangements should include provision of evidence that the new technique is safe and that all clinical staff who plan to use the new technique will undertake relevant training, mentorship and assessment.[2] Deciding what constitutes relevant training may not be straightforward – see Section 5. Healthcare providers should record the use of new procedures to support the monitoring of implementation and the impact they have.[12]

This guidance is echoed by NICE, which expects provider organisations to have a process in place for introducing a new procedure and for healthcare professionals planning to perform a new interventional procedure in the NHS to obtain approval using the appropriate governance structures of the organisation in which the procedure will be performed.[24] The medical director (or nominated deputy) should ensure that any new procedure falling within scope of the interventional procedures programme at NICE (see Appendix 4) is notified to NICE, unless the procedure is being used solely within a protocol approved by a research ethics committee. The use of a new surgical device or a clinical study using new devices also needs to be reported to the Medicines and Healthcare Products Regulatory Agency.

It should go without saying that any failure by a surgeon to comply with the above governance requirements in their local hospital when introducing new techniques or technologies demonstrates a lack of probity, subject to appropriate disciplinary procedures.

4.1 INNOVATIONS COMMITTEES

Often, ethics committees within healthcare organisations will provide oversight to surgical innovation. Where possible, it is recommended that dedicated surgical innovation committees are established, to carefully evaluate proposed surgical innovations.

The Macquarie Surgical Innovation Identification Tool can help committees identify planned surgical innovations (see Appendix 2), as well as guiding surgeons (and patients) through the process of informed consent, managing conflicts of interest and evaluating the outcomes. The committee should consider what type of training is needed and any other preparatory work needed to ensure the safety of the technique. Another task for the committee is to consider patients' rights of access to new techniques.

The composition of an oversight committee will vary according to the local context and the nature of the surgical innovation. It should at least include surgeons with an understanding of the proposed new technique, plus others able to represent the interests of patients. The committee will need to balance the need for caution when introducing innovations against the potential to improve patient outcomes.

Certain new techniques may benefit from oversight provided at regional or national level. This oversight is needed where the necessary specialist expertise is not available locally or where the innovation is being performed in several centres, making a centralised and standardised approach useful. National oversight can also provide monitoring of long-term outcomes.

Key questions an oversight committee should ask:

- Why is this new technique being proposed?
- Which patient groups could benefit?
- Has the innovation been performed elsewhere? If so, what is known about this?
- What is known of the risks associated with the new technique?
- What training/mentoring will the surgeon and/or surgical team have to make the technique as safe as possible?
- How will patients be informed before undergoing this new technique? What information will be included on the consent form they are asked to sign?
- How are the outcomes to be monitored and evaluated? Should these outcomes be shared with regional or national committees or registries?
- What ethical questions do we need to consider in deciding on the introduction of this new technique?

4.2 CLINICAL AUDIT

Clinical audit of new techniques should be built into the processes for introducing and overseeing surgical innovations. Clinical audit can have an important role in research by, for example:

- evaluating the efficacy of different techniques
- analysing variations in care
- facilitating further research into patterns of care.[18]

Clinical audits can also support improvements in outcomes by assessing variations in clinical practice, processes, patient outcomes, productivity and costs. Where more than one hospital is involved in the introduction of a new technique or device, it is important to ensure that the results of individual audits are collated in order to provide the most robust information possible through strength of numbers. Ideally, participating centres should be submitting data to a national audit, whether run as part of the evaluation process or sponsored by the relevant surgical specialty association. The outcomes of such audits should be transparent and readily available to both the participants and to those who might seek to adopt the innovation in their own hospital. Surgeons should be wary of commercial companies that restrict dissemination of preliminary data on novel devices under the cloak of commercial sensitivity, as such data may also conceal adverse outcomes.

In the case of surgical implants such as stents or joint prostheses, the RCS position is that all implants should be recorded on a national registry. While this requirement is not universally applied at present, it should certainly be mandatory for newly developed implants.

