Chapter 27
Learning New Operations and Introduction into Practice

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Introduction

Surgery continues to be a rapidly innovative field. Over the last three decades, we have seen the widespread adoption of laparoscopy to span beyond general surgery, to include colorectal, urology, gynecology, and thoracic surgery, in addressing the burden of surgical disease. More recently, robotic technology has also been added to the surgical armamentarium of tools available for minimally invasive approach to patient care in the twenty-first century.

However, these rapid advancements in the field of gastrointestinal and endoscopic surgery bring along new challenges that surgeons today must contend with. First, we need to define a common nomenclature around the adoption of what is considered a "new" procedure, surgical technique, or technology versus a modification or alternate use of existing device or technique. Hutchinson et al. in their work attempt

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J. R. Romanelli et al. (eds.), *The SAGES Manual of Quality, Outcomes and Patient Safety*,
https://doi.org/10.1007/978-3-030-94610-4_27

to lay out an original definition of the term "surgical innovation" (Table 27.1) that meets robust criteria that can be reliably and prospectively applied to both "new" techniques and devices [1]. They describe whether the innovative technique is entirely new to the field, new to an anatomic location, or new to a specific patient group. Similarly, they describe whether the innovative device is new to the field, new to an anatomical location, or new to a patient group. This is paired with a practical day-to-day survey termed the Macquarie Surgical Innovation Identification Tool (Fig. 27.1) that surgeons can utilize in identifying "new" innovation. This again differentiates if a procedure is new to the hospital, new to the surgeon, new to the field, or new to a particular patient group. This proposed theoretical framework could obviate the nuances surrounding the deployment of these specific terminologies in the field and help structure a standardized approach with regard to the introduction of surgical innovation from the industry.

Drawbacks of the aforementioned framework are reflected in its identification of "new" technique or technology. Most surgeons would agree that in daily practice, they repurpose existing technology or technique distinct from what is captured by the Macquarie Surgical Innovation Identification Tool. It is therefore important to describe the alternatives to "new" technique or technology as these may have practical implications, for example, with regard to credentialing and privileging at the institutional level and perhaps more importantly, patient safety.

In August 2014, the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) and its Board of Governors approved expert consensus statements outlining the adoption of new technology and techniques [2]. Outlined in these committee statements are further definitions of "new" and "modified" terminology to capture the breadth of possibilities that may arise in clinical practice. The SAGES Guideline Committee definitions are listed below and supplement the aforementioned framework:

Table 27.1 A definition of innovative surgery with illustrative examples

An innovative surgical procedure is any procedure that meets 1 or more of the following criteria:		
	Criteria	**Examples**
1	*Innovative technique*: The technique used is new or differs from the standard technique in one or more of the following ways:	Different incision position or size; combination of two procedures such as mastectomy and reconstruction; extension of microsurgical techniques; established procedure undertaken on a different category of patient
1a	Altogether new	Pioneering transplant surgery, e.g., first heart transplant, first face transplant, first uterus transplant; use of hypothermia for neurosurgery
1b	New to anatomical location[a]	Novel anatomical approach for existing procedure; use of established anastomotic techniques in new locations
1c	New to patient group	Expansion of indications to groups whose surgical outcomes may be different, such as children; people with comorbidities likely to influence surgical outcomes; patients of a different sex
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:	Surgical robot; new hip prosthesis; implant made from new material; use of laparoscope to perform procedure usually done without one; use of adult device or tool on a child

(continued)

Table 27.1 (continued)

An innovative surgical procedure is any procedure that meets 1 or more of the following criteria:		
	Criteria	**Examples**
2a	Altogether new	Invention of the da Vinci robot; first use of laparoscope; first use of the endotracheal tube for anesthesia
2b	New to anatomical location[a]	Application of laparoscopic instruments or robotic surgery to new organ or body cavity
2c	New to patient group	Use of device or tools in groups whose surgical outcomes may be different, such as children; people with comorbidities likely to influence surgical outcomes; patients of a different sex

From: Hutchinson et al. [1], with permission
[a]Here we exclude procedures, such as fixation of fractures, which are not standardized to a particular anatomical location

1. *Modified Device:* existing device the surgeon has experience with that has been altered to improve functionality or performance, e.g., a modified stapler, a new mesh, etc.
2. *New Device:* product of disruptive innovation or device that has not been previously used by surgeons. Includes modified devices that surgeons have no prior experience with, e.g., endoscopic hemoclips, when surgeons have not used similar clips before.
3. *Modified Procedure:* modification of known procedure or technique. Surgeons have experience with similar procedures/techniques, e.g., a surgeon experienced with laparoscopic Nissen wants to perform a laparoscopic Toupet fundoplication or a surgeon who performs a laparoscopic bypass wants to adopt laparoscopic sleeve gastrectomy.
4. *New Procedure:* novel technique that differs dramatically from what surgeons are used to or technique not previously

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 in this ***surgeon*** ☐ Yes ☐ No

A `No' response for either of these item identifies 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. pediatric and elderly patients) ☐ Yes ☐ No
   2d. In patients with this comorbidity ☐ N/A ☐ Yes ☐ No

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

FIGURE 27.1 Macquarie surgical innovation identification tool. This is a practical tool to identify potentially innovative procedures to prompt appropriate support. (*From*: Hutchinson et al. [1], with permission)

used by surgeons, e.g., POEM vs. laparoscopic myotomy or adaptation of a laparoscopic or robotic procedure by an open surgeon.

