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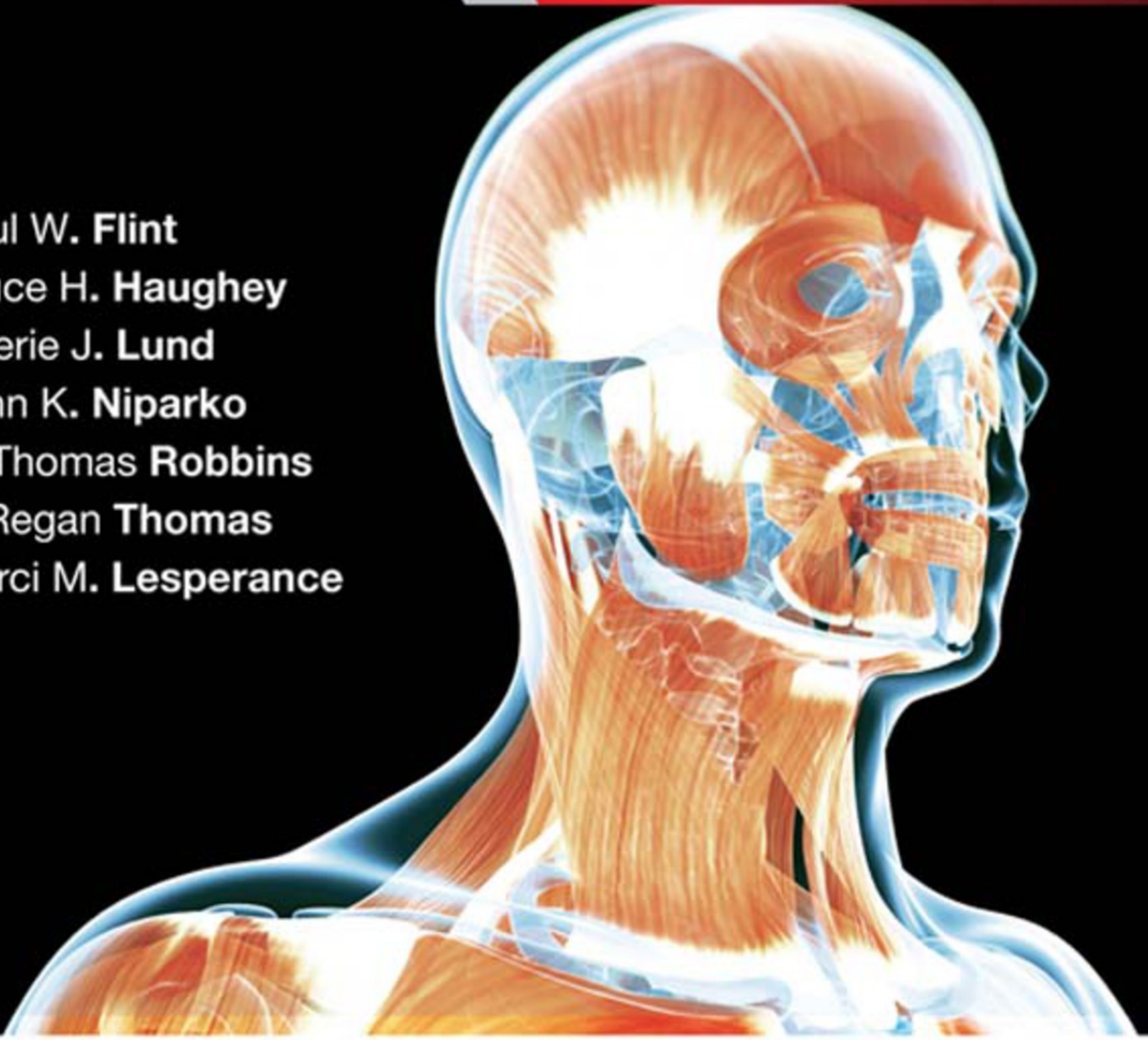

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Cummings Otolaryngology

Head and Neck Surgery

Sixth **Edition**

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SIXTH EDITION

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In Memoriam

Charles Krause, MD

Founding Editor of *Otolaryngology–Head and Neck Surgery*

On Feb. 7, 2013, the field of otolaryngology and the University of Michigan community lost one of its greatest leaders: Charles J. Krause, MD. Dr. Krause was a senior editor on the first three editions of *Otolaryngology–Head and Neck Surgery*. For his service and many contributions to the specialty, we dedicate the Sixth Edition to Charles J. "Chuck" Krause, MD, and offer this tribute.

Dr. Krause earned his medical degree in 1962 from the State University of Iowa, now known as the University of Iowa. After completing his otolaryngology residency there, he joined the Iowa faculty. Recruited to the University of Michigan in 1977, Dr. Krause served as Chair of the Department of Otolaryngology–Head and Neck Surgery from 1977 until 1992. He remained active on the faculty until 2000 and served in leadership positions in the Hospital and Health Centers and Medical School.

While at Michigan, Dr. Krause transformed the department by introducing specialty divisions into the faculty members' academic physician practice, recruiting new faculty, improving the clinical facilities, and bolstering basic research and residency training.

In addition to his role as department chair, he served U-M as the Chief of Clinical Affairs, Senior Associate Dean of the Medical School, and Senior Associate Hospital Director. He led the development of M-CARE, a health plan launched by U-M in 1986, and served as its first president. He directed strategic planning for U-M's first satellite health care facilities off the main medical campus.