5 Training in new techniques

New techniques often require the development of new skills for which training is necessary. Where a technique is being undertaken for the first time, training may involve practising the technique on a cadaver or in a simulation lab. When the technique has been performed previously by others, training might comprise:

- hands-on experience of the procedure under supervision
- scrubbing in to observe another surgeon operate
- undertaking a fellowship
- participating in a formal training programme
- performing the procedure under mentorship from a trained surgeon.

The surgeon should have a surgical mentor experienced in the technique to allow oversight for a defined number of initial procedures, sufficient to ensure proficiency before operating independently. The mentor must be approved by the hospital authorities to intervene during the procedure, if necessary.

The amount of training required will depend on the surgeon's experience and expertise. The underlying principle is that training must be delivered on the right scale and at the right pace to assure the quality, safety and efficiency of a new technique. The quality of delivery and the safety of many techniques requires the surgeon to undertake appropriate volumes of procedures.[12]

One of the factors that influences whether an innovation spreads is the establishment of training programmes to ensure that qualified surgeons are able to undertake new techniques to a high standard of quality and safety.[18] Training has played a critical role in ensuring the roll-out of techniques such as endovascular aneurysm repair, laparoscopic bowel surgery and sentinel node biopsy, for the benefit and safety of patients. Some practical solutions to support training in new techniques include treating national training programmes as part of the research implementation process and allocating a dedicated training uplift to the tariff for new techniques for an interim period.

A surgeon's experience and outcomes with the new technique should be shared across the surgical community, including negative outcomes.

A system of accreditation for performing a novel procedure is one approach to ensuring that surgeons are properly trained in a new surgical technique.[19] Suppliers of new surgical devices may insist on appropriate training and mentorship before they will supply a surgeon with the new technology, a requirement often driven by their legal and financial liability if things go wrong.

5.1 THE LEARNING CURVE

The 'learning curve' refers to the increased risks to patients during the time that a surgeon or surgical team gain competency in a new procedure.[25] It applies where the original innovator is gaining experience in the new technique but also where the technique is performed in different hospitals by other surgeons.

One of the problems associated with the learning curve is that it may not be apparent to the surgeon or surgical team that they are in the steepest arc of the curve until after they have moved beyond it. This creates an ethical challenge as 'it becomes very difficult to disclose the risks of the learning curve to patients when those risks may be unknown'.[13] Informing the patient of a surgeon's experience with an innovative procedure should be a core element of the informed consent process. Training, whether hands-on, simulated or apprenticeship, may not only improve the surgeon's confidence in performing the new technique but also accelerate the learning curve.

5.2 TRAINING IN ENTREPRENEURSHIP

Surgeons often demonstrate innovative tendencies, yet education on entrepreneurship tends not to be a component of surgical training programmes, which naturally concentrate on preparing surgeons for clinical roles.

For the next generation of surgeons, the NHS England Clinical Entrepreneur Training Programme offers opportunities for junior doctors and other health professionals to develop their entrepreneurial skills during their clinical training period. The programme offers time for entrepreneurial activity, mentoring, coaching, entrepreneurial placements and internships, and it also facilitates relationships with commercial organisations to develop business and procurement acumen (NHS England).[26]

6 Seeking patient consent

Gaining the patient's consent for a surgical procedure can be a challenging process at the best of times, relying as it does on the surgeon tailoring the discussion to the individual patient, to ensure that they are aware of any risks that are material to them and any available alternatives.[27] These difficulties are amplified when it comes to a new technique, particularly where there may be only a limited understanding of the potential risks and benefits at the early stages of innovation. Key challenges include a limited collective experience with the new approach and a lack of information on long-term results.[28]

Surgeons have a duty to have full and frank discussions with patients regarding proposed surgical procedures. But how do we do this when the surgeon is learning the new technique and the extent of the risks are unknown?