These definitions of specific terminology play a critical first step by providing language commonality for surgeons and administrators to utilize in developing policy and regulations around implementation of new procedures, techniques, or technology at the institutional level. The appropriate terminology could also redefine current procedural terminology (CPT) codes which invariably are tied to the healthcare reimbursements that hospitals and surgeons receive from

insurance agencies. Therefore, appropriate designation of either "new" or "modified" terminology to surgical techniques and technology as it is incorporated into the clinical setting could have important financial implications as well.

Some of the criticisms of developing strict definitions around surgical innovation could be the ensuing regulatory oversight which ultimately gets translated into both privileging and credentialing processes for surgeons, as well as day-to-day practice [1, 3]. This inadvertently could potentially discourage the widespread adoption of these terms by surgeons. The reality today for surgeons undergoing the privileging and credentialing process is that in most institutions, it is more often than not cumbersome and time consuming. It is then not too surprising that in the era of increasing administrative responsibilities placed on surgeons, especially with tedious electronic medical record documentation and billing, this additional regulatory oversight is yet another aspect of patient care that the modern surgeon needs to balance with other clinical responsibilities. While it is safe to say no expeditious solutions to this dilemma exist, defining common terminology as we integrate surgical innovation into patient care is a necessary first step that carries both legal and patient safety ramifications for clinical practice. Thus, the ensuing discussion will employ these definitions to designate "new or innovative" or "modified" techniques and technology in our discussion.

Finally, as we continue to make progress in the ever-changing field of surgery, we ought to have in place specific pathways to guide practicing surgeons on how best to adapt to the modern practice of surgery. Not surprisingly, surgical societies often play a significant role as flagship organizations to further delineate these responsibilities. Invariably, surgeons adopting new technology and techniques have to abide by their institution-specific privileging and credentialing criteria. Paramount to the success of effective adoption of new technique and technology is addressing the knowledge gap in safely integrating these new technologies into day-to-day surgical practice while maintaining delivery of high-value and high-quality healthcare to our patients. In this chapter, we

will highlight the hurdles met in instituting a uniform framework around incorporating surgical technology at the local level and provide some practical guidelines and checklists for practicing surgeons to utilize in establishing their implementation framework.

What Different Steps Need to Be Taken to Evaluate New Technology and Surgical Techniques?

Implementing new technology and surgical techniques (NT&T) into clinical medicine can be highly rewarding to both patients and care providers but may also cause harm if the technology or new surgical technique is not appropriately evaluated to determine its true safety and efficacy. Determining the safety and efficacy of a surgical technology or new procedure is a complex task as surgical research is difficult on many levels. To help assist the surgical innovator in evaluating NT&T, a general framework has been suggested to be of benefit.

The IDEAL (Idea, Development, Exploration, Assessment, Long-term monitoring) framework is one such paradigm to guide innovators in producing high-quality surgical studies for each stage of evolution of the particular NT&T. The IDEAL framework began in Oxford, England, from 2007 to 2009 to discuss the specific challenges of evaluating surgical innovation. These discussions resulted in a publication of a five-stage framework describing the natural stages of surgical innovation. The IDEAL framework was established to provide a pathway for evaluating surgical innovations at each stage of their development [4]. Each stage is defined by a key research question:

- Stage 1 (Idea): What is the new treatment concept and why is it needed?
- Stage 2a (Development): Has the new intervention reached a state of stability sufficient to allow replication by others?

- Stage 2b (Exploration): Have the questions that might compromise the chance of conducting a successful RCT been addressed?
- Stage 3 (Assessment): How does the new intervention compare with current practice?
- Stage 4 (Long-term study): Are there any long-term or rare adverse effects or changes in indications or delivery quality over time?

Various users and funders of research have acknowledged the utility of IDEAL; however, use has remained somewhat limited. For this reason, more recently, it has been updated to help clarify and offer more detailed guidance about how to implement the updated recommendations [5]. Updated descriptions of the IDEAL framework and stage appropriate study designs are briefly summarized as follows:

The Pre-IDEAL stage is research prior to first human trials of an innovation. Appropriate preclinical studies include material testing, simulator, cadaver, animal, modeling, and cost-effectiveness studies. Stage 1 (Idea) describes the first use of a new procedure or device in a patient. Appropriate studies involve a single case or a few cases. It is recommended that reports explain the need for the new treatment concept and why it might be better than currently available treatment. Video recording and sharing is highly recommended and can be part of online publication. Stage 2a (Development) involves modifying procedures toward a final stable version. Appropriate studies are small single center prospective trials. A typology which deconstructs interventions into their component parts may help with precise definition of procedures and clarify description of which parts of the procedure change as it is modified and updated. Stage 2b (Exploration) is a stage where the main purpose is to gain greater experience of the new intervention in a wider group of surgeons and patients. This will allow more information to be collected, which will determine whether and how to progress to a definitive comparison against current best treatment. Appropriate studies are typically collaborative

multicenter prospective studies and determine the feasibility of a RCT. Stage 3 (Assessment) is a pivotal comparative evaluation stage that usually occurs against the current standard treatment. Appropriate studies are a multi-surgeon, multicenter RCT when feasible. Variants, including cluster-randomized or expertise-based RCTs or stepped wedge designs, may be appropriate. Stage 4 (Long-term study) proposes registries for data collection. Their strength lies in recognizing late or uncommon safety outcomes. Key design issues for registries center on the dataset and on fostering engagement. Datasets should be as small and cheap to collect as possible, while reliably capturing patient and device/procedure identity, diagnosis, and the key influences on outcome [5].