On a national level, Dr. Krause served as president of organizations such as the American Academy of Otolaryngology–Head and Neck Surgery, the American Society of Head and Neck Surgery, the American Board of Otolaryngology, and the American Academy of Facial Plastic and Reconstructive Surgery.

Dr. Krause is remembered as a calm and thoughtful visionary who led by building consensus and bringing people together and mentored dozens of trainees toward successful careers.

As described by Dr. Charles W. Cummings, "Chuck was a steady person who could suppress any political foment. His demeanor was non-sensational and credible … a leavening personality. His input was seminal to the progress of the specialty in Head and Neck Oncology and Facial Plastic Surgery."

In November 2012, he and his wife Barbara attended the first appointment of the Charles J. Krause, MD, Collegiate Professorship in Otolaryngology, an honor given to Carol Bradford, MD, FACS, Chair of Otolaryngology–Head and Neck Surgery. The professorship will ensure that the department chair embodies Dr. Krause's ideals and promotes an environment that fosters excellence and integrity in clinical care, education, and research.

The editors of the Sixth Edition are forever grateful for Chuck Krause's dedication and commitment to his patients and Otolaryngology–Head and Neck Surgery.

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Preface

The sixth edition of *Cummings Otolaryngology–Head and Neck Surgery* is written as a definitive resource representing, in all of its diversity, the major components of the specialty as well as the latest advancements in minimally invasive surgery, image guidance, robotics, cochlear implantation, and more. Sections relevant to genetics of disease have been added or enhanced to address the most recent advances. In addition, the new chapter on evidence-based performance measurements is an outstanding reference for understanding the evolution of health care reform, the role of governing bodies and reporting measures, value-based purchasing, and impact on physician practice.

We continue to keep the text concise, yet still representing the major and notable developments in the field. The Contents reflects the extensive interrelationships of its various components. Every chapter contains Key Points at the start and a "most relevant" Suggested Readings list. As with the last edition, the sixth edition features access to the Expert Consult website, with enhanced text and images from the book, a full reference list for each chapter, as well as videos demonstrating the Accreditation Council for Graduate Medical Education Key Indicator Procedures and more. The video component provides residents with an excellent opportunity to better understand the critical elements of these core procedures.

Our goal is to further the education of those now associated with Otolaryngology–Head and Neck Surgery and provide a foundation for the generations to follow. By tradition, contributors demonstrate worldwide representation, thus recognizing the global contributions to the field. Through the combined effort of all contributors, the sixth edition remains the definitive resource for our specialty.

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Acknowledgments

I acknowledge my father, Roy Kenneth Flint, BG ret, soldier and teacher, for providing a lifelong example of leadership; and my wife Laurie and daughter Carlyn for ever reminding me that nobody is perfect. They keep me sane.

Paul W. Flint

It has been a distinct honor and pleasure to be part of the editorial and publishing team assembled for this edition of *Cummings Otolaryngology–Head and Neck Surgery*. The authors have been tireless in their efforts and have worked strongly to produce chapters that are truly comprehensive in scope and depth. My sincere thanks go to each one of them and their families, who inevitably have put up with liberal amounts of burning the midnight oil. My loyal assistant of 23 years, Debbie Turner, has kept us to our deadlines and liaised with both authors and publishers in a highly organized way, while my office nurses have provided generous amounts of patient care to cover for my time away from the front lines during this textbook's creation. Similarly, the residents and fellows at Washington University in St. Louis have held the fort when necessary.

The ability to purvey knowledge starts, and continues, with one's education, for which thanks go to my parents, the late Thomas and Marjorie Haughey, my teachers, medical professors, otolaryngology residency mentors in Auckland, New Zealand, and at the University of Iowa, and colleagues in the specialty, from whom I have and will continue to learn.

My family has unswervingly endorsed the time required for this project, so heartfelt love and thanks go to my wife, Helen, as well as to Rachel and Jack, Chris and Cindy, Will and Rachel, and Gretchen.

Finally, as we enjoy the teaching of this book and its online components, I try to keep in mind the source of all knowledge and truth: in the words of Proverbs 2:6, "… the Lord gives wisdom and from his mouth come knowledge and understanding." My sincere hope is that the readers everywhere will benefit from this textbook, better accomplishing our specialty's common goal of top-quality patient care.

Bruce H. Haughey

I thank Paul Flint and his colleagues for my continued involvement in this prestigious project, the publishers for their exemplary efficiency in its management, and my husband, David Howard, for his constant support and encouragement.

Valerie J. Lund

I am grateful to Charlie Cummings and Paul Flint for the honor of joining this marvelously collaborative editorial team, and to the many authors who have given their very best in composing this essential resource.

I dedicate my effort to those who have provided my guidance. To my parents, my wife and sons, and my patients, you have shown me the importance of dedication to others and that true compassion is shown in effort and action.

Twelve years of my early training were spent under the leadership of Chuck Krause and in the company of his and Barb's remarkable family. From Chuck, I learned that the important lessons are learned through preparation and patience.

John K. Niparko

As I reflect upon my academic career, there are many individuals who have provided positive influences in my pursuit of success. In addition to the important mentors acknowledged in previous editions, I am grateful for another group of talented and motivated individuals whom I have had the privilege to know during these past 35 years. They are faculty colleagues from multiple disciplines, fellows, residents, and medical students whose interactions and friendships have been encountered year after year. Such collegial relationships involving so many knowledgeable individuals from all levels of academic pursuit contribute substantially to one's maturation. For me, personally, it is truly an honor to engage in this ongoing experience. For this reason I would like to recognize the talented individuals with whom I have interacted and from whom I have benefited.