6.1 WHAT TO TELL PATIENTS

The College's guide *Consent: Supported Decision-Making* sets out the information that surgeons should provide to patients as part of the consent process.[27] This includes the purpose and expected benefit of the treatment, what it involves, the likelihood of success, the material risks of the procedure and the alternative options. If the recommended treatment is not in keeping with current guidelines (such as NICE or the Scottish Intercollegiate Guidelines Network), the surgeon must explain the reason for not following standard guidelines. Surgeons should also ensure that options are presented 'side by side' and that the relative risks and benefits of the different options for treatment are discussed.[27]

It is essential that patients understand that a technique is new and they must be given this information during the consent process. A systematic review of studies looking at consent and innovations by Broekman *et al* found that the information that should be provided to patients should include:[19]

- the innovative nature of the procedure
- the surgeon's learning curve (see Section 5.1 for more on this) and his or her experience with the procedure
- the risks and benefits of the procedure, including possible unforeseeable or unknown risks or outcomes due to the 'experimental and unvalidated nature of the procedure'
- the evidence (or lack thereof)
- alternatives to the innovative procedure.

This review found that a majority of patients consider the technical details of the procedure to be essential information informing their decision to undergo an innovative operation, even though only 20% of the surgeons thought so.

Char *et al* explored what information patients and surgeons consider essential to disclose before an innovative surgical procedure.[29] They found that, compared with surgeons, patients placed greater importance on nearly all types of information, particularly volumes and outcomes. For three techniques, around 80% of patients indicated that they could not decide on surgery without being told whether it would be the surgeon's first time doing the procedure. When considering innovative robotic surgery, a clear majority of both patients and surgeons agreed that it was essential to disclose the procedure's novel nature, potential unknown risks and benefits and whether it would be the surgeon's first time performing the procedure. When accurate volumes and outcome data are available, surgeons should also discuss these with patients.

Following the Montgomery ruling on consent, what to tell the patient will also depend on assessing what impact the new technology might have on them, on the basis of what a reasonable person in the patient's position would attach significance to when deciding consent. The burden of disclosure rests with the surgeon even though the surgeon rarely owns the new technology, because it is the surgeon who decides whether to offer this new technology to the patient.

The discussion about consent should include details of alternatives to the innovative procedure, which will generally be the traditional procedure or the choice of no procedure.

It is the surgeon's responsibility to ensure that the patient understands the information they are given well enough to allow them to objectively weigh the risks and benefits of a new procedure. Suggestions to support this process include the presence of a third-party communicator, the use of a patient advocate or the use of a multimedia presentation to explain the procedure to the patient.[19]

6.2 OPTIMISM BIAS

Both surgeon and patient bring inherent bias to discussions about consent, which may be increased when a new technique is being offered. There is often a tendency for patients to believe that what is new is improved and surgeons may be overly optimistic about an innovative procedure. The informed consent process is at risk of excluding a balanced discussion of the potential and unknown risks of the procedure, which fade into the background while both surgeon and patient focus on the potential benefits.

One way of tempering a patient's optimism bias is to impose a mandatory 'cooling off' period after the initial discussion and to require a second visit at which informed consent is formally obtained. The involvement of a patient advocate or other third party could also help to dampen any optimism bias and ensure that the patient's interests are properly served.

The surgeon's optimism bias should be robustly explored in the multidisciplinary team meeting setting, where consensus from colleagues should be obtained to offer the new procedure on a patient by patient basis.

7 Managing conflicts of interest

Surgeons must be open about any conflict of interest and provider organisations should make sure that they are aware of any conflicts arising for both the surgeon and for the organisation.

Potential conflict of interest can arise for the surgeon from their relationship with the companies that manufacture the innovative technology, particularly where this leads to significant financial or reputational gain. Surgeons should disclose to their organisations and to patients any ties with companies that manufacture technology used as part of a new technique.

Conflicts may also arise where the patient has been referred to or has specifically asked to see a particular surgeon because they are known to undertake an innovative procedure, placing pressure on the surgeon to undertake the procedure even though an alternative might be more suitable for that particular patient. There may be financial incentives for both the surgeon and for healthcare providers to offer an innovative procedure, in terms of the fees paid. In these situations, conflicts can arise for both the surgeon and the organisation.

Oversight mechanisms for the surgical innovation (see Section 4) must be aware of and exclude any temptation to encourage patients to undergo a new technique over an existing procedure or any over-statement of its benefits. Miller *et al* warn that the natural desire to obtain positive outcomes when implementing an innovation that is believed to be beneficial may lead to bias in patient management decisions and data collection and reporting.[14] The authors argue: 'The surgeon-innovator must preserve the best interests of the patient, rather than his or her own self-interest, and uphold ethical standards when making decisions about the application and dissemination of a new procedure or technique.'