The IDEAL framework is just one example of a stepwise evaluation tool to help innovators evaluate more accurately the safety and efficacy of complex interventions or new technology. Tools such as this are widely accepted as necessary in evaluating NT&T and to prevent adverse events or wide adoption of NT&T that later proves to be harmful.

What Are the Surgeon's Responsibilities to Start NT&T?

Today, new technology and new and more advanced surgical procedures are being introduced with ever-increasing frequency. To prevent from being left behind, modern surgeons must stay aware of new therapies and technology and find ways to safely implement these changes into their practice. However, for busy practicing surgeons, learning new techniques and implementing them safely can be a challenging task. One of the initial steps after identification of the new technique for implementation is proper training in order to acquire competence and proficiency. Learning any new technique to the expert level requires time and dedication. The amount of time to adequately learn the NT&T and overcome

the learning curve is often underestimated. Practicing surgeons must consider what tools are available to help them minimize the impact of a learning curve on their patient's outcomes.

Traditionally, short courses offered over weekends to accommodate practicing surgeons' busy schedules were the only training available. However, higher complication rates have been reported for such techniques as laparoscopic surgery when training was limited to short courses held over a weekend [6]. What additional options are then available to surgeons trying to modernize their practice or stay on the forefront of treatment options? SAGES has outlined additional modalities that may be helpful and beneficial to surgeons learning NT&T [2]. Some examples include informal familiarization of surgeon with device or procedure before introduction, review of existing data/literature, pursuit of expert input, video review of device use or procedure, practice on appropriate simulated models (e.g., realistic or virtual reality), practice on animate models, practice on cadavers or cadaveric tissues, participation at courses at society meetings (e.g., SAGES, ACS), participation in online courses, completion of formal training (e.g., fellowship), proctored initial cases, tele-proctoring of initial cases, and team training (if applicable). However, knowing where to start may be difficult and appropriate pathways are not well defined in many situations. Creating a learning contract has been suggested as a good place to start [7]. The learning contract starts with stating your goal. The learning contract includes your timeline, the steps you will take to learn the technique, and who you will engage to assist you with this task. The more modalities you implement as listed above, the greater the depth of your learning and the higher the likelihood that your implementation of NT&T will be successful.

Several barriers will inevitably need to be overcome to become competent in performing a new procedure. To illustrate this, we will outline a real-world example of the pathway one of the authors took to implement NT&T in their practice. As a relatively new faculty member, he set out to learn Per

Oral Endoscopic Myotomy (POEM) after completing a fellowship in minimally invasive surgery, which included only a limited number of therapeutic endoscopic cases but introduced our author to POEM (this procedure was still in the early phases of clinical experience). Our hospital had developed POEM privileging guidelines for the operating room, which also required surgeons to have upper endoscopy privileges in the general endoscopy center. The gastroenterologist-managed endoscopy center required a minimum of 200 upper endoscopies for privileging, which the author had not met despite the fellowship training and was unable to perform endoscopies at any other facilities as the author was an employed physician and this was not permitted under the hospital credentialing contract. So, in order to obtain privileges for POEM at our institution, additional POEM training was needed as well as credentialing for upper endoscopies in the GI endoscopy center. Through mentors within the department, a pathway was instituted that allowed for completion of the privileging requirements. The pathway was a program sponsored by SAGES and industry that offered advanced flexible endoscopy training to practicing surgeons. The program comprised two phases of training: first a 3-day hands-on training course in the USA with explant models, followed by a 2-week clinical hands-on advanced training at a high-volume international site, which included over 300 upper and lower endoscopies during the 2-week training period. Their POEM volume is also exceedingly high and on average a POEM per day was achieved with hands-on experience. Following completion of this program, credentialing requirements were met that then allowed for privileging for POEM after five proctored cases. This is just one of many possible pathways and no one pathway fits every surgeon or all NT&T. However, with adequate persistence and institutional support, a successful pathway can be managed and inevitable barriers overcome.

On the other hand, surgeons who want to incorporate a new technology into a procedure they already perform such as performing a procedure using a surgical robot in lieu of a

laparoscopic approach may face fewer barriers to success. In order to ensure and maintain the highest level of care, SAGES has outlined guidelines for training and credentialing on this topic [8]. The basic premise for credentialing is that the surgeon must have the judgment and training to safely complete the procedure intended, as well as have the capability of immediately proceeding to an alternative therapy when circumstances indicate. There are two broad aspects to training with robotic systems. The first is technical training and capability. The second aspect of training involves the use of the robot for specific operations. Currently, the Food and Drug Administration (FDA) has in place a mandate that companies provide at least some of this training; at thus, at a minimum, surgeons must be trained to meet these FDA standards.

