**Presidential Address**

# The challenge of emerging surgical technology:

## The College can help

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***Editor's note:*** *Following is the edited text of the Presidential Address that Richard R. Sabo, MD, FACS, delivered during the Convocation at the 2002 Clinical Congress.*

C. James Carrico, MD, FACS, died July 25. One year ago, he was chosen to become President of this College, an honor richly deserved and thoroughly appreciated. He wrote to the College in May, saying, "I have received no greater honor in my surgical career than being elected to serve as President of the American College of Surgeons."

I miss him. The College misses him. The whole world of surgery will miss him. I wish he were here to give this address, to share his wisdom, and to lead the College during the coming year. Although he can't talk to us tonight, his life speaks volumes about the highest ideals of a skilled and caring surgeon, a passionate educator, a distinguished scholar, and a true gentleman.

I am a general surgeon who practices in a community hospital in Bozeman, MT. Previous Presidents of the College have called upon their special expertise in surgery or unique world view to share on this occasion. My perspective is that of a practicing community surgeon whose professional life has been extremely rewarding. I have thoroughly enjoyed taking care of patients, enjoyed the friendship and support of my colleagues, and, for more than half of my career, enjoyed a rich association with the American College of Surgeons.

In this address, I'd like to share with you some of the challenges I have faced in my career. I'm going to talk about the problems of incorporating new technology into practice and how the College can help. Some of those problems are unique to a small community practice, but most are faced by all surgeons. I'm sure you'll find yourselves dealing with them during the course of your career. In discussing these challenges, it will become obvious how much Dr. Carrico and his associates on the Committee on Emerging Surgical Technology and Education (CESTE) have done to help us all.

## How things have changed

When I began my career in 1971, the practice of surgery was profoundly different. Radical mastectomy was done for most women with breast cancer regardless of the size or stage of the disease. Gastric surgery was common for the treatment of peptic ulcer disease. There were no surgical staplers or flexible endoscopes, and the thought of doing intraabdominal surgery with a laparoscope would have been incomprehensible.

How things have changed. Like most surgeons, my professional life has been characterized by continual change: changes in the concepts of disease, changes in the techniques of surgery, changes in the environment in which we practice, and changes in the expectations of patients.

Lawrence Way, MD, FACS, recently reported the results of a survey in which he asked 80 colleagues to name the major advances that have occurred in general surgery during the last 25 years.[1] The majority of respondents agreed that the most profound changes have been the better understanding and control of nutrition, improvements in critical care, the advent of fiber-optic endoscopy, and the introduction of laparoscopic surgery. When asked about major advances in the future, they predicted that the trend of less invasive surgery will continue as devices become smaller and even more sophisticated. They also predicted that new discoveries in molecular biology and genetics will result in dramatic therapeutic advances, especially in the treatment of malignant disease.

Changes such as these create much of the excitement and stimulation of surgical practice—the challenge to keep up with new ideas and the joy of learning and perfecting new skills. However, change may also produce stress and frustration because of the uncertainty that inevitably is associated with the transition from old to new ideas. That holds true whether you are a solo practitioner in rural Montana or an academic surgeon in the center of Boston, MA.

In the recent best-selling book, *Complications: A Surgeons' Notes on an Imperfect Science*, Atul Gawande, MD, characterized our profession in this way: "As a doctor, you come to find that the struggle in caring for people is more often with what you do not know than what you do. Medicine's ground state is uncertainty. And wisdom for both patients and doctors is defined by how one copes with it."[2]

Conceptual changes may be particularly difficult to diffuse into practice. Breast conservation surgery was shown to be equivalent to mastectomy in at least three randomized controlled trials published between 1981 and 1989.[3-5] Because of the slow adoption of the procedure into practice, a 1992 national consensus conference was convened and concluded that breast conservation was appropriate for most women with early primary carcinoma of the breast.[6] Five years later, 14 years after the results of the first trial became known, only 40 to 60 percent of eligible women received conservative surgery.[7] It is clear from this example that many physicians had difficulty giving up traditional therapy and incorporating a new concept of disease and treatment into their thinking.