K. Thomas Robbins

It is a great privilege and honor to serve as an editor for this outstanding textbook. Although the knowledge base for our specialty and, indeed, all of medicine is continuously evolving and growing, this contribution serves otolaryngologists and their patients throughout the world with the current expertise required for best ultimate treatment. As an academic department head, I treasure the wealth of information available to my resident physicians in training. As an individual who has centered his career in a subspecialty of Otolaryngology, I am especially proud to help enhance the information available to the reader in the area of facial plastic and reconstructive surgery.

On a personal note, I want thank and acknowledge the great help and assistance I received from my administrative assistant, Denise McManaman, in editing this textbook. Her tireless work ethic is always admirable and appreciated. Finally, thank you to my wife, Rhonda, and my children, Ryan, Aaron, and Evan, for their enthusiastic and never-wavering support in my professional activities.

J. Regan Thomas

I am honored to serve as editor of the Pediatric Otolaryngology chapters for the premier textbook in Otolaryngology–Head and Neck Surgery. It is particularly meaningful to follow in the footsteps of Dr Charles J. Krause, a founding editor of this textbook, who helped inspire me and many others to pursue a career in Otolaryngology throughout his long tenure as Chair of Otolaryngology–Head and Neck Surgery at the University of Michigan. Indeed, as residents we pored over each chapter in preparation for our evening teaching sessions, known as "Krause Club." It is gratifying to see how this textbook has grown and flourished in parallel to the growth and development of our field.

I thank Dr. Flint and Dr. Cummings for the opportunity to contribute to this work. I am grateful to all the authors for sharing their knowledge and for their patience in addressing all my queries. I thank my colleagues at the University of Michigan for their willingness to provide their expertise, and the hours of help from my administrative assistant, Mary Anne Nugent. Finally, I thank my husband, Edward Karls, and my children, Matthew, Michelle, Maria, and Melanie: they provide a daily source of wisdom and insight into pediatrics that cannot be easily captured in a textbook.

Marci M. Lesperance

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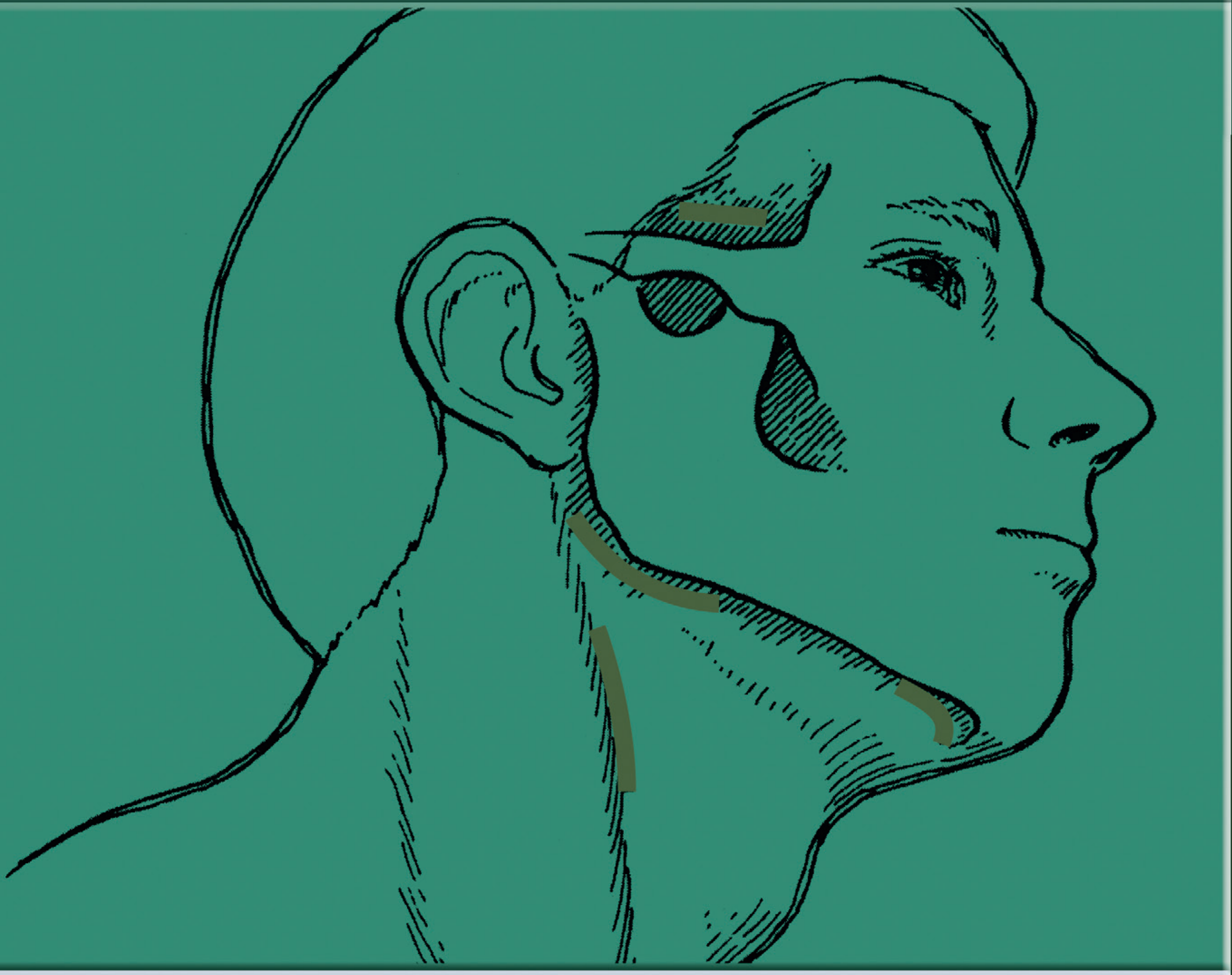
PART I