Training recommendations for surgeons without residency and/or fellowship training that included structured experience in therapeutic robotic procedures should mandate a structured curriculum. The curriculum should be defined by the institution and should include didactic education on the specific technology and an educational program for the specialty-specific approach to the organ systems. Hands-on training, which includes experience with the device in a dry lab environment as well as a specialty-specific model which may include animal, cadaveric, and/or virtual reality and simulation modeling, is necessary. Observation of live cases should be considered mandatory as well. Initial clinical experience on the specific procedure must be undertaken under the review of an expert and may include assisting and/or proctoring. An adequate number of cases to allow proficient completion of the procedure should be performed with this expert review. Criteria of competency as determined by the expert should be established in advance and should include evaluation of familiarity with instrumentation and equipment, competence in their use, appropriateness of patient selection, clarity of dissection, safety, and successful completion of the procedure [6].

What Are Institution-Level Responsibilities to Start NT&T?

As the pace of innovation is increasing, there are institutional-level responsibilities that have to be carried out as well. Institutional credentialing pathways have to keep up with the ability to introduce procedures that are either new to the institution or new to the field in general. These have to be anticipated in advance rather than coming up with last minute accommodations so appropriate balance can be struck between innovation and patient safety.

In the SAGES guidelines (which are based on available literature and expert opinion), the recommendation to the question of who should monitor the introduction of new procedures was given as follows:

> "To protect their patients, surgeons should demonstrate the highest level of professionalism and exercise self-assessment and self-regulation when introducing new technology and techniques in their practice. Besides the FDA, which regulates the production and sale of new devices, institutional credentialing and/or new technology committees and the IRB should monitor their introduction in clinical practice. The introduction of novel procedures should be overseen by the credentialing committee and/or the IRB, while the role of specialty societies and new technology committees needs further assessment." [2]

Who Approves and Monitors the Introduction of New Procedures?

Though self-assessment and self-regulation remains very important to ensure patient safety, it cannot be relied upon as one of the only safeguards. There are multiple factors that can influence the surgeon's decision to adopt a new procedure or using a new device/platform. These factors include pressures from industry or the healthcare systems, marketing pressures from patients and competing with colleagues, the novelty of a new procedure, or simply the desire to provide the most up-to-date care for their patients [2]. Due to these pressures, it's

reasonable to conclude that someone other than the surgeons should also be involved in approval and subsequent monitoring of new procedures.

In the SAGES guidelines, for the device modification category, a majority agreed that surgeons themselves should be able to monitor the introduction of NT&T into their practice. For new devices, again it was surgeons themselves as well as the FDA that were considered the best options, with the credentialing committee and new technology committee monitoring new devices as well. For entirely new procedures, the credentialing committee of the institution would be the most important monitoring entity, followed by the surgeons and the IRB. Specialty societies could also play a role in this aspect, but it is unclear how they would do so at the local level. There are certain prerequisite elements that have been described as important for introduction of new procedures. This includes being credentialed by the local institution to perform procedures on the affected organ system.

What Should Be Assessed Before and After Introduction of a New Procedure?

It is important to establish safety, efficacy, and cost-effectiveness of any new procedure that is going to be adopted. Currently, one of the tools used for this assessment is health technology assessments (HTAs) [9]. These include effectiveness compared to alternative treatments or procedures, the safety profile, the cost compared to existing therapies, and patient outcomes. National societies such as SAGES have now created committees such as the Technology and Value Assessment Committee (TAVAC) that have been tasked to generate HTAs for minimally invasive surgery.

It is important to distinguish between the introduction of new technology and a new technique or procedure. The pathways for introduction and subsequent monitoring for a modified device versus a new device or technology and that of a new procedure will be different. It is also relevant whether

that it is new procedure for the field or just new procedure locally for the surgeon as previously described.

In an academic setting, the Surgery Department Chair plays an important role in approving and/or recommending the initiation of a new procedure or technology at the hospital, as well as signing off on privileges for the practitioner. They may know and understand the current capabilities of the requesting surgeon and may have a better understanding of the training and courses taken thus far in preparation for the new procedure. They will also be able to follow the early experience closely and review the early patient outcomes closely as well. In smaller private and community hospitals, however, this can be less relevant. The Surgery Chair may be someone related to a completely different specialty (i.e., orthopedic surgery) and may not have the administrative setup or know-how to make a judgment on the practitioner's training and courses thus far and to follow the outcomes as closely.

Though national organizations and societies can provide guidelines regarding credentialing and privileging to perform a new procedure, this still largely remains the local institution's responsibility. They are responsible for verifying the requesting practitioner's training and determining its relevance and adequacy. Each institution may have its own system of privileging related to new procedures. The committee responsible needs to take into account guidance from existing literature as to what constitutes a completely new procedure or use of a completely new device versus what's a modified device in a modified or adaptation of a procedure and where there is overlap. Care must be taken to keep the credentialing and privileging process as objective as possible, as not to allow competing groups and local hospital politics to creep into the decision-making. Ultimately, each surgeon and institution bear the primary responsibility for establishing an appropriate and fair system that strikes the right balance between innovation and ensuring patient safety. Both the surgeon and institution have the most "skin in the game," aside from the patient, to ensure this is done appropriately as they may also have the highest liability risk.

