

Office of Evidence-Based Surgery

charts course for
improved system of care

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In 2000, the American College of Surgeons began a long-range strategic planning process, culminating in the reorganization of the College into four divisions: the Division of Advocacy and Health Policy, the Division of Education, the Division of Member Services, and the Division of Research and Optimal Patient Care. The Division of Research and Optimal Patient Care encompasses the cancer and trauma programs.

Additionally, in February 2001, the Board of Regents established the Office of Evidence-Based Surgery upon the recommendation of a special task force. This article primarily focuses on the new Office of Evidence-Based Surgery—its present responsibilities and its long-range goals, particularly in the realm of optimal patient care.

The new Office of Evidence-Based Surgery will provide the administrative support and infrastructure to support health services, clinical, and laboratory research. The office will foster the conduct of systematic reviews, clinical trials, and outcome studies. Another important goal of the office will be to provide practicing surgeons with easy access to the best evidence available to support best practices. This aim requires close collaboration with the Division of Education.

Background

All Fellows of the American College of Surgeons should concur that optimal patient care is the objective of each surgeon's professional life and of all facets of the medical profession. We all strive for optimal care, effective care, and high-quality care. If that is true, then we can all agree to work together to provide optimal, effective, high-quality patient care. We can define optimal patient care as a common goal.

While surgical care in North America is excellent, questions about quality frequently arise. Professionals, the government, and the public express concern about the safety of surgical care. The application of some operations, such as prostatectomy or coronary artery bypass grafting, varies by region and demographic groups. National morbidity or mortality rates for hospitals or for surgeons are unknown. Governments, public interest groups, and payors want quality indicators for medical and surgical care to assist in selecting surgeons and hospitals for their clients. Nationally,

we currently lack scientifically valid, accurate, and useful measures of surgical quality.

The accomplishment of optimal surgical care throughout North America will require planning and direction, a road map. Perhaps the best word here is system. The achievement of optimal surgical care throughout our land will require an organized and integrated system of surgical care, one that is organized and operated by surgeons. This system of surgical care consists of four interconnected steps (see Figure 1, p. 13): (1) the establishment and maintenance of an accessible reservoir or repository of the best available scientific evidence for translation into everyday practice; (2) documentation of the results of surgical care with reliable outcome studies; (3) development of a disciplined process for introducing new technology and innovative practices into everyday practice; and (4) a well-organized and productive clinical trials program to expand the scientific evidence base and elevate the overall quality of scientific evidence.

While establishing a system of high-quality surgical care will be a sufficiently formidable task, we must accomplish at least one more objective: we must communicate. We must communicate with the public, we must communicate with our state and federal governments, and we must communicate with all other stakeholders in the health care system. Our communication must be based on accurate data; it must be timely, truthful, and crystal clear.

The evidence base

Before proceeding we should define evidence. According to *The Random House Dictionary of the English Language* (Random House, New York, 1969), evidence means "ground for belief; that which tends to prove or disprove something; proof." This very definition provides a perfect prologue for the subject of this article. It implies a spectrum of confidence or rigor from "ground for belief" to "proof." All surgeons, of course, practice evidence-based surgery. Hippocrates practiced evidence-based surgery. Today, the catch is that some types of evidence are more evidence than other types of evidence.

Scholars recognize a hierarchy of evidence and have developed taxonomy to describe best evidence. Sackett and others defined evidence-based medi-

cine as the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients. They went on to stress the value of the physician's (or surgeon's) clinical expertise and urged the integration of best evidence with clinical skill.

Let's focus on "current best evidence." Thoughtful surgeons seek "proof" to support their decisions and actions. Unfortunately, "proof" remains scarce in the complex reality of clinical practice. Often "ground for belief" is the best we can do. Surgeons should always seek the best evidence to support their decisions.