Measuring Outcomes and Performance

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Outcomes Research

1

Amy Anne Lassig | Bevan Yueh

Key Points

- *Outcomes research,* or *clinical epidemiology,* is the study of treatment effectiveness or the success of treatment in a nonrandomized, real world setting. It allows researchers to gain knowledge from observational data.
- Bias and confounding can affect researchers' interpretations of study data, and an accurate assessment of baseline disease status, treatment given, and outcomes of treatment are critical to sound outcomes research.
- Many types of studies are available to evaluate treatment effectiveness; these include randomized trials, observational and case-control studies, case series, and expert opinions. *Evidence-based medicine* uses the level of evidence presented in various studies to grade diagnostic and treatment recommendations.
- Outcomes in clinical epidemiology are often difficult to quantify, and thus instruments that measure these outcomes must meet the criteria of classic test theory—*reliability, validity, responsiveness,* and *burden*—or the item response theory to be considered psychometrically valid.
- Many outcomes instruments have been created to assess health-related quality of life. These scales may be generic or disease specific and include assessment of head and neck cancer, otologic and rhinologic disease, disease in pediatric patients, and voice and sleep disorders.

The time is long past in which physicians chose treatment based solely on personal notions of what was best. Although chronologically recent, this era is now conceptually distant. In a health care environment altered by abundant information on the Internet and continual oversight by managed care organizations, patients and insurers are now active participants in selecting treatment. Personal notions, so-called expert opinions, have been replaced by objective evidence, and the physician's sense of what is best is supplemented by patients' perspectives on outcomes after treatment.

Outcomes research, or *clinical epidemiology,* is the scientific study of treatment effectiveness. The word *effectiveness* is a critical one, because it pertains to the success of treatment in populations found in actual practice in the real world, as opposed to treatment success in the controlled populations of randomized clinical trials (RCTs) in academic settings, or *efficacy.*[1,2] Success of treatment can be measured using survival, costs, and physiologic measures, but health-related quality of life (HRQOL) is often a primary consideration.

Therefore, to gain scientific insight into these types of outcomes in the observational (nonrandomized) setting, outcomes researchers must be fluent with methodologic techniques borrowed from a variety of disciplines that including epidemiology, biostatistics, economics, management science, and psychometrics. A full description of the techniques in clinical epidemiology[3] is clearly beyond the scope of this chapter; the goal here is to provide a primer on the basic concepts in effectiveness research and to provide a sense of the breadth and capacity of outcomes research and clinical epidemiology.

HISTORY

In 1900, Dr. Ernest Codman[4] proposed to study what he termed the "end results" of therapy at Massachusetts General Hospital. He asked his fellow surgeons to report the success and failure of *each* operation and developed a classification scheme by which failures could be further detailed. Over the next two decades, Dr. Codman's attempts to introduce systematic study of surgical end results were scorned by the medical establishment, and his prescient efforts to study surgical outcomes gradually faded.

Over the next 50 years, the medical community accepted RCTs as the dominant method for evaluating treatment.[5] By the 1960s, the authority of the RCT was rarely questioned.[6] However, a landmark 1973 publication by Wennberg and Gittelsohn[7] spurred a sudden reevaluation of the value of observational data. These authors documented significant geographic variation in rates of surgery: tonsillectomy rates in 13 Vermont regions varied from 13 to 151 per 10,000 persons, even though no variation in the prevalence of tonsillitis was reported. Even in cities with similar demographics and similar access to health care (Boston and New Haven), rates of surgical procedures varied tenfold. These findings raised the question of whether the higher rates of surgery represented better care or unnecessary surgery.

Researchers at the Rand Corporation[8] sought to evaluate the appropriateness of surgical procedures. Supplementing relatively sparse data in the literature about treatment effectiveness with expert opinion conferences, these investigators argued that rates of inappropriate surgery were high. However, utilization rates did not correlate with rates of inappropriateness and therefore did not explain all of the variation in surgical rates.[9,10] To some this suggested that the practice of medicine was anecdotal and inadequately scientific.[11] In 1988, a seminal editorial by physicians from the Health Care Financing Administration argued that a fundamental change toward study of treatment effectiveness was necessary.[12] These events subsequently led Congress to establish the Agency for Health Care Policy and Research in 1989, since renamed the Agency for

Healthcare Research and Quality (AHRQ) and charged with "systematically studying the relationships between health care and its outcomes."

In the past decade, outcomes research and the AHRQ have become integral to understanding treatment effectiveness and establishing health policy. Randomized trials cannot be used to answer all clinical questions, and outcomes research techniques can be used to gain considerable insights from observational data, which includes data from large administrative databases. With current attention on evidence-based medicine (EBM) and quality of care, a basic familiarity with outcomes research is more important than ever.

KEY TERMS AND CONCEPTS

The fundamentals of clinical epidemiology are best understood by thinking about an episode of treatment: a patient comes to medical attention at baseline with an index condition, receives treatment for that condition, and then experiences a response to treatment. Assessment of baseline state, treatment, and outcomes are all subject to bias; this chapter therefore begins with a brief review of bias and confounding.

