

Difficult Decisions in Surgery:  
An Evidence-Based Approach

Mark K. Ferguson *Editor*

# Difficult Decisions in Thoracic Surgery

An Evidence-Based Approach

*Fourth Edition*

 Springer

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# **Difficult Decisions in Surgery: An Evidence-Based Approach**

## **Series Editor**

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The complexity of decision making in any kind of surgery is growing exponentially. As new technology is introduced, physicians from nonsurgical specialties offer alternative and competing therapies for what was once the exclusive province of the surgeon. In addition, there is increasing knowledge regarding the efficacy of traditional surgical therapies. How to select among these varied and complex approaches is becoming increasingly difficult. These multi-authored books will contain brief chapters, each of which will be devoted to one or two specific questions or decisions that are difficult or controversial. They are intended as current and timely reference sources for practicing surgeons, surgeons in training, and educators that describe the recommended ideal approach, rather than customary care, in selected clinical situations.

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Editor

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*To my wife for her endless patience  
and support.*

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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 basis 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 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 the physician nor the 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 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.

Chicago, IL, USA  
March 27, 2006

Mark K. Ferguson



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## Preface to the Fourth Edition

Much has changed in the 14 years since the first volume of this book was published. At the time of this writing, there is a growing desire among many people worldwide to live in a more insular and homogenous environment. Coupled with this is a growing population of implacable individuals who choose to deny science, either through ignorance, mistrust, or the fervent wish that the facts they choose not to like really do not exist. Leaders now offer “alternative truths,” boldfaced falsehoods that, repeated often enough, acquire a ring of truth among those whose factual knowledge comes primarily from untrustworthy sources.

Fortunately, those who work in the medical sciences have not been influenced by these cultural changes. Medical science is built on a foundation of continuous questioning of accepted beliefs in the hope of improving our knowledge and our ability to care for our patients. Those who attack medical scientists for changing guidelines, standards, and algorithms for care as if being guided by whimsy do not understand the iterative process that is the scientific method. Change should not be seen as a sign of uncertainty, but as a hallmark of progress. It is evidence that our clinicians and scientists are adapting to new challenges and learning new facts, and applying this to the benefit of their patients. It is in the spirit of this process that the present volume was developed.

As always, recommendations made in this book are not meant to be followed blindly, but are intended as guides to the reader. Hopefully, a sufficient amount of data is presented in each chapter so that the interested reader can make an independent judgment about best decisions based on the practice setting, the individual patient, and the reader’s own skills.

I am, and the reader of this book should be, grateful for the sacrifices that the authors made to complete their chapters. The level of enthusiasm among the authors was high, and each of the chapters had an assigned author within 1 week of the project launch date. The authors were tasked to complete their chapters in less than 80 days and were asked to not only bring their clinical expertise to bear, but at the same time were required to assume an attitude of equipoise in order to foster an objective view of the data. I think the reader will find that the authors succeeded admirably. My high esteem for the contributors is due to the fact that, despite their very busy clinical and academic schedules, not a single author asked for monetary or other compensation for the hours of work that was required.

Working in the environment in which I do is a blessing that is increasingly apparent to me every day. I am surrounded by smart, enthusiastic, and caring attendings, physician assistants, nurses, and trainees who comprise our thoracic surgery team. Our fellows, residents, and medical students are bright, inquisitive, and hardworking individuals who put our patients and their educational goals above any personal interests. I have colleagues around the world who are collaborative in advancing the art and science of surgery and who are supportive when I need help.

My hope is that readers will use this book as a source to enhance their knowledge, stimulate further learning, and improve the care of their patients. If the book succeeds in even one of those domains, I will consider these efforts to have been worthwhile.

Chicago, IL, USA  
March 8, 2020

Mark K. Ferguson

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# Introduction

1

Mark K. Ferguson

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## Introduction

Dorothy Smith, an elderly and somewhat portly woman, presented to her local emergency department 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 and general 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. She was seen several weeks later in an outpatient setting by an experienced surgeon, who reviewed her history and the data from her emergency room visit. After evaluating a CT scan and barium swallow, the surgeon diagnosed a giant Type III paraesophageal hernia. The patient was told that an operation is often 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 strong expression of concern.