8 Translating a new technique into wider practice

The barriers to implementation of surgical innovation are various. One of the main challenges lies in establishing the evidence-base and difficulties in getting funding to produce the evidence.[18] Other common issues include:

- the need for new skills and training
- the need for new equipment, working arrangements or configuration of services, requiring capital investment as well as service redesign
- clinical and patient demand, which will require the provision of patient information on benefits and risks.[12]

More complex types of innovations that require engagement of teams from across different organisations, such as new models of care or pathways, have been found to make slower progress in scaling.[30] Other barriers are incompatibility of information technology systems, difficulties in navigating commissioning structures and identifying patients who can benefit from the innovation.

The RCS has identified six common factors that help to overcome these issues and encourage the spread of innovation:[12]

1. Early identification of the potential benefits of an innovation.
2. Leadership to champion and advocate its adoption.
3. Establishing the infrastructure to enable its use.
4. Defining what should be implemented and how its impact will be measured.
5. Developing levers and incentives to encourage appropriate adoption.
6. Providing information to support clinical adoption and patient choice.

Other factors that are key in influencing the spread of an innovation include:

- the availability of national guidance detailing appropriate use
- the establishment of training programmes to ensure that qualified surgeons are able to undertake the new techniques to a high standard of quality and safety
- the availability of readily accessible information on trials and studies in progress.[18]

8.1 SURGICAL LEADERSHIP

Surgeon preference is crucial in determining the adoption of a new surgical innovation. If surgeons are unconvinced of the benefits or prefer their familiarity with established techniques, they are unlikely to adopt the innovation into their own practice.

The perceived lack of robust evidence was an initial barrier to the timely adoption of sentinel lymph node biopsy in the UK. Clinicians who advocated change often met with resistance from surgical colleagues and managers who were reluctant to support a new technique that was being practised on a relatively small scale. The value of surgical leadership was demonstrated by the important role played by clinical champions in convincing the Department of Health to implement a national training programme and in driving participation in training across England. Strong clinical leadership was also key in pioneering the enhanced recovery pathway, in securing action and funding to provide training in laparoscopic colorectal surgery via the national Lapco programme and in pushing the implementation of total mesorectal excision.[12]

A key source of help for surgeon innovators looking to drive wider adoption of a new technique is the relevant surgical specialty association. The RCS has recommended that surgical specialty associations develop good practice guidance to support clinical teams to work together at a local level to deliver an effective business case and drive organisational change.[12]

Strategic clinical networks are another important resource. These networks support commissioners to improve services for particular conditions (eg cancer or cardiovascular conditions).[31] Among other things, these networks seek to encourage innovation in service provision and the RCS has

called for them to be required to review and advise on the roll-out of innovative surgical procedures at a regional level.[12]

8.2 INCENTIVES TO SUPPORT 'SCALING UP'

For those innovations with demonstrable value there are financial incentives to encourage their wider adoption. These include:

- **The NHS Innovation and Technology Payment** This payment builds on the Innovation and Technology Tariff (ITT) and aims to support the NHS in adopting innovation by removing financial or procurement barriers.[32] There is a competitive process to identify innovations and technologies that will offer the greatest quality and efficiency benefits with wider adoption. Successful innovations include 'Plus Sutures', a new type of surgical suture that reduces the rate of surgical site infection through the use of antimicrobial suture packs, and also 'Endocuff Vision', a new type of bowel scope that improves colorectal examination for patients undergoing bowel cancer tests.
- **The NHS Innovation Challenge Prize** may help individual surgeons gain support for an innovation. The prizes seek to encourage, recognise and reward front-line innovation and drive adoption of these innovations across the NHS.[33]
- **The Innovation Scorecard** seeks to reduce variation and strengthen compliance of the uptake of NICE Technology Appraisals, including those for surgical procedures, which the NHS is legally obliged to fund and resource. It does this by enabling benchmarking and increasing transparency to patients and the public. The scorecard is produced quarterly by the Health and Social Care Information Centre.[34]

Other levers to encourage appropriate uptake of surgical innovations, include:

- providing written information to patients to help them make an informed decision about the most appropriate treatment option, including newer technologies
- disseminating information on new techniques to clinicians
- incentivising the uptake of new technologies through schemes such as commissioning for quality and innovation
- creating best practice tariffs where a clinically superior intervention is available that may not otherwise be used (and may require upfront investment)
- ensuring that appropriate use of interventions is considered as part of the revalidation process for surgeons.