What Is the Pathway to Surgeon Credentialing and Privileging for NT&T?

Utilizing correct terminology is very important. Credentialing refers to the verification of the surgeon's training, education, malpractice claims, professionalism, etc. Privileging was defined as the surgeon's scope of practice and the clinical services they can provide [9]. Since there isn't good data available to guide the privileging committees regarding the number of procedures needed for competency in most of the new procedures, and taking into account differing learning curves of surgeons, it is difficult to set a minimum number of procedures with confidence. As mentioned earlier, apart from having the privileges of working in that specific organ system, the level of training obtained and verified will depend on the complexity of the procedure and new technology. The Society of Thoracic Surgery (STS) task force suggested that due to the variability in complexity of new procedures and technology, it is difficult to set a defined pathway that can be applied to all new privileges being requested. A better approach would be to stress the importance of preparation to align the surgeon's existing skill set with the complexity of the new procedure or technology being implemented [9]. The hospital's normal credentialing and privileging process may not include the ability or expertise to pass judgment on a new technology or procedure being requested. Larger institutions may have an innovation/new technology committee or a specialty committee that can collaborate. Smaller institutions may need to seek guidance from a local or regional larger institution as a consulting service.

The American College of Surgeons (ACS) has defined a five-level verification model for documenting a surgeon's participation in educational programs and assessment of their knowledge and skills [6, 9]. These five levels include verification of attendance, verification of satisfactory completion of course objectives, verification of knowledge and skills, verification of preceptor experience, and demonstration of satisfactory patient outcomes. Building upon these levels,

Blackmon et al. proposed five levels of supervision when training for new procedures as shown in Table 27.2 [9]. These levels can be used to standardize educational course certifications to better understand the depth of training and verification the participant went through. The Joint Commission recommends that practitioners applying for new privileges undergo a focused professional practice evaluation (FPPE) [9]. This in turn can be used by hospital credentialing and privileging committees to assess readiness. Most of the time, if a FPPE is requested, data will have to be collected prospectively, and institutional review board (IRB) approval and safety monitoring will be needed. This is recommended by most when performing a new procedure that is new to the field not just new to the institution. This is needed when performing research comparing the new technique or technology

Table 27.2 Five levels of supervision when training for new technology and advanced procedures

Level 1	Certifies the learner attended a lecture or completed a lecture format course (no verification of skills)
Level 2	Certifies the learner completed a course and was assessed with a test or other evaluation of training and was provided feedback regarding their assessment score (a better model incorporates a minimum pass rate)
Level 3	Certifies the instructor observed the learner perform a skill and verified completion of task(s). Alternatively, the learner completed a course and participated in a lecture and skills lab, allowing assessment of the skills on a synthetic or tissue-based model
Level 4	Certifies the learner performed the procedure on a patient in a clinical setting with supervision (proctor or preceptor)
Level 5	Certifies the learner performed a series of clinical cases, the outcomes of which have been reviewed and verified. An example of level 5 learning may be submitting a series of video-recorded cases with outcomes to a review committee for verification

Adapted from Blackmon et al. [9]

to existing therapy. There may be an established procedure that has been performed for years in the field but involves a technology that has been granted a humanitarian device exemption (HDE) by the FDA like the gastric electrical stimulator, for example. IRB approval is needed for HDEs. When an FDA-approved device is used off-label, IRB approval is not usually needed unless the use is novel and there exists a lack of safety data. Of note, not only informed consent but proper disclosure to patients is also recommended in these circumstances as will be discussed later in the chapter.

Last but not least, since the highest priority needs to be given to patient safety in any adoption of new technology, all aspects have to be considered. The entire procedure team plays a very important role in adoption and has to be involved in the implementation. The team's education has to be planned out, including the equipment needed, number of personnel to perform the procedure, failure scenarios, and trouble shooting. Getting the procedure suite leadership involved is key as well to making it all happen. Accounting for all the various important aspects in getting started with a new procedure, the STS has developed a checklist to use as a guide for privileging as shown in Table 27.3 [9].

What Supervisory Options Are Available to Surgeons Adopting NT&T: Preceptoring vs Proctoring vs Telementoring?

Industry, institutions, and specialty societies are all stakeholders in having programs for preceptorship and proctorship to help surgeons learn new procedures. It is important to clarify the differences between them. Preceptors are usually experts in the procedures being taught and their role is to help a trainee acquire new skills. They usually assist in the procedures and provide feedback to the learners to help achieve learning objectives. They can take over the

Table 27.3 STS committee checklist for privileging

Verification of knowledge and skills assessment
ABTS-eligible or ABTS-certified surgeon
Documented completion of a course or didactic session
For recent graduates of an accredited program, case logs and a program director letter attesting to competence
Team management
Draft of implementation program complete
Education plan for team members complete
Crisis management plan complete
Institutional collaboration
IRB and/or institutional innovative care/new technology committee approval
Monitoring of outcomes
Participation in a continuous quality improvement committee and/or morbidity/mortality conference
Participation in an auditable database (e.g., National Surgical Quality Improvement Program, STS National Database, Michigan Society of Thoracic and Cardiovascular Surgeons Quality Collaborative) or registry or shared database that is accessible by the host institution
Demonstration of ability to present accurate and detailed morbidity and mortality rates to administration upon request
Patient-centered transparency
Provide appropriate consent forms for IRB and/or innovative committee approval
Provide the patient information on the risks and benefits of the new procedure, alternative treatments, general costs (i.e., to the patient or payer, or both), and comparative effectiveness of the new technology vs existing treatment options

