Mark K. Ferguson *Editor*

Difficult Decisions in Thoracic Surgery

An Evidence-Based Approach

Second Edition



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Preface to the First Edition

Why do thoracic surgeons need training in decision making? Many of us who have weathered harrowing residencies in surgery feel that, after such experiences, decision making is a natural extension of our selves. While this is no doubt true, *correct* decision making is something that many of us have yet to master. The impetus to develop a text on evidence-based decision making in thoracic surgery was stimulated by a conference for cardiothoracic surgical trainees developed in 2004 and sponsored by the American College of Chest Physicians. During that conference it became clear that we as thoracic surgeons are operating from a very limited fund of true evidence-based information. What was also clear was the fact that many of the decisions we make in our everyday practices are not only uninformed by evidence-based medicine but often are contradictory to existing guidelines or evidence-based recommendations.

The objectives of this book are to explain the process of decision making, both on the part of the physician and on the part of the patient, and to discuss specific clinical problems in thoracic surgery and provide recommendations regarding their management using evidence-based methodology. Producing a text that will purportedly guide experienced, practicing surgeons in the decision making process that they are accustomed to observe on a daily bases is a daunting task. To accomplish this it was necessary to assemble a veritable army of authors who are widely considered to be experts in their fields. They were given the unusual (to many of them) task of critically evaluating evidence on a well-defined topic and provide two opinions regarding appropriate management of their topic: one based solely on the existing evidence, and another based on their prevailing practice, clinical experience, and teaching. Most authors found this to be an excellent learning experience. It is hoped that the readers of this book will be similarly enlightened by its contents.

How should a practicing surgeon use this text? As is mentioned in the book, wholesale adoption of the stated recommendations will serve neither physician nor patient well. The reader is asked to critically examine the material presented, assess it in the light of his or her own practice, and integrate the recommendations that are appropriate. The reader must have the understanding that surgery is a complex, individualized, and rapidly evolving specialty. Recommendations made today for one patient may not be appropriate for that same patient in the same situation several years hence. Similarly, one recommendation will not serve all patients well. The surgeon must use judgment and experience to adequately utilize the guidelines and recommendations presented herein.

To produce a text with timely recommendations about clinical situations in a world of rapidly evolving technology and information requires that the editor, authors, and publisher work in concert to provide a work that is relevant and up-to-date. To this end I am

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grateful to the authors for producing their chapters in an extraordinarily timely fashion. My special thanks go to Melissa Morton, Senior Editor at Springer, for her rapid processing and approval of the request to develop this book, and to her staff for the rapid processing of the manuscripts. My thanks go to Kevin Roggin, MD, for sharing the T.S. Eliot lines and the addendum to them. Finally, the residents with whom I have had the opportunity and privilege to work during the past two decades continually reinforce the conviction that quality information is the key to improved patient care and outcomes.

Mark K. Ferguson, MD Chicago, IL March 27, 2006

Preface to the Second Edition

Since the publication of the first edition of this book, considerable progress has been made in the fields of risk assessment, decision analysis, and evidence-based medicine. That this has occurred during a challenging period in our history is testament to the importance of these fields in the advancement of medical and surgical sciences. The recent world wide financial crisis, which, at the time of this writing has only just begun to reverse its course, has focused considerable attention on health care as a source of increasing financial burden, especially in the United States. Those seeking to reduce costs are looking more closely at innovative means for making therapeutic recommendations and use of objective measures of outcomes in assessing appropriateness of care. The term "comparative effectiveness," which until recently was unknown by the general public, has become a catch phrase that represents something good to some and everything evil to others, depending on their stance on health care reform.

In compiling the second edition of this book, I'd like readers to know that I don't have a dog in the fight over healthcare reform. The recommendations in this book were sought on topics that are clinically important in the daily lives of surgeons and for which there appeared to be lack of a standard approach to assessment and management. Possible reasons for such failure of consensus may be absence of suitable data, lack of access to such data, inability to apply innovations owing to cost or other constraints, or simple unwillingness to change. This book will hopefully define for each clinical question that is posed whether data of sufficient quality exist to permit recommendations regarding appropriate care, and certainly can serve as a source of clinical information for surgeons and other interested readers to consider. It is not intended to influence current constraints to proper care, and it unlikely to alter attitudes of surgeons who believe that their opinions and experience trump the dictums of quality data.