The decommissioning of practices that have no added value, or have been replaced by something new or better, is just as important as the implementation of innovations that do have value. This process is sometimes referred to as 'reverse innovation'. The never-events regimen may in future be extended to actively drive 'old practice' out of the system, especially where it is found to be unsafe.[8]

9 Measuring long-term outcomes

Once a surgical innovation is introduced into routine practice, there need to be mechanisms in place to monitor the long-term impact. The MRC recommends that monitoring should be undertaken to detect adverse events or long-term outcomes that could not be observed directly in the original evaluation or to assess whether the effects observed in earlier evaluation are replicated in routine practice.[35]

The full risks of a new technique may not be known at the time of implementation. Miller *et al* highlight the example of laparoscopic cholecystectomy, after it was widely adopted in the United States.[14] It was only after a registry of operative complications was published that it was understood that the low incidence of common bile duct injury in open cholecystectomy was increased 15-fold in laparoscopic cholecystectomy. It can take many years' worth of outcomes data to discover the true incidence of complications. It is therefore important to demonstrate the long-term outcomes of a surgical innovation and how they compare with the procedure that would otherwise have been performed.

Other risks that show themselves over time may be related to new equipment or technology that accompany the new technique, such as the risk of burns from fires caused by fibreoptic cables. There are also the risks associated with the learning curve (see Section 5.1) as dissemination of the innovation emerges and more surgeons begin to gain experience in performing the new technique.

The mechanisms for providing oversight when a surgical innovation is first introduced should also scrutinise the longer-term impact of the innovation at 12 months, 24 months, 5 years and beyond. Innovations committees should ensure that an innovation that initially shows promise and is beneficial in the first few years of implementation, continues to demonstrate value and that any unintended consequences are fully understood.

In some cases, the innovative procedure may demonstrate no more than equivalence with the traditional procedure that would otherwise have been performed. Mayer and Darzi observe that trials that show equivalence for an innovation are sometimes interpreted as supporting a return to existing practice, including re-diverting the training of a generation of surgeons who might have followed the innovation's evolution.[36] However, equivalence and non-inferiority could also be seen as positive, showing that the innovation has preserved the intended and well-established purpose of surgical intervention, such as good oncological outcomes balanced against acceptable functional adverse effects.

9.1 DATABASES AND REGISTRIES

Surgeons should keep an accurate and accessible record of all their surgical activity and submit activity data to national audits, registries and databases relevant to their practice. Surgeons should also present the results at appraisal for review against the national benchmark. Benchmarking data are unlikely to be available for a surgical innovation until its dissemination has had sufficient reach and depending on the numbers of patients eligible for the new technique. Work being undertaken by the surgical specialties to identify 'indicator' operations that would give a sound judgement of skill,[36] may assist in providing comparators against which the equivalence of new techniques can be measured.

Good Surgical Practice expects surgeons to contribute to the evaluation of a new procedure by auditing outcomes and reviewing progress with a peer group, and by complying with guidelines by NICE or the Scottish Intercollegiate Guidelines Network.[2]

IDEAL recommends the widespread use of prospective databases and registries, and for reports of new techniques to be registered as a professional duty, anonymously if necessary when outcomes are adverse. Stage 4 of the IDEAL framework focuses upon long-term study, to assess innovations for 'rare and long-term outcomes, and for variations in outcome', which may reveal differences in the quality of surgery or aftercare.[11] The IDEAL proponents argue that only key outcomes and relevant information should be obtained to encourage complete data entry. Depending on the frequency of the procedure, it may be possible to investigate outcome variations among subgroups.