(continued)

Table 27.3 (continued)

Provide the patient with information on the surgeons training and experience to date

Adapted from Blackmon et al. [9]
ABTS American Board of Thoracic Surgery, *IRB* Institutional Review Board, *STS* The Society of Thoracic Surgeons

care/surgery of the patient and carry more legal responsibility. An extended example of a preceptorship is a fellowship or a mini-fellowship.

Proctors also play an important role in the implementation of new procedures. They are involved in assessment and verification of knowledge and skills of the learner. They can provide feedback to the learner, but they generally do not teach the learner. They also usually don't scrub in the case and thus can't take over. The proctor reports their assessment to the accreditation body, such as the hospital credentialing committee. They are commonly used in assessment of surgeons starting new procedures in their practice as the logistical constraints are less, as is the legal risk for the proctor. These differences are highlighted in Table 27.4.

Telementoring

Telementoring is a further development in this field. This is especially relevant now since the COVID-19 pandemic. The definition of telementoring is "a relationship, facilitated by telecommunication technology, in which an expert (Mentor) provides guidance to a less-experienced learner (Mentee) from a remote location" [10]. Published systematic reviews on this topic showed no difference in clinical or educational outcomes for trainees that received on telementoring vs on-site mentoring [11, 12]. Some of the studies (four studies or 33% of them), in the most recent review, showed telementoring to be inferior to on-site mentoring, for example, with increased

Table 27.4 Principal differences between the roles and responsibilities of a preceptor and proctor

Preceptor
Principal role is to help the surgeon learner acquire new surgical knowledge and skills during the steep portion of the learning curve
Assesses and verifies the knowledge and skills of the surgeon learner to ensure achievement of learning objectives
Always provides feedback to the learner
Must be an expert in the performance of the new procedure or use of the new technology; such expertise is necessary for effective preceptoring
Generally assists in the operation and is readily available to take charge if the need arises
Associated with greater legal risk
Logistics more complex
Proctor
Principal role is to assess the knowledge and skills of the surgeon learner during the steep portion of the learning curve
Assesses and verifies the knowledge and skills of the surgeon learner to report the results to the Chief of Surgery or the institutional credentialing committee
May provide feedback to the learner
Does not always need to be an expert in the performance of a new procedure or use of a new technology; such expertise is desirable but not always necessary for effective proctoring
Generally serves as an observer
Associated with lesser legal risk
Logistics less complex

Adapted from Sacheva and Russell [6]

operative time; however, the majority showed telementoring to be as effective as on-site mentoring [12]. Telementoring was also thought to superior to no mentoring at all, but as the authors admit to in the limitations in their study, the data available has significant heterogeneity of the outcome measures and procedures [12]. Better designed studies are needed to draw more meaningful conclusions about telementoring, but it seems to be better than no mentoring, and maybe as good as on-site mentoring. Due to the logistical and financial challenges of on-site mentoring including its usually short time span, telementoring may have the ability to be superior as a training platform due to its ability to provide longitudinal training and follow-up with less logistical strain on the system. This recognition was the impetus for SAGES to convene the "Project 6 Summit" and publish a white paper [10]. They described the concerns regarding rapid adoption, using the example of laparoscopic cholecystectomies and the increase of common bile duct injuries by almost threefold initially. This technique was mostly adopted after attending weekend-type short courses without much longitudinal guidance. In contrast, there continue to be concerns about the very slow adoption of laparoscopy for colectomies [10]. The "Project 6" name was inspired by the military term "I got your six," meaning I got your back, describing the mentor and mentee relationship. One of the main barriers identified was availability of adequate training for surgeons in practice so they can feel comfortable to offer it to their patients. It may be that for more complex minimally invasive procedures, with a longer and steeper learning curve, more continued guidance may be needed. Due to the evolving field of surgery, with increased use of technology and new devices, surgeons may be required to undergo additional training several times in their career. A discussion of the details regarding the challenges and opportunities in telementoring is beyond the scope of this chapter, but they laid out the various areas that require work. These included legal and regulatory challenges of medical licensing, credentialing, liability, privacy, and consent. Business and value propositions for all the stakeholders

like the surgeon (trainee), the hospital, industry, health insurance, and government are key areas as well. This would require a coordinated effort by all the stakeholders for success. They also include establishing appropriate communication and education requirements for the trainees so the training episodes can be efficient and effective. They also discussed technology limitations, logistics, and requirements to advance the field forward [12].

What Is the Role of Surgical Societies in NT&T?

Expert consensus from the SAGES guidelines suggested that health technology assessments for new procedures should be done by medical societies while keeping the patient's interests as a priority. Keeping this as an active committee that works to provide timely information regarding new procedures can help surgeons and hospital credentialing committees to make appropriate decisions regarding adoption of new procedures. Surgical societies can also play a role in helping follow outcomes. Database management can be quite challenging when left completely on a voluntary basis at and the individual or local level. National databases like NSQIP from the ACS can provide an important framework for data collection and monitoring.

