Part One

General Principles
Chapter 1

Introduction

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“Learning without thinking is useless. Thinking without learning is dangerous.”
—Confucius

TOWARD EVIDENCE-BASED MEDICAL PRACTICE

The very roots of Osler's apprentice-based medical education and practice, to which we still largely adhere, are being severed. Lest this be interpreted as a call to arms, Osler noted that his textbook of medicine was based on "personal experience correlated with the general experience of others."

This is a far cry from practice based on randomized clinical trials or even scientific evidence from observational studies. With all due respect to Osler, it is a fact that his method of practice and learning should have little place in contemporary medicine.

Patients would find it almost laughable that the evolution of current medical care has largely followed a "trial and error" pattern, driven by an educational system that was centered on the apprenticeship model. Our forefathers were educated based on the clinical experience of their mentors, and propagated the perceptions, attitudes, and behaviors with which they were presented. While exceptions to this model clearly existed, it has only been in the very recent past that the medical literature began to demand careful statistical analysis of published conclusions. The era of rigorous review of published material marked the beginning of a sea change in medical thinking.

Information in medicine creates advantage, whether that is due to more rapid diagnosis and treatment or clarity of understanding that opens the doors to discovery and progress. The trouble has been that the discipline of medicine is so broad that no single physician could master every facet and be expected to constantly integrate the rapidly changing landscape of new findings. The effective practice of medicine requires that new information be constantly incorporated, and yet the information
sources that clinicians typically use fail to provide enough valuable data. To correct this problem, the notion of “evidence-based medicine (EBM)” has grown since its inception in the early 1990s. Evidence-based medicine was so-named as a means of communicating high-quality information to busy clinicians who were overwhelmed by the burgeoning body of literature in their field.

One widely published definition of EBM is “the conscientious, explicit and judicious use of the current best evidence in making decisions about the care of individual patients.” This definition highlights a critical piece of the EBM paradigm that is easily overlooked: medical evidence is generated based on evaluations of multiple measurements and yet, this information must be applied in the singular. Phrased another way, if we tell a patient that they have a 35% chance that their cancer will return after treatment, is it unreasonable for them to reply, “Which 35% of my body will the cancer involve?”

Evidence-Based Medicine [is] the process of systematically finding, appraising, and using contemporaneous research findings as the basis for clinical decisions. Evidence-based medicine asks (sic) questions, finds and appraises the relevant data, and harnesses that information for everyday clinical practice. Evidence-based medicine follows four steps: formulate a clear clinical question from a patient’s problem; search the literature for relevant clinical articles; evaluate (critically appraise) the evidence for its validity and usefulness; implement useful findings in clinical practice.

Public perception of medical care has evolved over the convoluted history of medicine. Surgeons no longer are double as barbers, and the general distrust of inpatient medicine has been replaced with an apparent reliance on the supremacy of the hospital. The modern era of medicine has heralded a widespread respect and wonder at the seemingly endless series of “miracles” that characterize progress from the days of Lister and childbed fever. In the current market of aggressive competition for faculty and patients, the role of information in medicine has never been more pronounced.

Radical changes are in motion in health-care delivery. So far they have been initiated externally and are often based on business and cost considerations. Much of this has been out of the individual physician’s control to say nothing about their understanding. As a result, health care has evolved from a cottage to a mainstream industry and the physician has largely been left out of this evolutionary loop. Is there some fault on the physician’s part that has allowed this loss of control? If so, what is it? Is it possible that maximum physician independence, revered above all else and at all costs, has undermined the ability for physicians to regain control of health-care delivery? If physician independence means preserving unexplained practice variance, which is currently out of control, perhaps physicians are their own worst enemy.

W. Edwards Deming, a statistician and management leader who taught quality as a system to the Japanese, spoke of variance management as being at the very core of quality improvement. Of course, in contrast to manufacturing, zero tolerance for variance and defects is not often possible in medicine. The focus must instead be on narrowing the range between upper and lower limits of a process. To this end, when a procedure or diagnostic test falls within a reasonable range of indications and evidence, the system process is in control. When procedures performed fall
well outside this range, or if the range is exceedingly wide, the system process is out of control. Such is the case with health care, both on a micro- and macroscale. For decades, many studies have documented overuse of specific medical services, which are sometimes solely based on geographic location (e.g., certain cities have higher coronary bypass surgery rates with no local increased epidemiologic risk factors to explain this). Essentially, these practice patterns are “unexplained” by reasonable common causes or indications. In other words, reasonable variation in practice patterns is exceeded too often. One study specifically noted that 10%–27% of hysterectomies among women enrolled in seven health plans were performed for totally inappropriate reasons. Multiple studies performed by the RAND Corporation and others document similar findings and illuminate a quality problem in that patients are being subjected to risk of adverse consequences without documented benefit. It is worth repeating that the goal is not to achieve zero variance, rather merely to reduce practice variance to levels supported by existing evidence of benefit.