9.2 PATIENT-REPORTED OUTCOMES

Since surgical innovation is often motivated by a desire to improve patient care, it is right that measurement of the impact of the innovation reflects

patient-defined benefits in addition to clinical analysis. In some situations, patient-defined outcomes are more important than clinical outcomes (for example, palliative surgery, and functional outcomes after joint replacement surgery).

The RCS has led the way in piloting a system of patient-reported outcome measures and, since 2008, these measures have been gathered for patients undergoing hip, joint, hernia and varicose vein operations.[37]

The RCS is also working to improve systems of measuring outcomes, to ensure greater public transparency and accountability, enable surgeons to have a better basis for judging and improving their practice, and to offer improved patient choice, service improvement and quality assurance of operations.[37] The intention is to have a system for outcome measurement that will combine existing statistics and audits, new clinical registries and patient attitudes to the results of their operation. These developments should be of value in measuring outcomes for surgical innovations, as well as for established procedures.

10 Summary

The introduction of new technology or new techniques in surgery has no place for the maverick surgeon who proceeds without appropriate peer review or training. All surgeons have a duty to consider carefully whether or not the innovation has a real patient benefit at an affordable cost, both in terms of morbidity and mortality and of cost effectiveness compared with established procedures. Such considerations should include widespread dissemination and debate of preliminary studies among peer groups to establish a consensus for the adoption of the innovation. Innovations should be the subject of clinical trials comparing them with established procedures to help inform these discussions and debate. Surgeons must be wary of the risks of optimism bias and conflict of interest when explaining the procedure and consenting their patients. No surgeon should attempt a novel procedure without appropriate institutional support, preliminary training and mentorship. Outcomes should be carefully monitored and audited, both locally and nationally, with open and transparent dissemination of results. It is also important to ensure that long-term outcomes are monitored through the use of databases and registries, to ensure that any innovation not only improves patient outcomes but is also durable when compared with established procedures.

Appendix 1:A definition of innovative surgery

An innovative surgical procedure is any procedure that meets one or more of the following criteria:

1. **Innovative technique**: the technique used is new or differs from the standard technique in one or more of the following ways:
   - 1a altogether new (eg pioneering transplant surgery: first face transplant)
   - 1b new to anatomical location (eg use of established anastomotic techniques in new locations)[a]
   - 1c new to patient group eg expansion of indications to groups whose surgical outcomes may be different, such as children.

Examples of innovative techniques: different incision position or size; combination of two procedures such as mastectomy and reconstruction; extension of microsurgical techniques.

Or

2. **Innovative device**: the tools or devices used are new, or the use differs from standard use in one of the following ways described:
   - 2a altogether new (eg first use of laparoscope)
   - 2b new to anatomical location (eg application of laparoscope to new organ/cavity)[a]
   - 2c new to patient group (eg use of device on people with comorbidities likely to influence surgical outcomes).

   Examples of innovative devices: surgical robot; new hip prosthesis; implant made from new material; use of laparoscope to perform procedure usually done without one.

[a] Excludes procedures, such as fixation of fractures, which are not standardised to a particular part of the body.

Source: Hutchinson *et al*.[6]

Appendix 2: Macquarie Surgical Innovation Identification Tool

1. The **techniques, instruments and/or devices** to be used in the operation for which the patient has consented:

   1a. Have all been used before in this **hospital**
   • yes • no

   1b. Have all been used before by this **surgeon**
   • yes • no

   A 'no' response for either of these items identified the first performance of the intervention by the surgeon or introduction of the intervention to the institution. This may flag innovation if the intervention has never been performed elsewhere. Further details should be requested regarding requirements for training and supervision, change in resources, extent of patient communication and prior experience of the intervention elsewhere.