This book is intended as a resource for clinical surgeons and other interested readers who wish to understand how experts in the field assess existing knowledge. The authors were asked to identify relevant publications in their selected topics, grade the quality of the evidence offered by those reports, apply that knowledge to objective management recommendations in an idealized world, and then comment on how they personally use the information in their own clinical practices. The book is not intended to be used as a recipe for management of patients in a rote manner. As with all clinical care, consideration must be given to the individual needs of patients as well as the clinical, institutional, and societal milieu in which the care is provided.

Why create a second edition of this book? The primary reason is that there has been considerable enthusiasm for an approach of this type, and it's necessary to create new

χ Preface to the Second Edition

recommendations periodically as the fields of medicine in general, and thoracic surgery in particular, evolve. That having been said, this is not just an update of the first edition. More than 50% of the clinical questions posed in this book are new, and of the questions that remain as holdovers from the prior edition, virtually all have been rewritten by new authors. In addition, the grading system used for evidence quality and strength of recommendations has been changed from the systems used in the previous text to make the summaries clearer and more user friendly.

To enable the reader access to up-to-date information, authors were asked to provide their chapters within five months of the inception of this edition, an extraordinarily brief period of time for busy clinical surgeons who also carry considerable additional academic and administrative roles. That they were almost universally able to comply is evidence of the commitment of each to the advancement of the art and science of surgery and to the welfare of their patients. These surgeons were also asked to do something that is typically quite difficult for individuals who are considered experts in their selected fields and have gained international reputations for their opinions. They were asked to look critically at the body of evidence, reexamine their opinions and practice patterns, and objectively arrive at what was sometimes a new approach to their area of expertise. Having worked with the authors through several iterations of some of their chapters, I know how challenging this process was for many, and applaud all for taking on this role.

My hope is that readers will find the information and recommendations in this book insightful, and that the summaries and recommendations will stimulate them to read the original source material, consider the data, and make their own objective assessments. Only in this way will we progress from the time honored traditional training format of "see one, do one, teach one," which stifles insight, objectivity and creativity. Instead, I encourage critical evaluation of information and innovation based in established principles (rather than patterns) of clinical care to improve the outcomes in our surgical patients.

Producing a book of this size in a short time requires the help of a number of individuals. I thank the residents and fellows with whom I work, who, through our daily clinical activities and teaching exercises, stimulate identification of the controversial questions found herein. My gratitude goes to the authors, their co-author residents, fellows, and students, and their administrative assistants for all of the hard work required to produce succinct and meaty chapters, and for putting up with my endless requests for revisions. I am indebted to Melissa Morton, Senior Editor at Springer, for fast-tracking the concept and expediting the production of this volume. I also am grateful to Denise Roland and Nadine Firth at Springer for keeping my colleagues on track and ushering the manuscripts through to the finished product.

Mark K. Ferguson, MD Chicago

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Part 1 Background

1 Introduction

Mark K. Ferguson

Dorothy Smith, an elderly and somewhat portly woman, presented to her local emergency room with chest pain and shortness of breath. An extensive evaluation revealed no evidence for coronary artery disease, congestive heart failure, or pneumonia. A chest radiograph demonstrated a large air-fluid level posterior to her heart shadow, a finding that all thoracic surgeons recognize as being consistent with a large paraesophageal hiatal hernia. The patient had not had similar symptoms previously. Her discomfort was relieved after a large eructation, and she was discharged from the emergency room a few hours later. When seen several weeks later in an outpatient setting by an experienced surgeon, who reviewed her history and the data from her emergency room visit, she was told that surgery is sometimes necessary to repair such hernias. Her surgeon indicated that the objectives of such an intervention would include relief of symptoms such as chest pain, shortness of breath, and postprandial fullness, and prevention of catastrophic complications of giant paraesophageal hernia, including incarceration, strangulation, and perforation. Ms. Smith, having recovered completely from her episode of a few weeks earlier, declined intervention, despite her surgeon's strenuous encouragement.