In contrast, laparoscopic cholecystectomy took the surgical world by storm. In less than two years, it replaced open cholecystectomy as the standard procedure for removing the gallbladder. That transition was chaotic, with extreme variability in the way it was introduced. Many patients suffered unnecessary complications and there were even some deaths because of inadequately trained surgeons.

Occurrences like these suggest that intuition, personal experience, physiologic reasoning, and tradition are inadequate guides for important clinical decisions.

## CESTE

Dr. Carrico became a Regent of the College in 1992, shortly after the adverse results of the laparoscopic cholecystectomy transition were recognized. The College responded by creating CESTE with Dr. Carrico as its chair. He, Jonathan Meakins, MD, FACS, who is the current chair, and the other dedicated Fellows on the committee spent the next decade analyzing the implications of new surgical technology. The fruits of their labor are five official "Statements" of the College that were published between 1993 and 2000 and are available on the College's Web site *(www.facs.org)*.

The first one, "Statement on Laparoscopic and Thoracoscopic Procedures," defines who should do minimally invasive procedures and outlines the general qualifications a surgeon should possess before doing these procedures.

The "Statement on Emerging Surgical Technologies and the Evaluation of Credentials" recognizes that the introduction of any new technology should proceed through a series of steps that ensure its safety, appropriateness, and cost-effectiveness. The process needs to be balanced and should not be so stringent that it unreasonably delays the development of an innovative procedure. On the other hand, the safety of the procedure must be established before it is widely disseminated into practice. The statement outlines three key steps. First, a procedure must have a strong evidence base, ideally from controlled clinical trials. Second, its diffusion into practice must be accomplished through appropriate education and training. Finally, the results of the new technique must be continuously monitored. This statement also provides guidelines for the evaluation of credentials before privileges for a surgical procedure are awarded.

The "Statement on Issues to Be Considered Before New Surgical Technology Is Applied to the Care of Patients" poses four questions that surgeons and institutions should ask about a new procedure: (1) Has it been tested adequately? (2) Is it cost-effective? and (3) Is the surgeon fully qualified? (4) Is it at least as safe as current techniques? There is enormous public pressure to reduce the invasiveness of procedures by using minimal-access techniques; however, these techniques may be less effective than their standard counterparts and might result in more complications.

The next statement from CESTE, "Approval of Courses in New Skills," defines standards for courses in new technology. Most new procedures are learned informally through commercial courses offered by experts or industry representatives, through mini-preceptorships, or simply through observation of surgeons who have begun to use the techniques. This sort of learning is irregular at best, and tends to focus only on the tech-

nique and not on the theoretical basis on which the technique is founded. By defining standards for courses, the committee provides a mechanism for surgeons to choose courses that will meet their needs and for institutions to know that a surgeon applying for privileges has the expected level of knowledge and skills.

The final statement from the committee, "Verification by the American College of Surgeons for the Use of Emerging Technologies," describes a method by which a Fellow could be verified by the College for the use of a new technology. The process would provide the surgeon with documentation sufficient to persuade the credentialing committee to grant privileges.

## Room for improvement

These statements provide an extremely helpful guide for surgeons introducing new technology into practice. However, the statements are less helpful in determining which procedures to select or when to select them.

Typically, a new procedure is introduced as a case report or series of favorable cases from a single institution. Confirmation from other institutions adds to its visibility and this technique might then become the topic of a panel discussion at national meetings. If the panel experts are using it in their own practices, surgeons in the audience are motivated to begin using it. The impetus becomes stronger if organizations such as the College offer training courses on the procedure. Ultimately, there may be a consensus conference or randomized controlled trials defining this method as the standard of care. Somewhere along this increasingly convincing stream of data, a surgeon may decide to incorporate the new procedure into his or her practice. If this method is a minor modification of existing techniques, the change is not difficult. However, if it involves a complex procedure or a significant conceptual change, the challenge becomes more difficult.