To date, the most common way of learning a new procedure after postgraduate training is through a hands-on course. This is typically a 1-day or weekend course, with a cognitive portion and a skills portion, usually on a simulated model like a cadaver or porcine model [13]. The concern is that the return on investment in such courses is very low, as most practitioners fail to adopt in their practice what they have learned at these courses [13, 14]. With rapid advances in most surgical fields, nearly all surgeons will have to learn a new or modified procedure at some point in their career. The surgical societies, as advocates of surgeons and the surgical field itself, do and can play an even more important role in ensuring safe and

timely adoption of new procedure, for the benefit of patients, surgeons, and society in general. With these concerns in mind, SAGES, through its Continuing Education Committee and its Quality, Outcomes, and Safety Committee, developed a hands-on course that employed standardized teaching techniques at the annual meeting and included a subsequent yearlong mentorship program. This was called the Acquisition of Data for Outcomes and Procedure Transfer (ADOPT) program.

The course participants were paired with a faculty member with whom they could communicate throughout the year to help them with case selection, preparation, etc. for starting new procedures in their practice. They were encouraged to participate in web meetings and submit videos for critique if needed. The timeline of training is shown in Fig. 27.2 [13]. The participants' experience was then compared to a standard hands-on course at the same meeting. The ADOPT participants performed significantly more procedures over the course of the first 3 months following the course compared to the stand hands-on course as shown in Fig. 27.3 [13].

Based on the positive results from the initial ADOPT course in 2015, all participants enrolled in the SAGES 2016 Annual Meeting Hands-on Hernia course were included in the ADOPT course (Fig. 27.3). This again demonstrated that adoption rates of the learned procedures were higher than before with increased confidence in participants as well [14].

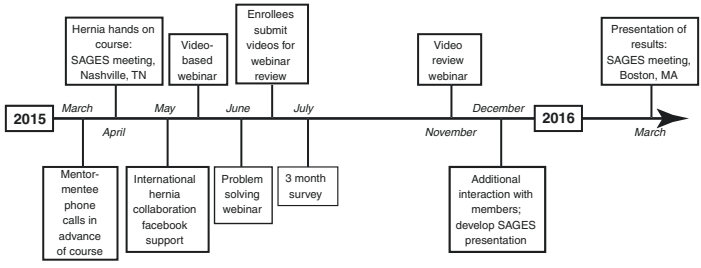

Figure 27.2 SAGES ADOPT program timeline 2015–2016. (Adapted from Dort et al. [13])

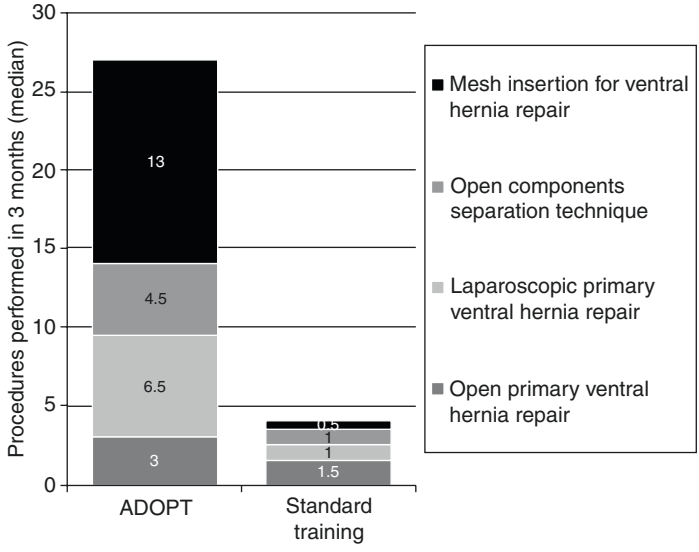

FIGURE 27.3 Median number of procedures performed over 3 months following training for ADOPT and standard training learners. (Adapted from Dort et al. [13])

This is thought to be in large part due to ongoing engagement and mentorship. Several barriers to mentorship have been described. These include time constraints, limited qualified mentors, lack of mentorship training and differences related to culture, and gender and generation gap between mentor and mentee [14, 15]. The SAGES ADOPT program enabled good mentorship by facilitating leaders in the field of hernia surgery to be available through a structured program. The program also mitigated potential barriers to good mentorship by standardizing instruction and feedback delivery and by selecting faculty from diverse backgrounds. As stated by Dort et al., the ADOPT program "…underscores the importance of standardized instruction by trained faculty, longitudinal mentorship, and the creation of a community of practice/learners as a forum for discussion and learning" [14].

The surgical societies have an obligation not just to their members and sponsors but also to the patients and society at large. They can play a very important role in not just dissemination of the current "state of the science" information but also providing structured programs, backed by science, to increase adoption of new procedures. The surgeons/members have trust and confidence in these societies to do the vetting of appropriate programs and courses that they can then use to learn new procedures. As with the program described earlier where one of the authors went to India for additional training or with the ADOPT program, they would not be possible without the leadership and guidance of the national and international societies.