She presented to her local emergency room several months later with symptoms of an incarcerated hernia and underwent emergency surgery to correct the problem. The surgeon found a somewhat ischemic stomach and had to decide whether to resect the stomach or just repair the hernia. If resection was to be performed, an additional decision was whether to reconstruct immediately or at

the time of a subsequent operation. If resection was not performed, the surgeon needed to consider a variety of options as part of any planned hernia repair: whether to perform a gastric lengthening procedure; whether a fundoplication should be constructed; and whether to reinforce the hiatal closure with non-autologous materials. Each of these intraoperative decisions could importantly affect the need for a subsequent reoperation, the patient's immediate survival, and her long-term quality of life. Given the dire circumstances that the surgeon was presented with during the emergency operation, it would have been optimal if the emergent nature of the operation could have been avoided entirely. In retrospect, which was more correct in this hypothetical situation, the recommendation of the surgeon or the decision of the patient?

Decisions are the stuff of everyday life for all physicians; for surgeons, life-altering decisions often must be made on the spot, frequently without what many might consider to be necessary data. The ability to make such decisions confidently is the hallmark of the surgeon. However, decisions made under such circumstances are often not correct or even well reasoned. All surgeons (and many of their spouses) are familiar with the saying "...often wrong, but never in doubt." As early as the fourteenth century physicians were cautioned never to admit uncertainty. Arnauld of Villanova wrote that, even when in doubt, physicians should look and act authoritative and confident.1 In fact, useful data do exist that could have an impact on many of the individual decisions regarding elective and emergent 4 M.K. Ferguson

management of the giant paraesophageal hernia scenario outlined above. Despite the existence of these data, surgeons tend to make decisions based on their own personal experience, anecdotal tales of good or bad outcomes, and unquestioned adherence to dictums from their mentors or other respected leaders in the field, often to the exclusion of objective data. It is believed that only 15% of medical decisions are scientifically based,² and it is possible that an even lower percentage of thoracic surgical decisions are so founded. With all of our modern technological, data processing, and communication skills, why do we still find ourselves in this situation?

Early Surgical Decision Making

Physicians' diagnostic capabilities, not to mention their therapeutic armamentarium, were quite limited until the middle to late nineteenth century. Drainage of empyema, cutting for stone, amputation for open fractures of the extremities, and mastectomy for cancer were relatively common procedures, but few such conditions were diagnostic dilemmas. Surgery, when it was performed, was generally indicated for clearly identified problems that could not be otherwise remedied. Some surgeons were all too mindful of the warnings of Hippocrates: "...physicians, when they treat men who have no serious illness, ... may commit great mistakes without producing any formidable mischief ... under these circumstances, when they commit mistakes, they do not expose themselves to ordinary men; but when they fall in with a great, a strong, and a dangerous disease, then their mistakes and want of skill are made apparent to all. Their punishment is not far off, but is swift in overtaking both the one and the other." Others took a less considered approach to their craft, leading Hunter to liken a surgeon to "an armed savage who attempts to get that by force which a civilized man would get by stratagem."4

Based on small numbers of procedures, lack of a true understanding of pathophysiology, frequently mistaken diagnoses, and the absence of technology to communicate information quickly, surgical therapy until the middle of the nineteenth century was largely empiric. For example, by that time fewer than 90 diaphragmatic hernias had been reported in the literature, most of them having been diagnosed postmortem as a result of gastric or bowel strangulation and perforation.⁵ Decisions were based on dogma promulgated by word of mouth. This has been termed the "ancient era" of evidence-based medicine.⁶

An exception to the empiric nature of surgery was the approach espoused by Hunter in the mideighteenth century, who suggested to Jenner, his favorite pupil, "I think your solution is just, but why think? Why not try the experiment?" Hunter challenged the established practices of bleeding, purging, and mercury administration, believing them to be useless and often harmful. Theses views were so heretical that, 50 years later, editors added footnotes to his collected works insisting that these were still valuable treatments. Hunter and others were the progenitors of the "renaissance era" of evidence-based medicine, in which personal journals, textbooks, and some medical journal publications were becoming prominent.