The point of decision will vary among surgeons. An academic surgeon in a high-volume tertiary care center will have a significantly different threshold than a rural surgeon in solo practice. Community surgeons must first ask if they will have the volume of patients necessary to acquire the skills and maintain their proficiency. What supporting resources does their hospital provide? Can unexpected complications that might arise from the procedure be addressed adequately?

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There is enormous pressure on surgeons to provide the latest technology and appear to be on the cutting edge. Patients are constantly bombarded with information about new techniques in the lay press—information that quite often is selected for its sensationalism more than its accuracy. Today's patients have access to much more medical information than their predecessors did; unfortunately, much of it is misinformation. They want the least invasive procedure available, and they expect a good outcome. If their surgeon can't provide the latest technique or offer a reasonable explanation for not making it available, patients will look elsewhere.

Surgeons tend to be risk-takers. They enjoy learning new procedures and pride themselves on their technical abilities. There are more pressures to adopt a new procedure than there are restraints to wait for solid evidence of its safety and efficacy. Where is the decision threshold? What is the trigger that tips the scale for a surgeon so he or she will sign up for a course and begin the training process? Surgeons, especially those of us who practice away from academic medical centers, are looking for guidance and the College can do much to help us.

The CESTE statements repeatedly call for an examination of the evidence supporting a new procedure. This may be the most difficult part of the evaluation process. Unbiased information is difficult to find. When we review the literature there is a tendency to select articles that suit our own point of view and fit into preconceived ideas. Information from industry is designed to sell products more than to educate surgeons. Suggestions from colleagues may or may not be based on facts.

## Evidence-based medicine

In 1990, a new philosophy of medical practice was developed at McMaster's University in Alberta, Canada. It emphasized that each clinical decision should be based on knowledge and understanding of the medical literature. This philosophy became known as evidence-based medicine (EBM), a term defined as follows in an internal document for medical residents:

"Residents are taught to develop an attitude of 'enlightened skepticism….' The goal is to be aware of the evidence on which one's practice is based, the soundness of the evidence, and the strength of inference the evidence permits."[8]

Evidence-based medicine also suggests that there is a formal set of rules that complements training and common sense when clinicians interpret the results of clinical research.

The details of this philosophy are spelled out in a series of articles published in the *Journal of the American Medical Association* starting in 1993 and culminating in the recent publication of the *Users' Guides to the Medical Literature: A Manual for Evidence-Based Clinical Practice*.[8] It outlines basic skills for evaluating the literature that every practicing physician should have. Since its conception the process has evolved, especially with regard to its application to surgery.

Using the strict criteria of evidence-based medicine to evaluate surgical procedures has been frustrating. In 1997, the Royal Australasian College of Surgery established a pilot project to provide an evidence base to support the introduction of new procedures into surgery. It's called ASERNIP-S, which is the acronym for the Australian Safety and Efficacy Register of New Interventional Procedures—Surgical, and its Web site is located at *http://www.surgeons.org/open/asernip-s.htm*. The Royal College developed a process to comprehensively review all relevant literature about a new procedure and to assign it to one of three categories: (1) the procedure is safe and efficacious; (2) it is unsafe; or (3) there is insufficient data to determine its safety and efficacy. Of the first 16 procedures reviewed, all but two fell into the undetermined category. There may be less scientific basis for our surgical practices than we would like to admit. Using classical rules of evidence on surgical procedures has not been productive.