BIAS AND CONFOUNDING

Bias occurs when "compared components are not sufficiently similar."[3] The compared components may involve any aspect of the study. For example, *selection* bias exists if, in comparing surgical resection to chemoradiation, oncologists avoid treating patients with renal or liver failure. This makes the comparison unfair, because on average the surgical cohort will accrue more ill patients. *Treatment bias* occurs if we attempt to compare standard stapedotomy with laser stapedotomy, but one procedure is performed by an experienced surgeon, whereas the other is performed by resident staff.

Similar to bias, *confounding* also has the potential to distort the results. However, confounding refers to specific variables; it occurs when a variable *thought* to cause an outcome is actually not responsible because of the unseen effects of another variable. Consider the hypothetical (and obviously faulty) case in which an investigator postulates that nicotine-stained teeth cause laryngeal cancer. Despite a strong statistical association, this relationship is not causal, because another variable—cigarette smoking—is responsible. Cigarette smoking is confounding, because it is associated with both the outcome (laryngeal cancer) and the supposed baseline state (stained teeth).

Assessment of Baseline

Most physicians are aware of the confounding influences of age, gender, ethnicity, and race. However, accurate baseline assessment also means that investigators should carefully define the disease under study, account for disease severity, and consider other important variables such as comorbidity.

Definition of Disease. It would seem obvious that the first step is to establish diagnostic criteria for the disease under study, yet this is often incomplete. Inclusion criteria should include all relevant portions of the history, the physical examination, and laboratory and radiographic data. For example, the definition of chronic sinusitis may vary by pattern of disease (e.g., persistent vs. recurrent acute infections), duration of symptoms (3 months vs. 6 months), and diagnostic criteria for sinusitis (clinical exam vs. ultrasound vs. computed tomography [CT] vs. sinus taps and cultures). All of these aspects must be delineated to put studies in the proper context.

In addition, advances in diagnostic technology may introduce a bias called *stage migration*.[13] In cancer treatment, stage migration occurs when more sensitive technologies—such as CT scans in the past, and now positron emission tomography (PET) scans—may "migrate" patients with previously undetectable metastatic disease out of an early stage, thereby improving the survival outcomes of that group, and it may place them into a stage with otherwise advanced disease, improving this group's survival outcomes as well.[14,15] The net effect is an improvement in stage-specific survival outcomes but no change in overall survival.

Disease Severity. Severity of disease strongly influences response to treatment. This reality is second nature for oncologists, who use tumor-node-metastasis (TNM) staging to select treatment and interpret survival outcomes. It is intuitively clear that the more severe the disease, the more difficult it will be, on average, to restore function; yet this concept has not been fully integrated into the study and treatment of common otolaryngologic diseases, such as sinusitis and hearing loss.

Recent progress has been made in sinusitis. Kennedy[16] identified prognostic factors for successful outcomes in patients with sinusitis and has encouraged the development of staging systems. Several staging systems have now been proposed, but most systems rely primarily on radiographic appearance.[17-20] Clinical measures of disease severity (symptoms, findings) are not typically included. Although the Lund-Mackay staging system is reproducible,[21] often radiographic staging systems have correlated poorly with clinical disease.[22-26] As such, the Zinreich method was created as a modification of the Lund-Mackay system, adding assessment of osteomeatal obstruction.[27] Alternatively, the Harvard staging system has been reproducible[21] and may predict response to treatment.[28] Scoring systems have also been developed for specific disorders, such as acute fungal rhinosinusitis,[29] and clinical scoring systems based on endoscopic evaluation have likewise been developed.[30] The development and validation of reliable staging systems for other common disorders, and the integration of these systems into patient care, is a pressing challenge in otolaryngology.

Comorbidity. *Comorbidity* refers to the presence of concomitant disease unrelated to the *index disease,* the disease under consideration, that may affect the diagnosis, treatment, and prognosis for the patient.[31-33] Documentation of comorbidity is important, because the failure to identify comorbid conditions such as liver failure may result in inaccurately attributing poor outcomes to the index disease being studied.[34] This baseline variable is most commonly considered in oncology, because most models of comorbidity have been developed to predict survival.[32,35] The Adult Comorbidity Evaluation 27 (ACE-27) is a validated instrument for evaluating comorbidity in cancer patients that has shown the prognostic significance of comorbidity in a cancer population.[36,37] Given its impact on costs, utilization, and quality of life (QOL), comorbidity should be incorporated into studies of nononcologic diseases as well.

Assessment of Treatment

Control Groups. Reliance on case series to report results of surgical treatment is a time-honored tradition. It is also inadequate for establishing cause and effect relationships. A recent evaluation of endoscopic sinus surgery reports revealed that only 4 of 35 studies (11%) used a control group.[38] Without a control group, the investigator cannot establish that the observed effects of treatment were directly related to the treatment itself.[3]

It is also particularly crucial to recognize that the scientific rigor of the study will vary with the suitability of the control group. The more fair the comparison, the more rigorous the results. Therefore a randomized cohort study, in which subjects are randomly allocated to different treatments, is more likely to be free of biased comparisons than observational cohort studies, in which treatment decisions are made by an individual, a group of individuals, or a health care system. Different levels of rigor are also found within observational cohorts. In a recent evaluation of critical pathways in head and neck cancer, a "positive" finding in comparison with a *historic control group,* a comparison group assembled in the past, was not significant when compared with a concurrent control group.[39]

Assessment of Outcomes

Efficacy. The distinction between efficacy and effectiveness, briefly discussed earlier, illustrates one of the fundamental differences between randomized trials and outcomes research. *Efficacy* refers to whether a health intervention in a controlled environment achieves better outcomes than a placebo. Two aspects of this definition need emphasis: first, *efficacy* is a comparison to placebo; so as long as the intervention is better, it is considered efficacious. Second, controlled environments shelter patients and physicians from problems in actual clinical settings. For example, randomized efficacy trials of medications provide continuing reminders for patients to use their medications, and nonadherent patients are dropped from further study.