The discovery of x-rays in 1895 and the subsequent rapid development of radiology in the following years made the diagnosis and surgical therapy of a large paraesophageal hernia such as that described at the beginning of this chapter commonplace. By 1908 x-ray was accepted as a reliable means for diagnosing diaphragmatic hernia, and by the late 1920s surgery had been performed for this condition on almost 400 patients in one large medical center.^{7,8} Thus, the ability to diagnose a condition was becoming a prerequisite to instituting proper therapy.

This enormous leap in physicians' abilities to render appropriate ministrations to their patients was based on substantial new and valuable objective data. In contrast, however, the memorable anecdotal case presented by a master (or at least an influential) surgeon continued to dominate the surgical landscape. Prior to World War II, it was common for surgeons throughout the world with high career aspirations to travel to Europe for a year or two, visiting renowned surgical centers to gain insight into surgical techniques, indications, and outcomes. In the early twentieth century Murphy attracted a similar group of surgeons to his busy clinic at Mercy Hospital in Chicago. His publication of case reports and other observations evolved into the Surgical Clinics of North America. 1. Introduction 5

Seeing individual cases and drawing conclusions based upon such limited exposure no doubt reinforced the concept of empiricism in decision making in these visitors. True, compared to the strict empiricism of the nineteenth century there were more data available upon which to base surgical decisions in the early twentieth century, but information regarding objective short-term and long-term outcomes still was not readily available in the surgical literature or at surgical meetings.

Reinforcing the imperative of empiricism in decision making, surgeons often disregarded valuable techniques that might have greatly improved their efforts. It took many years for anesthetic methods to be accepted. The slow adoption of endotracheal intubation combined with positive pressure ventilation prevented safe thoracotomy for decades after their introduction into animal research. Wholesale denial of germ theory by US physicians for decades resulted in continued unacceptable infection rates for years after preventive measures were identified. These are just a few examples of how ignorance and its bedfellow, recalcitrance, delayed progress in thoracic surgery in the late nineteenth and early twentieth centuries.

Evidence-Based Surgical Decisions

There were important exceptions in the late nineteenth and early twentieth centuries to the empiric nature of surgical decision making. Among the first were the demonstration of antiseptic methods in surgery and the optimal therapy for pleural empyema. Similar evidence-based approaches to managing global health problems were developing in non-surgical fields. Reed's important work in the prevention of yellow fever led to the virtual elimination of this historically endemic problem in Central America, an accomplishment that permitted construction of the Panama Canal. The connection between the pancreas and diabetes that had been identified decades earlier was formalized by the discovery and subsequent clinical application of insulin in 1922, leading to the awarding of a Nobel prize to Banting and Macleod in 1923. Fleming's rediscovery of the antibacterial properties of penicillin in 1928 led to its development as an antibiotic for humans in 1939, and it received widespread use during World War II. The emergency use of penicillin, as well as new techniques for fluid resuscitation, were said to account for the unexpectedly high rate of survival among burn victims of the Coconut Grove night-club fire in Boston in 1942. Similar stories can be told for the development of evidence in the management of polio and tuberculosis in the midtwentieth century. As a result, the first half of the twentieth century has been referred to as the "transitional era" of evidence-based medicine, in which information was shared easily through text-books and peer-reviewed journals.⁶