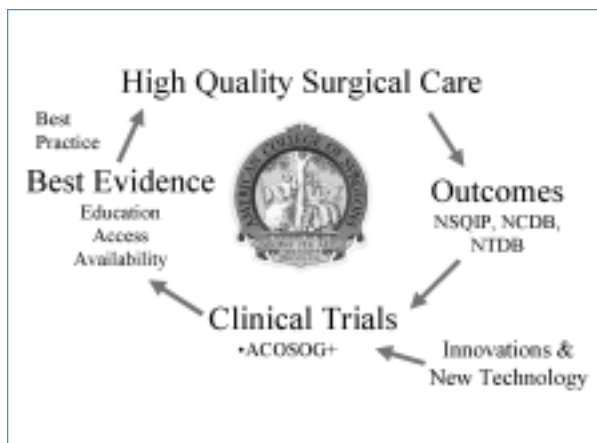
And, indeed, there is an evidence hierarchy. About 25 years ago clinical scholars began to focus on decision making in medical practice and observed that care was often based on individual experience, dogma, animal experiments, and outmoded information. This realization led to critical inspection of the evidence used in practice and a systematic ranking. The ranking has improved with time, culminating in the establishment of the Oxford Centre for Evidence-Based Medicine Levels of Evidence in May 2001 (see Figure 2, p. 14-15).

Today, the highest level of evidence is the systematic review of homogeneous randomized clinical trials. The next level is an individual randomized clinical trial with narrow confidence intervals. The 1c level of evidence, called "all or none," occurs when all patients died before the treatment became available, but some live with the treatment; or when some patients died before the treatment, but none die after the treatment became available. Level 2 evidence includes systematic reviews of cohort studies, individual cohort studies, and outcomes research. Systematic reviews of case-control studies and individual case-control studies comprise level 3 evidence. Case series, poor-quality cohort, and case-control studies provide level 4 evidence. The lowest level of evidence, level 5, comes from expert opinion without explicit appraisal based on physiology, bench research, or first principles. The evidence hierarchy is clear. Figure 2 spells it out.

Evidence-based medicine

The evidence-based medicine movement has evolved more rapidly and effectively in medical disciplines than in surgical disciplines for many

Figure 1.



reasons. Prospective randomized clinical trials represent the highest level of evidence to support clinical practice. Because of federal regulations, pharmaceutical companies cannot enter new products into routine use without proof of safety. Clinical trials, therefore, became essential for the introductions of new drugs and devices, and pharmaceutical companies found it in their best interests to fund clinical trials. Clinical trials are relatively easy to carry out with drugs. Surgical clinical trials are very difficult, and most surgeons are unwilling to participate in trials because of the paperwork, the hassle, and the discipline required. Patients, too, are frequently unwilling to participate in trials. Furthermore, government imposes less stringent regulations on the introduction of new technology and new operations than for new drugs. For these reasons, surgeons have less understanding of clinical trials and less clinical-trial evidence upon which to base their practice than do nonsurgeons. Today, in North America, most surgical specialists base their practice on uncontrolled case series and uncontested expert opinion.

A surgeon seeking to apply the best evidence to the care of his or her patients certainly can do so, because much high-level evidence exists. Best evidence resides on the shelves and in the stacks of every hospital library and every medical center

Figure 2. Oxford Centre for Evidence-Based Medicine—Levels of Evidence

Level	Therapy/ prevention, aetiology/harm	Prognosis	Diagnosis	Differential diagnosis/ symptom prevalence study	Economic and decision analysis
1a	SR (with homogeneity) of RCTs	SR (with homogeneity) of inception cohort studies; CDR validated in different populations	SR (with homogeneity) of level 1 diagnostic studies; CDR with 1b studies from different clinical centres	SR (with homogeneity) of prospective cohort studies	SR (with homogeneity) of level 1 economic studies
1b	Individual RCT (with narrow confidence interval)	Individual inception cohort study with 80% follow-up CDR validated in a single population	Validating cohort study with good reference standards; or CDR tested within one clinical centre	Prospective cohort study with good follow-up	Analysis based on clinically sensible costs or alternatives, systematic review(s) of the evidence, and including multi-way sensitivity analyses
1c	All or none	All or none case-series	Absolute SpPins and SnNouts	All or none case-series	Absolute better-value or worse-value analyses
2a	SR (with homogeneity) of cohort studies	SR (with homogeneity) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity) of level > 2 diagnostic studies	SR (with homogeneity) of 2b and better studies	SR (with homogeneity) of level > 2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., < 80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; derivation of CDR or validated on split sample or databases	Exploratory cohort study with good reference standards; CDR after derivation, or validated only on split-sample or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives, limited review(s) of the evidence, or single studies, and including multi-way sensitivity analyses