Effectiveness. An efficacious treatment that retains its value under usual clinical circumstances is *effective,* therefore effective treatment must overcome a number of barriers not encountered in the typical trial setting. For example, disease severity and comorbidity may be worse in the community, because healthy patients tend to be enrolled in (nononcologic) trials. Patient adherence to treatment may also be imperfect. Consider continuous positive airway pressure (CPAP) treatment for patients with obstructive sleep apnea (OSA). Although CPAP is efficacious in the sleep laboratory, the positive pressure is ineffective if patients fail to wear the masks when they return home.[40] A different challenge is present for surgical treatments, because community physicians learning a new procedure cannot be expected to perform it as effectively as the surgeon investigator who pioneered its development.

FUNDAMENTALS OF STUDY DESIGN

A variety of study designs are used to gain insight into treatment effectiveness. Each has advantages and disadvantages. The principal trade-off is between complexity and rigor, because rigorous evidence demands greater effort. An understanding of the fundamental differences in study design can help to interpret the quality of evidence, which has been formalized by the EBM movement. EBM is the "conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients."[41] It is discussed in detail elsewhere in this textbook but is mentioned here because of its overlap with clinical epidemiology. The major categories of study designs is reviewed, with reference to the EBM hierarchy of levels of evidence (Table 1-1).[41,42]

RANDOMIZED TRIAL

Randomized clinical trials represent the highest level of evidence, because the controlled, experimental nature of the RCT allows the investigator to establish a causal relationship between treatment and subsequent outcome. The random distribution of patients also allows unbiased distribution of baseline variables and minimizes the influence of confounding. Although randomized trials have generally been used to address efficacy, modifications can facilitate insight into effectiveness as well. RCTs with well-defined inclusion criteria, double-blinded treatment and assessment, low losses to follow-up, and high statistical power are considered quality RCTs and represent Level 1 evidence. Lower quality RCTs are rated as Level 2 evidence.

OBSERVATIONAL STUDY

In observational studies, sometimes called *cohort studies,* patients are identified at baseline *before* treatment—or before "exposure," in standard epidemiology cohort studies that investigate risk factors for disease—similar to randomized trials. However, these studies accrue patients who receive routine clinical care. Inclusion criteria are substantially less stringent, and treatment is assigned by the provider in the course of clinical care. Maintenance of the cohort is also straightforward, because there is no need to keep patients and providers doubly blinded.

The challenge in cohort studies is to find an appropriate control group. Rigorous prospective and retrospective cohort studies *with a suitable control group* represent quality studies and can represent Level 2 evidence. To obtain insight into comparisons of treatment effectiveness, these studies must use sophisticated statistical and epidemiologic methods to overcome the biases discussed in the prior section. Even with these techniques comes the attendant risk that unmeasured confounding variables will distort the comparison of interest. Poor quality cohorts without control groups or those with inadequate adjustment for confounding variables are considered Level 4 evidence, because they are essentially equivalent to a case series (see Case Series and Expert Opinion in this chapter).

TABLE 1-1. **Summary of Study Designs**

Design	Advantages	Disadvantages	Level of Evidence
Randomized clinical trial (RCT)	Only design to prove causation Unbiased distribution of confounding	Expensive and complex Typically targets efficacy	If high quality, 1 If low quality, 2
Observational (cohort) study	Cheaper than RCT Clear temporal directionality from treatment to outcome	Difficult to find suitable controls Confounding	With control group, 2 If no control group, 4
Case-control study	Cheaper than cohort study Efficient study of rare diseases or delayed outcomes	Must rely on retrospective data Directionality between exposure and outcome unclear	3
Case series	Cheap and simple	No control group No causal link between treatment and outcome	4
Expert opinion	NA	NA	5

NA, not available.

CASE-CONTROL STUDY

Case-control studies are typically used by traditional epidemiologists to identify risk factors for the development of disease. In such cases, the disease becomes the "outcome." In contrast to randomized and observational studies, which identify patients before "exposure" to a treatment or a pathogen, and then follow patients forward in time to observe the outcome, case-control studies use the opposite temporal direction. This design is particularly valuable when prospective studies are not feasible, either because the disease is too rare, or because the time interval between baseline and outcome is prohibitively long.

For example, a prospective study of an association between a proposed carcinogen (e.g., gastroesophageal reflux) and laryngeal cancer would require a tremendous number of patients and decades of observation. However, by identifying patients with and without laryngeal cancer and comparing relative rates of carcinogen exposure, a case-control study can obtain a relatively quick answer.[43] It should be noted that because the temporal relationship between exposure and outcome is not directly observed, no causal judgments are possible. These studies are considered Level 3 evidence.

CASE SERIES AND EXPERT OPINION

Case series are the least sophisticated format. As discussed earlier, no conclusions about causal relationships between treatment and outcome can be made because of uncontrolled bias and the absence of any control group. These studies are considered Level 4 evidence. If case studies are unavailable, expert opinion is used to provide Level 5 evidence.

OTHER STUDY DESIGNS

Numerous other important study designs exist in outcomes research, but a detailed discussion of these techniques is beyond the scope of this chapter. The most common approaches include decision analyses,[44,45] cost-identification and cost-effectiveness studies,[46-48] secondary analyses of administrative databases,[49-51] and meta-analyses[52,53] (critiques of these techniques are referenced here for completeness).