Among the first important examples of the use of evidence-based medicine is the work of Semmelweiss, who in 1861 demonstrated that careful attention to antiseptic principles could reduce mortality associated with puerperal fever from over 18% to just over 1% (Semmelweiss). The effective use of such principles in surgery was investigated during that same decade by Lister, who noted a decrease in mortality on his trauma ward from 45% to 15% with the use of carbolic acid as an antiseptic agent during operations. However, both the germ theory of infection and the ability of an antiseptic such as carbolic acid to decrease the risk of infection were not generally accepted, particularly in the United States, for another decade. In 1877 Lister performed an elective wiring of a patellar fracture using aseptic techniques, essentially converting a closed fracture to an open one in the process. Under practice patterns of the day, such an operation would almost certainly lead to infection and possible death, but the success of Lister's approach secured his place in history. It is interesting to note that a single case such as this, rather than prior reports of his extensive experience with the use of antiseptic agents, helped Lister turn the tide towards universal use of antiseptic techniques in surgery

The second example developed over 40 years after the landmark demonstration of antiseptic techniques and also involved surgical infectious problems. Hippocrates described open drainage for empyema in 229 BC, indicating that "when empyema are opened by the cautery or by the knife, and the pus flows pale and white, the patient survives, but if it is mixed with blood and muddy and foul

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smelling, he will die." There was little change in the management of this problem until the introduction of thoracentesis by Trusseau in 1843. The mortality rate for empyema remained at 50–75% well into the twentieth century. The confluence of two important events, the flu pandemic of 1918 and the Great War, stimulated the formation of the US Army Empyema Commission in 1918. Led by Graham and Bell, this commission's recommendations for management included three basic principles: drainage, with avoidance of open pneumothorax; obliteration of the empyema cavity; and nutritional maintenance for the patient. Employing these simple principles led to a decrease in mortality rates associated with empyema to 10–15%.

The Age of Information

These surgical efforts in the late nineteenth and early twentieth centuries ushered in the beginning of an era of scientific investigation of surgical problems. This was a period of true surgical research characterized by both laboratory and clinical efforts. It paralleled similar efforts in nonsurgical medical disciplines. Such research led to the publication of hundreds of thousands of papers on surgical management. This growth of medical information is not a new phenomenon, however. The increase in published manuscripts, and the increase in medical journals, has been exponential over a period of more than two centuries, with a compound annual growth rate of almost 4% per year (Fig. 1.1).10 In addition, the quality and utility of currently published information is substantially better than that of publications in centuries past.

Currently there are more than 2,000 publishers producing works in the general field of science, technology, and medicine. The field comprises more than 1,800 journals containing 1.4 million peer-reviewed articles annually. The annual growth rate of health science articles during the past two decades is about 3%, continuing the trend of the past two centuries and adding to the difficulty of identifying useful information (Fig. 1.2). When confronting this large amount of published information, separating the wheat from the chaff is a daunting task. The work of assessing such information has been assumed to some extent by

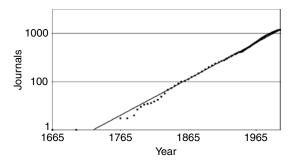


FIGURE 1.1. The total number of active refereed journals published annually (Data from Mabe [10]).

experts in the field who perform structured reviews of information on important issues and meta-analyses of high quality, controlled, randomized trials. These techniques have the potential to summarize results from multiple studies and, in some instances, crystallize findings into a simple, coherent statement.

An early proponent of such processes was Cochrane, who in the 1970s and 1980s suggested that increasingly limited medical resources should be equitably distributed and consist of interventions that have been shown in properly designed evaluations to be effective. He stressed the importance of using evidence from randomized controlled trials, which were likely to provide much more reliable information than other sources of evidence.11 These efforts ushered in an era of high quality medical and surgical research. Cochrane was posthumously honored with the development of the Cochrane Collaboration in 1993, encompassing multiple centers in North America and Europe, with the purpose of "helping healthcare providers, policy makers, patients, their advocates and carers, make well-informed decisions about human health care by preparing, updating and promoting the accessibility of Cochrane Reviews."12