SR = Systematic Review, RCT = Randomized Clinical Trial, CDR = Clinical Decision Rule.

library in North America. Surgeons who want to spend every night, every weekend, and every day off in the library can maintain a fair base of best evidence to support a practice. Of course, that level of activity is impractical.

Fortunately, computerized literature search capabilities are at the fingertips of every surgeon.

Medline, Ovid, and PubMed are available at low cost, permitting access to the best evidence extant.

Nonetheless, practicing surgeons live under an avalanche of information about the diseases they treat. No one today can keep up with all the publications in all of the journals even in a small and focused specialty. Fortunately, we can turn to other

Figure 2. Oxford Centre for Evidence-Based Medicine—Levels of Evidence (contd.)

Level	Therapy/ prevention, aetiology/harm	Prognosis	Diagnosis	Differential diagnosis/ symptom prevalence study	Economic and decision analysis
2c	“Outcomes” research: ecological studies	“Outcomes” research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity) of case-control studies		SR (with homogeneity) of 3b and better studies	SR (with homogeneity) of 3b and better studies	SR (with homogeneity) of 3b and better studies
3b	Individual case- control study		Non-consecutive study; or without consistently applied reference standards	Nonconsecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies)	Case-series (and poor quality prognostic cohort studies)	Case-control study, poor or non- independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”	Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or “first principles”	Expert opinion without explicit critical appraisal or based on physiology, bench research, or “first principles”	Expert opinion without explicit critical appraisal, or based on economic theory or “first principles”

Source: The Oxford Centre for Evidence-Based Medicine, Web site: http://www.indigojazz.uk/cebm/levels_of_evidence.asp. May 2001.

sources for help. Professional organizations have developed standardized methods for reviewing the literature to select the best scientifically disciplined publications into collections or other formats readily accessible to practicing physicians and surgeons electronically. Figure 3 (p. 16) lists the available excellent sources of best evidence. The

Cochrane Library has been available for about 10 years and has set the standard for providing high-quality critically edited and evaluated summaries of prospective randomized trials. The *British Medical Journal* also sponsors a collection of excellent information on wide array of topics (www.clinicalevidence.org). Practicing surgeons

Figure 3. Medical information resource contact information

Resource	Internet address	Annual cost, \$
<i>Best Evidence</i>	http://www.acponline.org/catalog/electronic/best_evidence.htm	
Cochrane Library	http://www.updateusa.com/cochrane.htm	225
UpToDate	http://www.uptodate.com	495 (CD-ROM)
MEDLINE		
PubMed	http://www.ncbi.nlm.nih.gov/PubMED	Free
Internet Grateful Med	http://www.nlm.nih.gov	Free
Other sources	http://www.medmatrix.org/info/medlinetable.asp	Free
<i>Scientific American Medicine</i>	http://www.samed.com	245 (print and online versions) (159 for online access only)
<i>Clinical Evidence</i>	http://www.evidence.org/index-welcome.htm	To be announced (115 in print)
<i>Harrison's Online</i>	http://www.harrisonsonline.com	89
eMedicine	http://www.edmedicine.om	Free
Medical Matrix	http://www.medmatrix.org/reg/login.asp	Free
SchHARR Netting the Evidence	http://www.shef.ac.uk/uni/academic/R-Z/scharr/lr/netting.html	Free
Medical World Search	http://www.mwsearch.com	Free
Journal listings	http://www.nthames-health.tpmde.ac.uk/connect/journals.htm	Free
	http://www.pslgroup.com/dg/medjournals.htm	Free
Clinical practice guidelines	http://www.guidelines.gov	Free
	http://www.cma.ca.cpgs	Free
MD Consult	http://www.mdconsult.com	199.95
EBMR Reviews (OVID)	http://www.ovid/products/cip/ebmr/cfm	1,275 (institutional price for one user)