She presented to her local emergency department several months later with symptoms of an incarcerated hernia and underwent an urgent operation 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

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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 the 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. Arnould 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 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. In addition, it has recently been reported that standards of care based on accepted clinical evidence have been debunked after begin in use for long periods of time, sometimes decades [3]. With all of our modern technological skills, big data, machine learning/artificial intelligence, 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” [4]. 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” [5].

Based on small numbers of procedures, lack of a true understanding of pathophysiology, frequently mistaken diagnoses, and the absence of technology to disseminate new 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 [6]. Decisions were based on dogma promulgated by word of mouth. This has been termed the “ancient era” of evidence-based medicine [7].

An exception to the empiric nature of surgery was the approach espoused by Hunter in the mid-eighteenth century, who suggested to Jenner, his favorite pupil, “I think your solution is just, but why think? Why not try the experiment?” [5] Hunter challenged the established practices of bleeding, purging, and mercury administration, believing them to be useless and often harmful. These 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 [7].

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 parasophageal 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 at the Mayo Clinic [8, 9]. 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 master (or at least an influential) surgeons 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 2, visiting renowned surgical centers to gain insight into surgical techniques, indications, and outcomes. An example is described in the memoir of Edward D. Churchill, who was being groomed for leadership at the Massachusetts General Hospital in the late 1920s [10]. 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. 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 [11]. 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 physicians in the United States for decades resulted in continued unacceptable infection rates for years after preventive measures were identified [12]. 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 nightclub fire in Boston in 1942. Similar stories can be told for the development of evidence in the management of polio and tuberculosis in the mid-twentieth 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 textbooks and peer-reviewed journals [7].

Among the first important examples of the use of evidence-based medicine is the work of Semmelweis, who in 1861 demonstrated that careful attention to antiseptic principles could reduce mortality associated with puerperal fever from over 18% to just over 1%. The effective application 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 thereafter.

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 is muddy and foul smelling, he will die" [4]. 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 [13]. 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 support for the patient. Employing these simple principles led to a decrease in mortality rates associated with empyema to 10–15%.

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## 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 non-surgical 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 [14]. 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 2000 publishers producing works in the general field of science, technology, and medicine. The journals publish more than 2.5 million articles annually [15]. 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 [14]. The number of citations of medical publications has more than doubled in the past two decades, and in 2018 exceeded 900,000 [16]. As of 2009, over 50 million science papers had been published since the first paper in 1665. There is also a trend towards decentralization of publication of biomedical data, which offers challenges to identifying useful

information that is published outside of what are considered traditional journals [17]. For example, publication rates of clinical trials relevant to certain specialties vary from one to seven trials *per day* [18].

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 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 [19]. 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” [20].

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 rating system (GRADE) that is outlined and updated in Chap. 2 [21].

Techniques such as those described above for synthesizing large amounts of quality information 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 [22]. 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 [23]. 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, the International Society for Diseases of the Esophagus, 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, dissemination of and 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 [24]. 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 [25, 26]. Even at centers with expertise in preoperative evaluation adherence to evaluation algorithms can be challenging, especially for higher risk patients [27]. 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 [28, 29]. Failure to adhere to accepted standards of care for surgical lung cancer patients results in higher postoperative mortality rates [30, 31], and the selection of super specialists for one's lung cancer surgery confers an overall long-term survival advantage [32]. Overall compliance with guideline recommendations for management of lung cancer is less than 45% [33].

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 long-term 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?

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## The Age of Data

We have now entered into an era in which the amount 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. A National Cancer Institute Genomic Data Commons contains more than 14 petabytes of data.

Large databases in which surgical information is stored include the National Medicare Database, the Surveillance Epidemiology and End Results (SEER), Nationwide Inpatient Sample (NIS), the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), and the Society of Thoracic Surgeons (STS) database. Other foreign national and international databases contain similar large amounts of information.

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, 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 compiled 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. Ultimately, databases become four-dimensional complex clinical and research resources as time emerges as an important factor in assessing outcomes and the changing molecular signatures of cancers, as examples [34]. These latter characteristics are true of most electronic medical records that are used in routine medical care.