Methods originally espoused by Cochrane and others have been codified into techniques for rating the quality of evidence in a publication and for grading the strength of a recommendation based on the preponderance of available evidence. In accord with this, the clinical problems addressed in this book have been assessed using a modification of a single relatively new rating system (GRADE) that is outlined thoroughly in chapter 2.¹³

Techniques such as those described above for synthesizing large amounts of quality information 1. Introduction 7

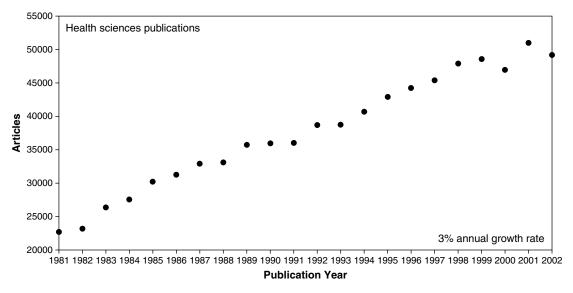


FIGURE 1.2. Growth in the number of published health science articles published annually (Data from Mabe [10])

were introduced for the development guidelines for clinical activity in thoracic surgery, most commonly for the management of lung cancer, beginning in the mid-1990s. An example of these is a set of guidelines based on what were then current standards of care sponsored by the Society of Surgical Oncology for managing lung cancer. It was written by experts in the field without a formal process of evidence collection.¹⁴ A better technique for arriving at guidelines is the consensus statement, usually derived during a consensus process in which guidelines based on published medical evidence are revised until members of the conference agree by a substantial majority in the final statement. An example of this iterative structure is the Delphi process.¹⁵ The problem with this technique is that the strength of recommendations, at times, is sometimes diluted until there is little content to them. Some organizations that appear to have avoided this pitfall in the general of guidelines of interest to thoracic surgeons include The American College of Chest Physicians, the Society of Thoracic Surgeons, the European Society of Thoracic Surgeons, the European Respiratory Society, the American Thoracic Society, the National Comprehensive Cancer Network, the Society of Clinical Oncology, the British Thoracic Society, and the Society of Surgical Oncology, to name but a few.

Despite the enormous efforts expended by professional societies in providing evidence-based algorithms for appropriate management of patients, adherence to these published guidelines, based on practice pattern reports, is disappointing. Focusing again on surgical management of lung cancer, there is strong evidence that standard procedures incorporated into surgical guidelines for lung cancer are widely ignored. For example, fewer than 50% of patients undergoing mediastinoscopy for nodal staging have lymph node biopsies performed. In patients undergoing major resection for lung cancer, fewer than 60% have mediastinal lymph nodes biopsied or dissected.¹⁶ Only one-third of physicians routinely assess diffusing capacity in lung cancer patients who are candidates for lung resection in Europe, and in the United States fewer than 60% of patients who undergo major lung resection for cancer have diffusing capacity measured. 17,18 There are also important regional variations in the use of standard staging techniques and in the use of surgery for stage I lung cancer patients, patterns of activity that are also related to race and socioeconomic status. 19,20 Failure to adhere to accepted standards of care for surgical lung cancer patients results in higher postoperative mortality rates,21,22 and the selection of superspecialists one's lung cancer surgery confers an overall long-term survival advantage.23

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The importance of adherence to accepted standards of care, particular those espoused by major professional societies, such as the American College of Surgeons, The Society of Surgical Oncology, the American Society of Clinical Oncology, the American Cancer Society, the National Comprehensive Cancer Network, is becoming clear as the United States Centers for Medicare and Medicaid Services develops processes for rewarding adherence to standards of clinical care. This underscores the need for surgeons to become familiar with evidence-based practices and to adopt them as part of their daily routines. What is not known is whether surgeons should be rewarded for their efforts in following recommended standards of care, or for the outcomes of such care? Do we measure the process, the immediate success, or the longterm outcomes? If outcomes are to be the determining factor, what outcomes are important? Is operative mortality an adequate surrogate for quality of care and good results? Whose perspective is most important in determining success, that of the patient, or that of the medical establishment?