Grading of Evidence-Based Medicine Recommendations

EBM uses the levels of evidence described above to grade treatment recommendations (Table 1-2).[54] The presence of quality RCTs allows treatment recommendations for a particular intervention to be ranked as Grade A. If no RCTs are available, but Level 2 or 3 evidence exists (observational study with a control group, or case-control study), the treatment recommendations are ranked as Grade B. The presence of only a case series would result in a Grade C recommendation. If even case series are unavailable, and only expert opinion is available, the recommendation for the index treatment is considered Grade D.

TABLE 1-2. **Relationships Between Grades of Recommendation and Level of Evidence**

Grade of Recommendation	Level of Evidence
A	1
B	2 or 3
C	4
D	5

MEASUREMENT OF CLINICAL OUTCOMES

Clinical studies have traditionally used outcomes such as mortality and morbidity or other "hard" laboratory or physiologic endpoints[55] such as blood pressure, white cell counts, or radiographs. This practice has persisted despite evidence that interobserver variability of accepted so-called hard outcomes, such as chest radiology findings and histologic reports, are distressingly high.[56] In addition, clinicians rely on "soft" data, such as pain relief or symptomatic improvement, to determine whether patients are responding to treatment. Because it has been difficult to quantify these variables, these outcomes have until recently been largely ignored.

PSYCHOMETRIC VALIDATION

An important contribution of outcomes research has been the development of questionnaires to quantify these "soft" constructs, such as symptoms, satisfaction, and QOL. Under the classic test theory, a rigorous psychometric validation process is typically followed to create these questionnaires, more often termed *scales* or *instruments*. These scales can then be administered to patients to produce a numeric score. The validation process is briefly introduced here; a more complete description can be found elsewhere.[57-59] The three major steps in the process are the establishment of *reliability*, *validity*, and *responsiveness*; in addition, increasing consideration is also given to *burden*.

- *Reliability*. A *reliable* scale reproduces the same result in precise fashion. For example, assuming no clinical change, a scale administered today and next week should produce the same result; this is called *test-retest reliability*. Other forms of reliability include *internal consistency* and *interobserver reliability*.[59,60]
- *Validity*. A *valid* scale measures what it is purported to measure. This concept is initially difficult to appreciate. These scales are designed to measure constructs that have not previously been measured, and the constructs are difficult to define in the first place (what is "quality of life"?)—so how do we determine what the scales are supposed to measure? The abbreviated answer is that the scales should behave in the hypothesized way. A simple example of an appropriate hypothesis is that a proposed cancer-specific QOL scale should correlate strongly with pain, tumor stage, and disfigurement but less strongly with age and gender. For more complete discussion, several excellent references are listed.[57-61]
- *Responsiveness*. A *responsive* scale is able to detect clinically important change.[62] For instance, a scale may distinguish an individual with moderate hearing impairment from a deaf individual (the scale is *valid*), but can it detect a different score if the individual's hearing improves mildly after surgery? Alternatively, the minimum improvement in score that represents a clinically important change might be provided.[63,64]
- *Burden*. The term *burden* refers to the time and energy patients must expend to complete a scale along with the resources necessary for observers to score the questionnaire. A scale should not be an excessive encumbrance to a patient or caregiver nor to the provider using it.

More recently, *item response theory* (IRT) has been used to create and evaluate self-reported instruments; however, a full discussion of IRT is beyond the scope of this chapter. In brief, IRT uses mathematic models to draw conclusions based on the relationships between patient characteristics (latent traits) and patient responses to items on a questionnaire.

A critical limitation is that IRT assumes that only one domain is measured by the scale. This may not fit assumptions for multidimensional QOL scales. However, if this assumption is valid, IRT-tested scales offer several advantages. IRT allows for the contribution of each test item to be considered individually, thereby allowing the selection of a few test items that most precisely measure a continuum of a characteristic. In other words, because each test item is scaled to a different portion of the characteristic being tested, the number of questions can be reduced.[65-68] Therefore IRT lends itself easily to adaptive computerized testing and allows for significantly diminished testing time and reduced test burden.[65] In the future, IRT will likely be the basis for more and more new questionnaires to evaluate outcomes that include QOL.

CATEGORIES OF OUTCOMES

In informal use, the terms *health status*, *function*, and *quality of life* are frequently used interchangeably. However, these terms have important distinctions in the health services literature. *Health status* describes an individual's physical, emotional, and social capabilities and limitations, and *function* refers to how well an individual is able to perform important roles, tasks, or activities.[58] *Quality of life* differs, because the central focus is on the *value* that individuals place on their health status and function.[58]

Because many aspects of QOL are unrelated to a patient's health status, outcomes researchers typically focus on scales that measure only health-related quality of life (HRQOL). Such scales may be categorized as either *generic* or *disease specific*. *Generic,* or general, scales are used for QOL assessment in a broad range of patients. The principal advantage of generic measures is that they facilitate comparison of results across different diseases (e.g., how the QOL of a heart transplant patient compares to that of a cancer patient). *Disease-specific scales,* on the other hand, are designed to assess specific patient populations. Because these scales can focus on a narrower range of topics, they tend to be more responsive to clinical change in the population under study. To benefit from the advantages of each type of scale, rigorous studies often use both a generic and a disease-specific scale to assess outcomes.