Perhaps we are asking the wrong primary questions and setting the wrong goals. For example, a commonly debated question is, “how can we reduce costs?” Should we instead be asking how we could improve the quality of care, minimizing unjustifiable and unexplainable practice variance? Is it possible that costs could be effectively reduced as a byproduct to this alternative and more palatable primary question? If the correct goals were set, could there be an alignment of effort toward true physician driven optimally managed care?

Is practice variance reduction and quality improvement via evidence-based guidelines just another medical “management fad” being foisted upon physicians? After all, there is a veritable alphabet soup proliferation of managed care and business based “buzz” words, reflecting the driving forces in the evolution of health-care delivery, usually not in concert with medical terminology: CQI, TQM, PDCA, EBM, LOS, Juran, Deming, etc. There are also more than 1500 practice guidelines in print and countless critical pathways. Most organizations seemingly have generated a set, but practical impact has been underwhelming. Can these help? How exactly? Are guidelines the same as critical pathways? Are these pathways just a “nursing thing”? How can we expect externally applied forces, embodied by practice guidelines forged by “expert” consensus panels, to be truly incorporated into better practice patterns at the local level? Certainly, unless the very best concepts in guideline development and evidence-based practice are actually implemented, there would be no net effect in patient care and cost efficiencies. Thus far, in fact, there has been no net impact. Perhaps we are not only asking the wrong questions but also taking the wrong approach. Perhaps the best solutions will come from individual physicians self-adjusting practice patterns based on evidence and outcomes rather than directives mandated from externally generated guidelines.

Is there a paradigm among all of the confusion that is workable? Is there a means by which the positive thrust toward value-added (outcomes/cost) care, as opposed to cheapest care, could be directed by physicians? One answer might be to practice the “best medicine” possible. Obviously, this is not a new concept. However, as we generate more and more data and publish it in a forest of journals, the ability to keep up gives way to information overload. Additionally, not all data has the same
strength and the quality varies, and thus the data may not translate into good practical information. Along these lines, the randomized controlled clinical trial has been a gold standard and usually carries more weight than a case report/series or a consensus panel report. However, despite the estimated 250,000 or so randomized clinical trials that have confirmed the relative efficacy of many treatments, there is still a paucity of such studies to guide certain medical practice decisions. Without actually reading every single published journal, often in specialties that do not normally cross our desk, it is simply impossible for the average clinician to keep up with what is proven and what is not, and with what strength of evidence.

Ideally, to optimally obtain and use information, physicians would need electronic databases with continually updated data that is properly analyzed and processed. Most, if not all, practicing physicians either don’t have this readily available or are not facile in searching current literature. Problem-based electronic database searches, using tools such as the MEDLINE, to answer specific questions are still infrequently used and may be incomplete since full article text may not be immediately available. In practice, the tendency is to evaluate problems based only on personal and often antiquated experience, or refer to respected authorities. Commonly, we refer to readily available resources such as textbooks to answer specific questions. The challenge inherent to this approach is in maintaining a full and up-to-date library, which is usually impossible.

Printed text, such as this book, will be criticized as being outdated no sooner than its publication. This is a potentially valid criticism. Much of what is summarized in this textbook is in fact not new, and in some areas quite dated but axiomatic. Nevertheless, it represents the best evidence known to the contributors to date. As long as one is aware of this limitation, by the 80/20 rule, it is generally true that 80% of evidence is relatively static and 20% represents new findings. In most cases, it is really the former scenario that is the bigger problem in practice variance minimization. In many instances, the main point is the lack of data to support efficacy of generally accepted common interventions. Of greater concern, despite strong data to support one point or another in patient care improvement, is that many physicians continue to practice status quo simply because “that is the way we have always done it.” In some cases, the available evidence is rapidly evolving and in other areas good solid evidence in existence for years or even decades has not been incorporated into general practice.

Are we discussing “cookbook medicine” here? Not at all. Medicine is still both an art and science and will continue as such so long as we treat human beings and not machines or biomechanical hybrids. However, we now have the operational tools to maximize the science while still supporting the art of delivering compassionate and effective care. Some of these tools are introduced in this text and the best evidence for perioperative and supportive care issues is presented. Selected chapters contain more axiomatic material than others. We have attempted to highlight controversial areas. However, this is a synopsis of evidence regarding general principles of perioperative care. As such, this textbook is not intended to be comprehensive and the reader is referred to the multiple excellent references within each chapter or to other works.
For all of the major technological advances in medicine, it is the struggle between art and science that defines medicine and separates it from aviation or manufacturing “widgets.” EBM demands that clinicians integrate the best available information on the behalf of their patients, simultaneously considering the individual patient factors and the best available evidence pertinent to the clinical situation. It is the critical thinking of the physician that allows EBM to thrive and acts as a counterbalance against practice limited by the most proximate clinical experience. Good physicians can integrate individual clinical expertise and the best available evidence because neither alone is enough. The centrality of this concept is summarized expertly by Sackett:

Without clinical expertise, a practice risks becoming tyrannised by evidence, for even excellent external evidence may be inapplicable to or inappropriate for an individual patient. Without current best evidence, practice risks becoming rapidly out of date, to the detriment of patients.