The Age of Data

We have now entered into an era in which the number of data available for studying problems and outcomes in surgery is truly overwhelming. Large clinical trials involving thousands of subjects render databases measured in megabytes. As an example, for the National Emphysema Treatment Trial (NETT), which entered over 1,200 patients, initial data collection prior to randomization consisted of over 50 pages of data for each patient.²⁴ Patients were subsequently followed for up to 5 years after randomization, creating an enormous research database. The size of the NETT database is dwarfed by other databases in which surgical information is stored, including the National Medicare Database, the Surveillance Epidemiology and End Results (SEER; 170,000 new patients annually), Nationwide Inpatient Sample (NIS; 7 million hospital stays annually), and the Society of Thoracic Surgeons (STS) database (1.5 million patients).

Medical databases are of two basic types: those that contain information that is primarily clinical in nature, especially those that are developed specifically for a particular research project such as the NETT, and administrative databases that are maintained for other than clinical purposes but that can be used in some instances to assess clinical information and outcomes, an example of which is the National Medicare Database. Information is organized in databases in a hierarchical structure. An individual unit of data is a field; a patient's name, address, and age are each individual fields. Fields are grouped into records, such that all of one patient's fields constitute a record. Data in a record have a one-to-one relationship with each other. Records are complied in relations, or files. Relations can be as simple as a spreadsheet, or flat file, in which there is a one-to-one relationship between each field. More complex relations contain many-to-one, or one-to-many, relationships among fields, relationships that must be accessed through queries rather than through simple inspection. An example is multiple diagnoses for a single patient, or multiple patients with a single diagnosis.

In addition to collection of data such as those above that are routinely generated in the process of standard patient care, new technological advances are providing an exponential increase in the amount of data generated by standard studies. An example is the new 64 slice computed tomography scanner, which has quadrupled the amount of information collected in each of the x-y-z axes as well as providing temporal information during a routine CT scan. The vast amount of additional information provided by this technology has created a revolutionary, rather than evolutionary, change in diagnostic radiology. Using this technology, virtual angiograms can be performed, three dimensional reconstruction of isolated anatomic entities is possible, and radiologists are discovering more abnormalities than clinicians know what to do with.

A case in point is the use of CT as a screening test for lung cancer. Rapid low-dose CT scans were introduced in the late 1990s and were quickly adopted as a means for screening high risk patients for lung cancer. The results of this screening have been mixed. Several reports suggest that the number of radiographic abnormalities identified is

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high compared to the number of clinically important findings. For example, in the early experience at the Mayo clinic over 1,500 patients were enrolled in an annual CT screening trial, and in the 4 years of the trial, over 3,100 indeterminate nodules were identified, only 45 of which were found to be malignant.²⁵ Similar results have been reported by others during screening or surveillance activities.²⁶ Many additional radiographic abnormalities other than lung nodules were also identified. In addition, the increase in radiation exposure owing to more complex exams and more frequent exams has led to concerns about radiation-induced neoplasms, an unintended consequence of the good intentions of those performing lung cancer screening.^{27,28}

What Lies in the Future?

What do we now do with the plethora of information that is being collected on patients? How do we make sense of these gigabytes or terabytes of data? It may be that we now have more information than we can use or that we even want. Regardless, the trend is clearly in the direction of collecting more, rather than less, data, and it behooves us to make some sense of the situation. In the case of additional radiographic findings resulting from improved technology, new algorithms have already been refined for evaluating nodules and for managing their follow-up over time, and have yielded impressive results in the ability of these approaches to identify which patients should be observed and which patients should undergo biopsy or surgery.²⁹ What, though, of the reams of numerical and other data than pour in daily and populate large databases? When confronting this dilemma, it useful to remember that we are dealing with an evolutionary problem, the extent of which has been recognized for decades. Eliot aptly described this predicament in *The Rock* (1934), lamenting:

Where is the wisdom we have lost in knowledge? Where is the knowledge we have lost in information?

To those lines one might add:

Where is the information we have lost in data?