In addition to collection of data such as those above that are 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 640 slice computed tomography scanner, which has vastly expanded the amount of information collected in each of the x-y-z axes as well as providing temporal information and routine 3-D reconstruction capabilities during a routine CT scan. The 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 were mixed. Several reports suggested that the number of radiographic abnormalities identified was high compared to the number of clinically important findings. For example, in the early experience at the Mayo clinic over 1500 patients were enrolled in an annual CT screening trial, and in the 4 years of the trial, over 3100 indeterminate nodules were identified, only 45 of which were found to be malignant



[35]. Similar results were reported by others during screening or surveillance activities [36]. 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 led to concerns about radiation-induced neoplasms, an unintended consequence of the good intentions of those performing lung cancer screening [37, 38]. However, recent reports of improved lung cancer survival resulting from screening appropriately selected individuals for screening has led to formal recommendations for screening such populations [39–41]. This is changing the practice of medicine, even though cost-effectiveness of such interventions has not been demonstrated.

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## 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 [42]. What, though, of the reams of numerical and other data that pour in daily and populate large databases? When confronting this dilemma, it is 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 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 precious 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 our 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 evidence-based 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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# Evidence Based Medicine: Quality of Evidence and Evaluation Systems

# 2

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## Introduction

Evidence based medicine is defined as “a systematic approach to clinical problem solving which allows the integration of the best available research evidence with clinical expertise and patient values” [1]. Arguably, the most important application of evidence based medicine is the development of clinical practice guidelines. Commenting on clinical practice guidelines, the Institute of Medicine [2] says:

*Clinical Practice Guidelines are statements that include recommendations intended to optimize patient care. They are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options. To be trustworthy, guidelines should be based on a systematic review of the existing evidence; be developed by a knowledgeable, multidisciplinary panel of experts and representatives from key affected groups; consider important patient subgroups and patient preferences, as appropriate; be based on an explicit and transparent process that minimizes distortions, biases, and conflicts of interest; provide a clear explanation of the logical relationships between alternative care options and health outcomes, and provide ratings of both the quality of evidence and the strength of recommendations; and be reconsidered and revised as appropriate when important new evidence warrants modifications of recommendations.*

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As knowledge grows exponentially, clinicians' treatment decisions increasingly depend on well done clinical practice guidelines [3]. However, a major impediment to the implementation and adoption of such guidelines is that they are often confusing and not actionable. The lack of clarity in guidelines creates confusion for not only the healthcare provider, but for patients as well. On the other hand, good clinical practice guidelines are actionable and easy to understand. In order to formulate clinical practice guidelines that can effectively guide clinicians and consumers, guidelines need to be derived from the best available evidence from which information can be obtained to support clinical recommendations.

Systematically developed guidelines have the potential to improve patient care and health outcomes, reduce inappropriate variations in practice, promote efficient use of limited healthcare resources and help define and inform public policy [4]. Despite an explosion in the field of guideline development in recent years, guidelines often lack transparency and useful information.

In the past, guideline developers usually relied solely on evidence hierarchies to determine the "level of evidence" with randomized controlled trials (RCTs) always being considered high level evidence and observational studies to be of lower quality. Such hierarchies suffer from oversimplification as RCTs can be flawed and well done observational studies may be the basis of higher quality evidence. Although the past 30 years have shown an enormous increase in evidence rating systems, almost all relied on a variation of those simple hierarchies. In addition, strong recommendations were routinely attached to high levels of evidence without regard to potentially closely balanced benefits and harms trade-offs which usually does require eliciting patient values and preferences and instead should result in conditional recommendations.

GRADE began as an initiative to offer a universally acceptable, sensible and transparent approach for grading the quality of evidence and strength of recommendations (<http://www.gradeworkinggroup.org/>). With the overarching goal of having a single system that avoids confusion and is methodologically rigorous, yet avoids the shortcomings of other systems, the GRADE framework helps to formulate clear, precise and concise recommendations. The uses of the GRADE framework are two-fold:

1. Defines the strength recommendations in the development of clinical practice guidelines
2. Assist in rating the quality of evidence in systematic reviews and other evidence summaries on which those recommendations are based

The GRADE framework has been widely adopted (>80 societies and organizations) including the WHO, the COCHRANE collaboration, the American Thoracic Society, and the European Society of Thoracic Surgeons [5]. In this chapter, we elaborate the GRADE approach to rating the quality of evidence and implications for strong and weak guideline recommendations and how patient values and preferences as well as resource use considerations can change those recommendations.