Source: Hunt DL, Jaeschke R, McKibbin KA: User's guides to the medical literature XXI: Using electronic health information resources in evidence-based practice. *JAMA*, 283:1875-1879, 2000.

can efficiently search these sources and find the best evidence.

These special sources of best evidence strive for high relevance and validity, with low work for the user. Slawson and others express this very clearly when they state: the usefulness of any source of information is equal to its relevance, multiplied by its validity, divided by the work required to extract the information.

The problems

So, what are the problems? The first problem is a pervasive lack of understanding and appreciation of the scientific method. Every medical school graduate has experienced instruction in the sci-

entific method and the role of evidence in research and in clinical practice. But after a period of active surgical practice, even in research-oriented hospitals, surgeons are apt to make practice decisions based on their recollection of past experience, a recent journal article (usually an uncontrolled case series), or what they learned in residency from their chief many years ago.

The second problem is the lack of access to best evidence to support surgical care. Although excellent resources such as the Cochrane Collection are available, they fail to provide a wide array of information on surgical problems. While the Cochrane Collection has expert surgeons on its review panels and excellent reviews appear, generally we find carefully assembled information on

asthma, heart failure, arthritis, arrhythmia, and so on. A wide selection of surgical topics is lacking—not absent for sure, but lacking. There are several possible reasons for this dearth of material. One explanation is that these important resources have been organized and are operated by nonsurgeons who, quite naturally, focus on matters they face regularly.

The third problem we face is the relative lack of high-quality, well-designed, and well-conducted prospective randomized clinical trials on surgical conditions. Surgical journals abound with case series alongside a paucity of clinical trials. Several factors impede the conduct of surgical clinical trials. Few surgeons have the knowledge, skills, and commitment needed to carry out clinical trials. Clinical trials require time, energy, and paperwork. Clinical trials in surgery are difficult to design and conduct. Patients are more reluctant to participate in surgical trials than in medical trials. And, importantly, clinical trials cost a lot of money, and because drugs usually are not involved, pharmaceutical companies generally are not involved, so funding for surgical trials must come from government sources or private funds.

Some surgical problems do not require prospective randomized clinical trials to guide proper treatment. Some surgical problems do not lend themselves to clinical trial investigation. We should strive to identify important surgical issues that need study with clinical trials.

The challenges

Implementation of the practice of evidence-based surgery poses several formidable challenges. The first and most important is to educate surgeons. This process should begin immediately in postgraduate training and continue for the remainder of the surgeon's professional life.

The American College of Surgeons should include courses on evidence-based surgery at the Clinical Congress and the Spring Meeting. For several years, the College has provided an excellent annual clinical trials course. This year, the Clinical Congress will include a postgraduate course on evidence-based medicine. In addition to courses on the principles of evidence-based medicine, the College should insist that all courses, symposia,

and other presentations at its official programs reflect the best available evidence.

Several authors have criticized various surgical journals for lacking scientific rigor and discipline. As mentioned previously, uncontrolled case series substantially outnumber the publication of randomized trials. Editors should strive to publish manuscripts of the highest scientific discipline that are relevant to current practice. Publications should provide new knowledge or insights that have the potential for changing surgical practice for the better. Slawson and others, in selecting material for an evidence-based source of information for family doctors, refer to good manuscripts as POEMS—patient-oriented evidence that matters.

The best work includes prospective randomized clinical trials. The patients in the trials should be reflective of the overall patient population, so that the results of the study can be applied broadly.