PERIOPERATIVE AND CRITICAL CARE ECONOMICS

At the societal decision-making level, we must ultimately balance the focus on maximum acute care with optimal care of an aging population. While some chronic and catastrophic diseases, such as cancer, often cannot be cured, patients still need relief from symptoms and minimization of disease-related complications and dysfunction. All of these issues touch upon supply and demand realities and opportunity costs. Maximizing efficiencies and minimizing unexplained practice variance will go a long way toward conservation of scarce resources and improved outcomes, and will contribute to overall cost reduction in health-care delivery services.

If one adopts a classic economic marginal analysis approach toward mortality, morbidity, level and extent of ICU care, complications, and avoidance thereof, one can isolate the incremental impact of each decision on quality and costs. Key questions might be as follows: During preoperative evaluation, prevention of complications is key to decreased morbidity and length of stay. How much more, or perhaps less, is required as a diagnostic input to achieve a given superior quality output? During perioperative care, what incremental opportunities exist for prevention with appropriate surveillance and management that are based on good evidence? In using new technologies, or even older technologies, what is the appropriate incremental use of such resources and what are their limitations toward optimizing outcomes?

EBM exists then as a tool, but not a substitute for the clinician. The proper implementation of EBM has driven the growth of an entire field of medicine, replete with its own experts, critics, proponents, and detractors. The most widely understood conceptual framework of EBM is the idea of the hierarchy of evidence. This is referred to as the first fundamental principle of EBM, and is discussed in more detail in Chapter 2. Even though randomized clinical trials are the gold standard, there absolutely is a place for cohort studies, case–control studies, and other “lesser” evidence. This does not mean that issues that are not defined by randomized trials are incompletely tested. All levels of evidence are worthwhile, and best evidence is exactly that—the best that
can be generated for a topic. The second fundamental principle of EBM is the idea that regardless of the level of evidence, value and preference judgments are implicit in every clinical decision.8

It is important to recognize that EBM is not without its limitations. As with any effective tool, it is perhaps easier to misuse rather than properly utilize it. Tragedy can result from paying attention to poor quality evidence instead of good quality evidence, and critical appraisal cannot be abandoned for blind acceptance. Many medical schools and training programs, in a form of premature closure, are moving away from teaching the fundamentals of careful evidence appraisal to emphasize the implementation of evidence. The intent of this new focus is to produce high-quality, safe, and low-cost care (i.e., Accreditation Council for Graduate Medical Education competencies of systems-based practice and improvement and practice-based learning). However, abandoning appropriate skepticism regarding the effectiveness of these interventions may lead to large investments in quality improvement, safety, and efficiency activities that fail to yield the expected benefits.

The same can be said for incorrectly applying population-based models to best practices in individual care. Major pronouncements about a particular action or intervention are not served by EBM, and those who try to misuse the literature in this way risk harming the very group that they have sworn to protect. Regardless of one’s perspective on EBM, the discipline reflects the desire of all involved in patient care to improve the quality of patient care.

OPERATIONAL TOOLS OVERVIEW

This textbook strives to present the best available evidence for decision making in perioperative and supportive care in the gynecologic oncology patient. It also introduces some operational mindsets and tools. Questions that this textbook addresses include the following:

- What is evidence-based medicine? How does one find all the available data? What if there is no good data? How does one evaluate which evidence is best for the given situation?
- What evidence exists toward minimizing unexplained variance and optimizing practice patterns?
- Are there any formal decision analysis methodologies that can help?
- Can these principles translate into practice guidelines that can actually be implemented and contribute to improvement?
- Is this just cookbook medicine? Or, is it a guide toward evolution of best practices specific to each physician’s and patient’s environment?

This textbook primarily addresses gynecologic oncology care, but can readily apply to complicated gynecologic perioperative care. Key issues are associated with a level of evidence score within the text or in algorithm form. Some chapters also contain more axiomatic information than others, and as such are not always subject to
grading. In other subject areas the lack of extensive underlying evidence is striking. Chapter 2 addresses information gathering and interpretation tools. The subsequent clinical chapters present the contributing authors’ best efforts to gather and synthesize up-to-date information addressing best approaches to common as well as uncommon problems in perioperative, supportive, and critical care. Some authors found data gathering and grading more second nature than others and so some biases remain. These areas should be apparent and interpreted to mean that the subject area is heavily influenced by level III data. Editing cannot always alleviate this and may confuse the reader if expert opinion meaning is altered.

This second edition is constructed largely as the first. Many of the chapter topics have remained the same, and others have been updated to include major changes in practice since the publication of the first edition. Some chapters have been deleted to narrow the focus on the perioperative nature of the text, and new chapters have been included in herbal and complimentary medicine, end-of-life decision making, and fertility-specific issues pertinent to the gynecologic oncology patient.

In summary, this is an imperfect but focused and genuine effort to present the best available information designed to help decrease practice variance toward predictable improved clinical outcomes. As presented, it is anticipated to be a kernel work in progress, constantly improved through revision, and a guide for reader-directed updating and local adaptation.

REFERENCES