Ethics of Patient Disclosure

Patient safety is of utmost importance every time the decision is made to proceed with surgery. "*Primum non nocere*," the famous Hippocrates oath that guides our principal role as physicians, translates to "First, do no harm." As surgeons, we bear the foremost responsibility of effectively detailing the risks and benefits of a particular procedure to our patient including a discussion of alternatives, and thus obtaining "informed consent." In the era of surgical innovation, this is a delicate task for modern surgeons to balance, and we need to be well equipped to handle the ethical questions that arise especially as we deploy such new techniques and technology.

New surgical techniques and procedures fall outside the regulatory purview of the US Food and Drug Administration (FDA). Consequently, innovative procedures that are not performed under the supervision of IRB-approved research protocols are regulated at the local institutional level, and as a result, no uniform standards exist. Ultimately for patients, this translates to variability in timing and access to new surgical techniques and procedures based on practice patterns in their local community.

In 2014, SAGES released a detailed document outlining important ethical questions that are relevant to the implementation of new surgical techniques and technology in surgery [16]. In their manuscript, the authors pose six critical ethical questions that currently exist:

1. How is the safety of a new technology or technique ensured?
2. What are the timing and process by which a new technology or technique is implemented at a hospital?
3. How are patients informed before undergoing a new technology or technique?
4. How are surgeons trained and credentialed in a new technology or technique?
5. How are the outcomes of a new technology or technique tracked and evaluated?
6. How are the responsibilities to individual patients and society at large balanced?

This is followed by a thoughtful reflection on how best institutional strategies and cohesive efforts can be made to provide optimal execution of new surgical techniques in clinical practice. While the nuances of their manuscript are outside the scope of this discussion, we do want to highlight one of the key ethical and common questions that surgeons might encounter as they integrate novel surgical technique into their practice: How do we consent patients? This is an introspective question that reflects the important underlying theme of patient safety. When a patient is selected for a novel procedure or technique, in reality we are accepting potential morbidity and mortality that could very well befall patients that are exposed to so-called early adopters of new techniques and technology that is not present compared to the standard of care. In the 1990s, before laparoscopic cholecystectomy became standard of care, the learning curve associated with the operation most likely contributed to the prevalence of common bile duct injuries [16, 17].

The learning curve associated with the adoption of new surgical technique into clinical practice poses a serious ethical

dilemma for the surgeon-patient relationship. In surgical innovation, the inability of the surgeon-innovator to flatten the learning curve without gaining experience from patients in clinical practice compounds this ethical dilemma. Of note, this dilemma is not entirely akin to the situation that exists with trainees in surgical residency programs specifically in two distinct ways. Firstly, residents are ultimately subject to oversight from credentialed surgeons as mandated by ACGME clinical competency guidelines [18]. Secondly, surgeon-innovators are typically experienced physicians with demonstrated proficiency in their field of practice seeking out a new skill set. Thus, surgical innovation portends a different ethical entity.

In 2014, Bracken-Roche et al. published a systematic review regarding patient disclosure and autonomy in surgical innovation [19]. In their manuscript, they highlight "four central tension points" identified in the literature that impact the patient disclosure process and autonomy. One of these points is the "misconception" that patients might construe "new or innovative" to mean better care for their surgical disease. They also describe the notion of the skewed surgeon-innovator and patient relationship with its inherent asymmetric power differential that exists – "patients feel they owe a certain deference to surgeon." This could be further exacerbated by the fact that "surgeons may lack objectivity when they themselves are the innovator or strong supporters of the innovation." All of these contribute to a complicated disclosure process that preserves patient autonomy and legal determination.

Against this backdrop, surgeons must understand and develop equitable inclusion-exclusion criteria of patient selection for novel procedures and techniques. At the crux of this selection algorithm is patient-centered transparency. Clear communication of known risks, benefits, long-term outcomes if available, and how this novel technique compares to the standard of care should be provided to the patient. Conflicts of interests that exist, for example, any financial relationships with medical industry sponsoring proposed technique or device, must also be disclosed to the patient [17].

Additionally, in our increasingly litigious society, the learning curve should be addressed as part of the disclosure process [20]. In their manuscript, Healy and Samanta tackle the ethical and legal implications of this learning curve in clinical practice. As alluded to earlier, the "drive to … enhance (clinical) outcomes places surgical innovation as pivotal to clinical progress." However, as the authors point out, this comes with a learning curve that poses "material risk" to patients and therefore subject to disclosure in law. Therefore, given this legal precedence, the "performance data of a surgeon may be a material factor for a patient in the consent process" and ideally should be disclosed. An important final point to highlight is that the decision to proceed or not is a shared decision process between the surgeon and patient after weighing both merits and risks of the proposed technique or technology.

Finally, as surgeons, we must recognize biases inherent in our role as physician. In essence, our duty is not just to our individual patients at a single point in time. We also hold a larger responsibility to society in our role as stewards of surgical innovation in order to advance the fields of science and surgery. We also ought to weigh the financial cost of implementing new technology in today's economy of ballooning healthcare costs and be cognizant of our role in providing cost-effective care to patients. Against this milieu of competing interests, we must always strive to provide high-quality care to our patients as we make strides in surgical innovation and technology.

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