Proper clinical trials must employ concealed allocation of subjects to treatment or control groups. The study could be biased if investigators know or influence which group the subjects enter.

An accounting must be taken of all patients entering the trial. Patients who are lost during the trial and follow-up must be acknowledged. Studies with large drop-out rates should not be published. Most biostatisticians favor the intention-to-treat analysis. That is, if a subject is randomly assigned to a treatment or control group and subsequently refuses the therapy or control designation, or otherwise changes status, he or she will continue to be regarded as a member of the assigned group.

Studies work better if neither the subjects nor the investigators know if the subjects are in the experimental or the control group. These double-blind studies are frequently impossible in surgical research. The experimental and control groups must be similar. The randomization process must provide comparable groups. Dissimilar groups may introduce bias. A valid study must include enough subjects to permit confidence in the results. Statistical power is very important, particularly in negative studies.

Another important challenge facing surgeons is to expand the available pool of best evidence. Today, we face a shortage of 1a and 1b evidence in most surgical disciplines. Obviously, random-

ized clinical trials are not necessary for the treatment of many surgical diseases. Trials cannot answer all questions, but we should systematically identify those areas in which trials are needed and marshal the resources to conduct the trials. When we lack 1a and 1b evidence, experts and scholars in the field should recognize and communicate the best evidence available and encourage surgeons to incorporate best evidence into their practices.

Office's response

A vision and long-term goal of the ACS Office of Evidence-Based Surgery is to establish and maintain a repository of best evidence for the practice of surgery. This database could be developed in partnership with an existing organization or independently as a service provided by the College. This project would require substantial resources and expertise but would greatly facilitate the quality of surgical practice. A best-evidence repository assembled through systematic literature searches and data from ongoing surgical trials would become the basis of guidelines to assist surgeons in their practices. Best evidence would shape high-quality surgical practice.

How can we ever know if best evidence will lead to high-quality surgical practice? We measure it. In 1994 the Veteran's Administration (VA) Health System established the National Surgical Quality Improvement Program (NSQIP), the first and only prospective, risk-adjusted, validated database for quantifying 30-day surgical outcomes. A NSQIP nurse at each of 122 VA hospitals collects and verifies the data, then submits it electronically to the data coordinating centers. Feedback to the surgical services includes: (1) comparative, site-specific, and outcome-based annual reports; (2) periodic assessment of performance; (3) self-assessment tools; (4) structured site visits; and (5) dissemination of best practices. Since NSQIP's inception, 30-day postoperative mortality following major surgery decreased by 27 percent and 30-day morbidity by 45 percent.

The investigators tested NSQIP in three nonfederal university hospitals: the University of Michigan, Ann Arbor; the University of Kentucky, Lexington; and Emory University Hospital, Atlanta, GA. In these three alpha sites NSQIP per-

formed very well in general surgery and in vascular surgery.

Now NSQIP and the ACS, with support from a grant from the Agency for Healthcare Research and Quality (AHRQ) are testing NSQIP in 11 additional university hospitals, making 14 beta sites. Presently, the investigators are evaluating the data from the first year of this study. If NSQIP is valid in the beta sites, the VA and ACS in collaboration will work to establish NSQIP throughout the private sector as rapidly and efficiently as possible. Also, the investigators will expand the project to include quality-of-life measures and to continue measures beyond 30 days.

NSQIP has the potential to quantify surgical quality in every hospital in North America and beyond. This will be a great service and resource to patients, to the public, and to our profession. In addition, our profession must address the issue of surgical errors. Quantification is an important step in minimizing surgical errors. NSQIP can document errors and allow systematic and methodical approaches to their elimination. The NSQIP database will also direct attention to those areas of surgical care that have high priority for improvement and can therefore facilitate the planning of surgical trials.