2. The conditions under which this operation will take place do not depart from those under which such a procedure would usually occur, for example the **techniques, instruments and/or devices** to be used in the operation for which the patient has consented are routinely used:

   2a. For this indication • yes • no

   2b. In patients of this sex (where sex differences relevant) • yes • no

   2c. In patients of this age (c.f. paediatric and elderly patients) • yes • no

   2d. In patients with this comorbidity
   • N/A • yes • no

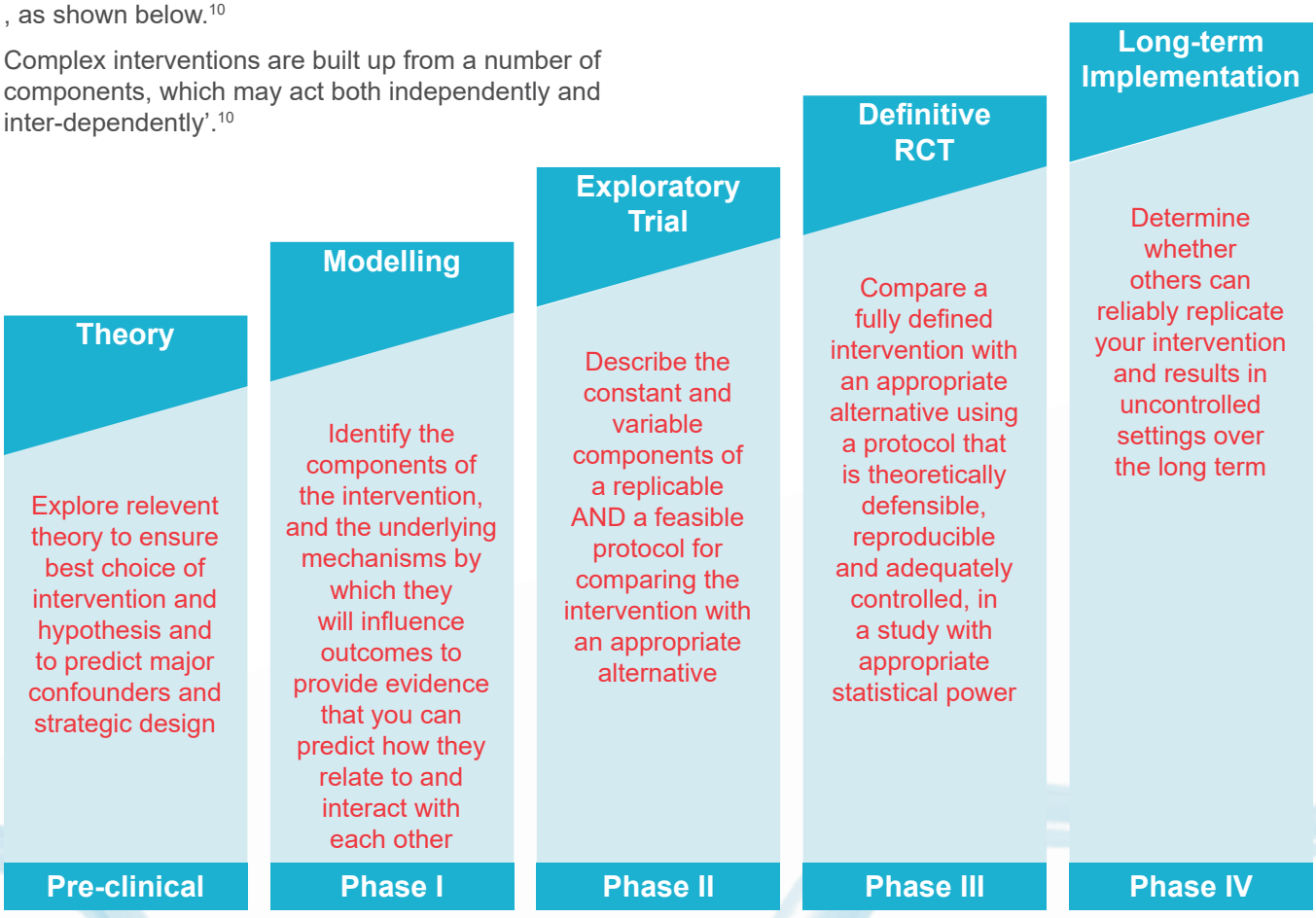
   A 'no' response for either of these items suggests that innovation may be occurring. Further details should be requested regarding the surgeon's knowledge of the likely outcomes of the procedure, whether the outcomes of the surgery are likely to be of interest to surgical peers (eg publishable) and whether special preparation are needed (such as training or special instructions to the anaesthetist or the preoperative, perioperative or postoperative teams.