Dr. Meakins, former Vice-Chair of the Board of Regents and current chair of CESTE, has written extensively on changes in technology and the usefulness of evidence-based medicine in surgery.[9] He makes a strong case for modifying the rules of evidence for surgical procedures and for including carefully controlled observational studies in their evaluation. He summarizes the five steps involved in the practice of EBM: (1) define the question or problem; (2) search for the evidence; (3) critically appraise the literature; (4) apply the results; and (5) audit the outcome.[10]

Dr. Meakins and his colleagues at McGill University Health Center in Montreal, PQ, have done this. They have set up a diverse committee that routinely scans the horizon for potentially significant new data and new procedures. The members of the committee critically evaluate the data, assess its applicability, make a decision to incorporate the new procedure into their group practice, and have a refined process to ensure that all surgeons offering the new procedure are adequately trained and proctored. Performance is monitored and all outcomes are recorded. This process is a model for assessing new technology that all of us could emulate.

However, most practicing surgeons don't have the time, skill, or resources to do systematic reviews of the original literature. There were over 2,000 surgically related randomized controlled trials published last year. Fortunately, preassessed critical reviews and published practice guidelines are becoming increasingly available. The *British Journal of Surgery* has a section specifically directed to critical appraisal, entitled "Systematic Reviews." The October issue of the *Journal of the American College of Surgeons* introduced a new section called "Evidence-Based Surgery," which will be a regular feature of the journal.

Several collections of critical reviews are also available on the Internet: Here are some examples of their home pages:

- The Cochrane Library, *www.cochrane library.com*
- National Guideline Clearinghouse, *www. guideline.gov*
- Cancer Care Ontario's Program in Evidence-Based Care, *www.ccopebc.ca*.

## Future steps

The College has an opportunity to use its communications resources, like our electronic newsletter *ACS NewsScope*, to quickly disseminate information on significant new critical reviews and practice guidelines.

An exciting development at the College is a project headed by Alden Harken, MD, FACS, a Regent, called the American College of Surgeons Safety and Efficacy of Innovative Procedures and Technology in Surgery. Although similar to the ASERNIP-S program of the Royal Australasian College of Surgery, it uses recently developed data-review strategies and creates additional categories that include a place for surgical procedures that may be recommended but that have not yet reached the level of standard of care.[11] A recommendation of this type might be just the information surgeons considering a procedure for their practice might need.

Once a surgeon makes a decision to learn a new technique or procedure, his or her training must be adequate. Surgeons need to choose courses that incorporate well-defined objectives, clear structure, and thorough evaluation. The College needs to develop mechanisms to verify that the courses in new technology meet these standards.

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The final step in the process of incorporating new technology into practice is proctoring the procedure. There is a learning curve for any new technique. In other words, complications are more frequent during a surgeon's first few procedures. For example, a 1995 study of 55 surgeons who performed more than 8,000 laparoscopic cholecystectomies showed that 90 percent of the injuries occurred within a surgeon's first 30 cases.[12] Thus, it is mandatory that the surgeon is as high on the learning curve as reasonably possible before he or she operates independently. Proctors provide the necessary bridge between a surgeon's technical training and his independent performance of a new procedure. Their role includes super-

vision, teaching, role modeling, and evaluation. Many surgeons have difficulty finding suitable proctors. The College needs to facilitate this necessary link by encouraging experienced surgeons to offer their services and by assisting surgeons in locating proctors. In rural areas, the College might consider setting up regional preceptor programs and providing proctors with assistance and guidelines.

Evolving theories of adult education will result in more efficient techniques of teaching, methods that will ensure changes in physicians' performance. The College needs to develop new ways to teach surgeons by using skill laboratories, surgical simulators, and eventually distance learning techniques using high-speed Internet communications. Surgeons will need to discover new sources of information and adapt to new ways of learning.

Let me leave you with a final thought. All of you in the class of 2002 will be faced with continual changes in your practice and will confront the challenges of incorporating new technology into the work that you do. Dr. Carrico left us all with a legacy both by example and through the work of CESTE. Ultimately, the responsibility of wisely incorporating new technology into your daily practice lies in the principles you have sworn to uphold as a Fellow of the College and will depend on your integrity, your commitment to lifelong learning, your professionalism, and your desire to put the welfare of your patients above all other considerations. Ω

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