One might ask, in the presence of all this information, are we collecting the correct data? Evidence-based guidelines regarding indications for surgery, surgical techniques, and postoperative management are often lacking. We successfully track surgical outcomes of a limited sort, and often only in retrospect: complications, operative mortality, and survival. We don't successfully track patient's satisfaction with their experience, the quality of life they are left with as a result of surgery, and whether they would make the same decision regarding surgery if they had to do things over again. Perhaps these are important questions upon which physicians should focus. In addition to migrating towards patient-focused rather than institutionally-focused data, are we prepared to take the greater leap of addressing more important issues requiring data from a societal perspective, including cost-effectiveness and appropriate resource distribution (human and otherwise) and utilization? This would likely result in redeployment of resources towards health prevention and maintenance rather than intervention. Such efforts are already underway, sponsored not by medical societies and other professional organizations, but by those paying the increasingly unaffordable costs of medical care.

Insurance companies have long been involved, through their actuarial functions, in identifying populations who are at high risk for medical problems, and it is likely that they will extend this actuarial methodology into evaluating the success of surgical care on an institutional and individual surgeon basis as more relevant data become available. The Leapfrog Group, representing a consortium of large commercial enterprises that covers insurance costs for millions of workers, was founded to differentiate levels of quality of outcomes for common or very expensive diseases, thereby potentially limiting costs of care by directing patients to better outcome centers. These efforts have three potential drawbacks from the perspective of the surgeon. First, decisions made in this way are primarily fiscally based, and are not patient focused. Second, policies put in place by payors will undoubtedly lead to regionalization of health care, effectively resulting in de facto restraint of trade affecting those surgeons with low individual case volumes or comparatively poor outcomes for a procedure, or who work in

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low volume centers. Finally, decisions about point of care will be taken from the hands of the patients and their physicians. The next phase of this process will be requirements on the part of payors regarding practice patterns, in which penalties are incurred if proscribed patterns are not followed, and rewards are provided for following such patterns, even if they lead to worse outcomes in an individual patient.

Physicians can retain control of the care of their patients in a variety of ways. First, they must make decisions based on evidence and in accordance with accepted guidelines and recommendations. This text serves to provide an outline for only a fraction of the decisions that are made in a thoracic surgical practice. For many of the topics in this book there are preciously few data that can be used to formulate a rational basis for a recommendation. Practicing physicians must therefore become actively involved in the process of developing useful evidence upon which decisions can be made. There are a variety of means for doing this, including participation in randomized clinical trials, entry of their patient data (appropriately anonymized) into large databases for study, and participation in consensus conferences aimed at providing useful management guidelines for problems in which they have a special interest. Critical evaluation of new technology and procedures, rather than merely adopting what is new to appear to the public and referring physicians that one's practice is cutting edge, may help reduce the wholesale adoption of what is new into patterns of practice before its value is proven.

Conclusion

Decisions are the life blood of surgeons. How we make decisions affects the immediate and long-term outcomes of care of individual patients. Such decisions will also, in the near future, affect our reimbursement, our referral patterns, and possibly our privileges to perform certain operations. Most of the decisions that we currently make in our surgical practices are insufficiently grounded in adequate evidence. In addition, we tend to ignore published evidence and guidelines, preferring to base our decisions on prior training,

anecdotal experience, and intuition as to what is best for an individual patient.

Improving the process of decision making is vital to our patients' welfare, to the health of our specialty, and to our own careers. To do this we must thoughtfully embrace the culture of evidencebased medicine. This requires critical appraisal of reported evidence, interpretation of the evidence with regards to the surgeon's target population, and integration of appropriate information and guidelines into daily practice. Constant review of practice patterns, updating management algorithms, and critical assessment of results is necessary to maintain optimal quality care. Documentation of these processes must become second nature. Unless individual surgeons adopt leadership roles in this process and thoracic surgeons as a group buy into this concept, we will find ourselves marginalized by outside forces that will distance us from our patients and discount our expertise in making vital decisions.

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