The National Cancer Data Base (NCDB) represents another quality improvement tool at the College's disposal. The Commission on Cancer and the American Cancer Society established the NCDB approximately 10 years ago. Reports from 1,500 hospitals in 50 states form this nationwide database, which contains information on more than 11 million cancer patients. The database includes detailed information about pathology, staging, treatment, and outcomes, including five-year survival. Currently the NCDB provides feedback information to the approved cancer centers. Soon the data in the NCDB will be available to Fellows through the College Web site. The NCDB is available for scholars to pursue research questions and to plan clinical research projects.

Another College repository, the National Trauma Data Bank™ (NTDB™), exists as a result of collaboration between the American College of Surgeons and 130 hospitals dedicated to the care of injured patients. This maturing resource owes its success to the leadership and the abundant energy and talent of the Committee on Trauma.

Improving software and attention to information technology contribute to improvement in the NTDB. From 1994 through 1999 data pertaining to 542,841 injured patients were included. The bank records 92 data points on each patient and covers demographics, diagnosis, procedures, outcomes, as well as injury scene and facility characteristics. The NTDB, therefore, represents an important resource for improving the quality of care of trauma victims by enabling outcome studies as well as a broader range of clinical research.

Technological innovation

The American College of Surgeons must play a leading role in the introduction of new technology into clinical practice. New knowledge and technology are growing and advancing at far faster rates than the medical profession can safely and effectively incorporate the changes into practice. In 1994, the College established the Committee on Emerging Surgical Technologies and Education (CESTE), which developed guidelines for emerging surgical technologies and their application to the care of patients. The *Statements on Principles* of the American College of Surgeons require early and continued institutional review board evaluation of the protocol, a full description of the procedure, and the informed consent of the patient. These guidelines are open to interpretation and are not restrictive.

Today uncertainty about what constitutes surgical innovation and surgical research remains in the minds of surgeons and in the minds of the editors of surgical journals. CESTE will take a leading role in resolving this ambivalence. The reason for mentioning this point is that after CESTE recognizes new technology and defines surgical research, we must facilitate the examination of new technology and innovations by prospective randomized clinical trials. Our profession must encourage innovation and encourage the development of new technology. No two surgical operations are identical, and surgeons often encounter unexpected findings. Innovation is fundamentally essential for successful surgical practice. When innovative change becomes research is difficult to define. Marked departures from prior practice deserve evaluation before acceptance.

The introduction of new technology presents a

slightly different problem. Of course the introduction of new technology is essential to progress and improved care. But, new operations and new devices should be evaluated for safety and efficacy before they are introduced for general use. In addition, new operations and devices should be compared with current practice before general application. Our profession must protect the public from ineffective and potentially dangerous new devices and operations.

Clinical trials

Clinical trials provide the most important source of information recognized by evidence-based medicine scholars. In 1996, Samuel A. Wells, Jr., MD, FACS, proposed to the Board of Regents that the American College of Surgeons establish a multicenter cooperative group to conduct prospective randomized clinical trials to evaluate the surgical management of patients with malignant solid tumors. With support from the College and the National Cancer Institute, a group of surgeons worked with Dr. Wells to develop a clinical trials program called the American College of Surgeons Oncology Group (ACOSOG). With five years' funding, ACOSOG began in May of 2000 as one of nine cooperative clinical trials groups funded by the National Cancer Institute. Of the nine groups, only ACOSOG has the primary responsibility of studying the surgical treatment of cancer.

Initially ACOSOG was based in the College's Chicago headquarters. As the program grew, however, the leadership of ACOSOG recognized that it would function better and develop faster if located in an academic environment. For that reason, ACOSOG moved to the Duke Clinical Research Institute (DCRI) at Duke University in Durham, NC, January 1, 2002. The DCRI possessed the personnel, the infrastructure, and proper research environment to provide optimal opportunity for ACOSOG's growth and development. ASOSOG's current success underscores and validates the wisdom in the decision for relocation into an established clinical research environment.

The DCRI provided abundant, well-designed offices and facilities to house the current staff of 50 individuals, including surgeons, biostatisticians, data managers, and other clinical research staff.

