Ethical issues in endoscopic surgery

Although each of us presumes that we are ethical in our daily practice of endoscopic surgery, we rarely take the time to assess critically what this means. In certain specific situations, such as the planning of an investigation that involves human subjects, we must address these concerns in an application to an institutional review board. At other times, however, we simply don't think much about it.

Because many of our procedures and the technology that enables us to perform them are still sufficiently novel, perhaps now more than ever we must take the time to consider whether what we do adheres to the high ethical standards expected of us by our patients.

There are several specific issues worth considering. In no particular order of importance, we will discuss training, the introduction of new procedures and technology, and our relationships with patients and our partners in the biomedical industry.

How is one trained to perform endoscopic surgery? For our residents, this is an easy question to answer. General surgery training programs today have an obligation to teach endoscopic skills. Since this is most likely the way that a majority of surgery is and will continue to be performed, it would be remiss of us not to teach these skills to our residents. Most training programs today probably make the effort to teach their trainees the basics of the commonly performed procedures, such as laparoscopic cholecystectomy, and perhaps laparoscopic appendectomy or fundoplication for gastroesophageal reflux disease, but the programs don't routinely include the teaching of more advanced skills. We recognize that the skill set necessary to perform laparoscopic procedures is different from that of open surgery. And, we have taken it upon ourselves to develop a didactic and practical instructional course through SAGES that is being considered for adoption by the American College of Surgeons.

So how do the trainers become qualified to train? There are two groups of trainers. The first group consists of relatively young faculty who themselves were recent trainees, and who were mentored as they learned to perform endoscopic procedures in the same way that residents have been trained for decades in open surgery. The second group perhaps is more problematic. This group consists of the pioneers in endoscopic surgery—those surgeons who began to perform these procedures with little or no experience. Although many of them are skillful surgeons who excel in endoscopic surgery, some attended early courses in laparoscopic cholecystectomy taught by a few adventuresome souls,

and others remain, for the most part, self taught. It is true that there has to be a starting point, but is it ethical to take a course from someone whose expertise amounts to the fact that he or she adopted endoscopic surgery early on, practice with a group of other "students" on a couple of pigs, and then perform procedures on actual patients and teach others to do the same?

Perhaps, after a little more than a decade, endoscopic surgery is sufficiently integrated into our practice and our training programs that this point may seem to be less important. Yet, as each new procedure is introduced, issues are raised again every time a maloccurrence results in a poor outcome and becomes the subject of litigation.

What about the new procedure or the use of a new instrument? What's the proper way to develop, learn, and become skilled today? In days past, we may have gone to the laboratory to learn a new procedure on animate, nonhuman subjects after submitting a proposal to a research review committee, or we may have thought the procedure sufficiently similar to other commonly performed procedures that we were "comfortable" starting out on human subjects. Is the latter practice ethical in today's medicine? The answer depends on several factors, including the procedure, the surgeon, and the patient.

If one is skilled and privileged in the insertion of a Veress needle and the safe introduction of cannulae, and the procedure to be carried out is, essentially, the same as the open version of the procedure, other than access, then the procedure may be considered an extension of our current surgical armamentarium and simply discussing the options with the patient and obtaining appropriate informed consent may be sufficient. The same is true for a new device, such as a new endoscopic clip applier or stapler. If, on the other hand, a new procedure or device is sufficiently different from that used in any open procedure that we commonly perform, then the procedure or device first should be tested in the laboratory, and then it should be the subject of human experimentation with review by the appropriate institutional review board with its mandatory informed consent.

Before performing an endoscopic procedure or using an unusual device or instrument, the patient (or appropriate legal guardian), should be informed of the options, surgical and otherwise. The patient should be told of any risks and potential complications, should be told of the surgeon's experience and results, and should be told of any problems specific to the use of the new

device or instrument. This exchange of information should be documented in detail so that, in the event of a mishap, there will be no question that the patient had sufficient information to make an informed decision. Today, the guidelines are clear and the performance of a new procedure without going through the aforementioned process is unethical.

What about documentation of a procedure? Does the patient need to give permission to record still or video images of a procedure? Absolutely! The permission can be included as part of the general admission process with the consent to treat, or it can be included as part of the consent to operate. It is probably better, though, to have a consent specifically written to grant permission to record images. But, after you have the images, what can you do with them?

As you record the images, keep in mind that if they are stored, they are considered part of the medical record and are no different in that regard than if they were part of the patient's chart. To record and store an image, label it with a patient identifier, and then to discard the image is to destroy a medical record and is as unethical as altering the patient's chart. To record an image of a procedure for teaching or demonstration purposes, and to label it without patient identifiers, is not necessarily part of the medical record. Since there is no way to identify the patient, such image is not part of the patient's medical record nor would it be admissible as evidence in court since the chain of evidence is always in question. Thus, the deletion of such an image is not unethical.

These issues should be taken into consideration as you design rooms for endoscopic surgery with image capture and storage capabilities. Some configurations, with mainframe storage capabilities provided by an institution such as a hospital or university, set the institution up for potential medico-legal issues (if not ethical issues), as far as storage and retrieval of those images is concerned.

Let's turn for a moment to the relationship between surgeons and industry. Many of us have business relationships with industry. Although it's ethical to use products from companies with whom you have a financial relationship, as long as it's in the patient's best interest, it's unethical to use an inappropriate product, or to use a product in a situation that's not in the patient's interest, simply to support your interest in the company. Similarly, it's unethical not to disclose your relationship with the company when you lecture or teach a course. As an educator, it's wise to shy away from such relationships in any form, including serving as a paid consultant or investing in the company. That way, you can tout products, devices, and companies that you believe to be the best simply because of the way they perform or serve a specific function.

This is not to say that, as a representative of a hospital, you shouldn't try to get the best deal possible, including perks such as teaching and research support. To be ethical, these relationships should be disclosed when appropriate, even though you may not benefit from the relationship personally.

There are certainly other issues that could be discussed, but these seem to be the most common concerns, other than specific issues that relate to medical liability. If you have other specific concerns and are a member of SAGES, the Members Only section has a forum for submitting ethical and legal issues to members of the Ethics and Legal Issues committee and they will respond: The site can be found at <http://www.SAGES.org>.

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