Source: Blakely *et al*.[7] Also found in Hutchinson *et al*.[6]

Appendix 3: Medical Research Council stages of investigation and evaluation

The MRC distinguishes between five stages of investigation in the evaluation of a complex intervention , as shown below.[10]

Complex interventions are built up from a number of components, which may act both independently and inter-dependently'.[10]



The MRC's framework sets the objectives to be met at each stage before moving to the next. Updated MRC guidance refers to the development-evaluation-implementation process.[35]

Appendix 4: National Institute for Health and Care Excellence requirements

Interventional procedures guidance: NICE defines an interventional procedure as one that is used for diagnosis or for treatment that involves:

- making a cut or a hole to gain access to the inside of a patient's body (eg carrying out an operation on inserting a tube into a blood vessel)
- gaining access to a body cavity without cutting (eg carrying out treatment inside the stomach using an instrument inserted via the mouth)
- using electromagnetic radio (eg using a laser to treat eye problems).[38]

NICE states that where it has not published interventional procedures guidance for the procedure, a surgeon's organisation can still approve it as long as the clinician has appropriate training and experience, patients are made aware and give their consent and arrangements are made for data collection and audit (all addressed in other sections of this guidance).

Technology appraisals: NICE undertakes technology appraisals of existing and new medicines and treatments, including medical devices, diagnostic techniques and surgical procedures. The guidance is based on a review of clinical evidence (to show how well the medicine or treatment works) and economic evidence (to show how well it works in relation to how much it costs the NHS).

Appendix 5: The IDEAL framework

Defining characteristics of IDEAL framework phases

Phase 1	Phase 2a	Phase 2b	Phase 3	Phase 4
IDEA	DEVELOPMENT	EXPLORATION	ASSESSMENT	LONG-TERM MONITORING
Initial report	Tinkering (rapid iterative modification of technique and indications)	Technique now more stable	Gaining wide acceptance	Monitoring late and rare problems, changes in use
Innovation may be planned, accidental or force	Small experience from once centre	Replication by others	Considered as possible replacement for current treatment	
Focus on explanation and description	Focus on technical details and feasibility	Focus on adverse effects and potential benefits	Comparison against current best practice	
		Learning curves important		
		Definitions and quality parameters developed		

Key recommendations for research design at each IDEAL phase

IDEA	DEVELOPMENT	EXPLORATION	ASSESSMENT	LONG-TERM MONITORING
Professional innovation database	Prospective development studies	Phase IIS study[a]	Surgical RCT	Prospective registries
Compulsory reporting of all new innovations	Detailed description of selection criteria	To evaluate technique prospectively and cooperatively	RCT – question agreed in phase IIS	Should monitor indications as well as outcomes
Confidential entry allowed to encourage reporting of failed innovations	Detailed technical description	To develop a consensus over definition of the procedure, quality standards and indications	Use power calculations from phase IIS	Statistical process control used for quality control (Shewart charts, CUSUM, VLAD)
Hospital or institution to be informed separately as a professional duty	Prospective account of ALL cases consecutively, including those NOT treated with new technique/device	To gather data for *power calculations*	Use learning curve data to decide entry points for clinicians	
	Clear STANDARDISED definitions or outcomes reported	To evaluate and monitor *learning curves*	Use phase IIS consensus to define operation, quality control AND outcome measures	
	Descriptions of ALL modifications and when they were made during the series	To achieve consensus on the *trial question*	Use modified RCTs or recognised alternative if RCT not feasible	
	Registration of PROTOCOL before study starts	To develop a multicentre *randomised trial (RCT)*	Feasibility RCT, expertise-based RCT, cohort multiple RCT, step-wedge design, controlled interrupted time series	
	Use of statistical process control methods to evaluate progress			

[a] Prospective collaborative studies.

CUSUM, cumulative sum control chart; RCT, randomised controlled trial; VLAD, variable life adjusted display.

Source: The IDEAL Collaboration

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