While the program is working well, it will need to increase in size substantially if it is to reach its anticipated level of productivity. It especially needs more personnel in statistics and in clinical trials management.

There are currently 3,079 members of ACOSOG and 643 active member participating groups. The membership includes surgeons in academic centers, surgeons in private practice, medical oncologists, radiation oncologists, diagnostic oncologists, and nurses. Members from Australia, Canada, and Ireland currently contribute actively to patient accrual. Surgeons in private practice enter a large proportion of patients into ACOSOG trials. This is a splendid opportunity for practicing surgeons of all venues and specialties to participate in important clinical research and to stay abreast or even ahead of new scientific and clinical concepts in cancer treatment. The program also provides an opportunity for practicing surgeons to learn how to perform new operations and to apply new techniques. We encourage Fellows of the College, whether in private practice or in academic practice, to join ACOSOG, to enter patients into trials, and to participate in the programs.

Today, ACOSOG manages 16 clinical trials investigating a wide range of neoplasms, including breast cancer, lung cancer, prostate cancer, melanoma, metastatic brain cancer, esophageal cancer, pancreatic cancer, gastrointestinal stromal tumors, and head and neck cancer. ACOSOG recently completed a trial testing the effectiveness of PET scanning in staging lung cancer.

ACOSOG meets twice a year, in November and June, to plan and review the activities of the group as well as to provide continuing education to the participants. The group devotes one afternoon to a basic science seminar for active and prominent scientists to present lectures and discussions of the latest research relevant to the pathogenesis, diagnosis, and treatment of solid tumors. During these meetings, 14 organizing committees meet to address such issues as ethics, membership, patient advocacy, nursing education, special populations, auditing, and basic science. Committees also address diagnostic radiology, international relations, quality of life, radiation oncology, and tumor registries. The Executive Committee reviews and directs the total activities of the group. The 10 Organ Site Committees develop topics for trials, pre-

pare protocols for NCI review, and monitor the progress of open trials.

In addition to ACOSOG, the Office of Evidence-Based Surgery manages clinical trials in fields other than cancer. We are working to expand clinical trial opportunities in other disciplines. For example, the Committee on Trauma is currently focusing on conducting clinical trials upon which to establish guidelines for trauma care. Important questions abound in other disciplines such as vascular surgery, thoracic surgery, cardiac surgery, general surgery, and so on, which could be answered with clinical trials.


Conclusions

It was the best of times, it was the worst of times, it was the age of wisdom, it was the age of foolishness, it was the epoch of belief, it was the epoch of incredulity, it was the season of Light, it was the season of Darkness, it was the spring of hope, it was the winter of despair, we had everything before us, we had nothing before us, we were all going direct to Heaven, we were all going direct the other way—in short, the period was so far like the present period, that some of its authorities insisted on its being received, for good or for evil, in the superlative degree of comparison only. (Charles Dickens, *A Tale of Two Cities*.)

Today, medicine in general and surgery in particular can cure more disease with greater effectiveness, with greater precision, and less pain than ever before. But, today, the rising cost of health care continues to erode the fabric of our society. Patients are suing physicians, patients are suing health insurance companies, physicians are suing health insurance companies, professional organizations are suing the government, governments are suing the pharmaceutical industry, the pharmaceutical industry is suing governments, physicians are going on strike, and union workers disgruntled about health care are going on strike.

Lawyers cannot solve this problem; health insurance companies cannot solve this problem; government cannot solve this problem; a discontented public cannot solve this problem. The medical profession can and must solve this problem. The American College of Surgeons must work to solve this problem by systematically addressing the chal-

lence of improving the quality of surgical care throughout North America.

The American College of Surgeons will promote a system of surgical care for the twenty-first century designed for safety and high quality. This article describes the loop of related sequential steps that provide the framework for the system: a system of quality improvement. The components of the system are in place today but will require support and management. The American College of Surgeons must do this. 

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