In addition to these measures, a number of other outcomes are increasingly popular. These include patient satisfaction, costs and charges,[47,48] health care utilization, and patient preferences such as willingness to pay (descriptions of these methods are referenced here for completeness).[47,69,70]

EXAMPLES OF OUTCOMES MEASURES

As mentioned above, one of the principle contributions of outcomes research has been the development of scales to measure HRQOL and related outcomes. Several validated scales relevant to otolaryngology are briefly discussed here. Unless otherwise indicated, these scales are completed by the patient, and the references contain details about validation data, and most also include a listing of sample questions and scoring instructions. The most widely used scales in each category are listed in Table 1-3.

Generic Scales

The best known and most widely used outcomes instrument in the world is the Medical Outcomes Study Short Form 36 (SF-36).[71] This 36-item scale is designed for adults, and it surveys general health status. It produces scores in eight health constructs—such as vitality, bodily pain, limitations in physical activities—and gives two summary scores of overall physical and mental health status. Normative population scores are available, and the scale has been translated into numerous languages. Reference to instructions, numerous reference publications, and other related information can be found at the SF-36 website, www.sf-36.org.

TABLE 1-3. Outcomes Measures Relevant to Otolaryngology

Disease Category		Examples
Generic	Health status	SF-36[71]
	Quality of life	WHO-QOL[77]
	Utility	QWB[73]
Head and neck cancer	General	UWQOL,[85] FACT,[86] EORTC,[82] HNQOL[88]
	Radiation specific	QOL-RTI/H&N[90]
	Clinician rated	PSS[87]
Otologic	General	HHIE[99]
	Conductive loss	HSS[102]
	Amplification	APHAB,[103] EAR[163]
	Dizziness	DHI[113]
	Tinnitus	THI[114]
	Cochlear implants	Nijgemen,[106] CAMP[107]
Rhinologic	Nasal obstruction	NOSE[125]
	Chronic sinusitis	SNOT-20,[115] CSS,[116] RhinoQOL[123]
	Rhinitis	mRQLQ,[120] ROQ[121]
Pediatric	Tonsillectomy	TAHSI[136]
	Otitis media	OM-6[132]
	Sleep apnea	OSD-6,[134,135] OSA-18[133]
Other/symptoms	Adult sleep apnea	FOSQ,[151] SAQLI[152,153]
	Swallowing	MDADI,[159] SWAL-QOL[160]
	Voice	VHI,[140] VOS,[141] V-RQOL[147]
	Cosmetic	ROE, BOE[162]

See text for additional scales and more information about the examples given.

A variety of other popular generic scales are also available and are referenced here. Another health status measure is the Sickness Impact Profile (SIP).[72] The Quality of Well-Being (QWB) index[73,74] and the Health Utilities Index (HUI)[75,76] measure patient preferences, or "utilities." The World Health Organization (WHO) has developed a QOL scale, known as the *WHO-QOL,*[77] to measure generic quality of life; this is in addition to the International Classification of Functioning, Disability, and Health, better known as the *ICF,* which evaluates patient function and disability.[78] The ICF has been used not only as an instrument itself but also as a stand-alone reference by which to evaluate other measures of QOL and functioning.[79,80]

Disease-Specific Scales

Head and Neck Cancer. In 2002, the National Institutes of Health (NIH) sponsored a conference to achieve consensus on the methods used to measure and report QOL assessment in head and neck cancer.[81] It was agreed that an adequate number of scales already exist to measure general QOL in head and neck cancer patients. The three most popular scales are the European Organization for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC-HN35),[82] the University of Washington Quality of Life (UW-QOL) scale,[83-85] and the Functional Assessment of Cancer Therapy Head and Neck module (FACT-HN).[86] Both the EORTC and FACT instruments offer additional modules that measure general cancer QOL in addition to head and neck cancer–specific modules, but they are longer than the 12-item UW-QOL scale.

With a clinician-rated scale, the clinician does the scoring, rather than the patient. One such instrument that has achieved widespread use is the Performance Status Scale

(PSS), a three-item instrument that correlates well with many of the above-mentioned cancer scales.[87] A number of other excellent, validated, patient-completed scales are also available, including the Head and Neck Quality of Life (HNQOL)[88] scale and the Head and Neck Survey (H&NS),[89] although these scales have not been used as widely. Several validated scales that focus on QOL of patients undergoing radiation are also in use.[90,91]

A few measures focus on symptom inventory and symptom distress directly related to head and neck cancer. These include the Head and Neck Distress Scale (HNDS)[92] and the M.D. Anderson Symptom Inventory, Head and Neck Module (MDASI-HN).[93]

Several new instruments have been developed as disease-specific measures within the field of head and neck cancer. For example, to assess the impact of cutaneous malignancy on QOL, the Skin Cancer Index (SCI) was validated and found to be sensitive and responsive.[94,95] In addition, the Patient Outcomes of Surgery–Head/Neck (POS-Head/Neck) measure was developed to assess surgical outcomes in cutaneous malignancy,[96] and another instrument was designed to assess QOL after treatment of anterior skull base lesions.[97] A questionnaire has also been developed to evaluate outcomes directly related to the use of voice prostheses after total laryngectomy.[98]

Otologic Disease. The most widely used, validated measure to quantify hearing-related QOL is the Hearing Handicap Inventory in the Elderly (HHIE), a 25-item scale with two subscales that measure the emotional and social impact of hearing loss.[99,100] The minimum change in score that corresponds to a clinically important difference has been established[101]; however, the scale does not distinguish between conductive and sensorineural loss. The Hearing Satisfaction Scale (HSS) is specifically designed to measure outcomes after treatment for conductive hearing loss; therefore it addresses side effects or complications of treatment and is brief (15 items).[102]

Numerous validated measures exist to assess outcomes after hearing amplification. One popular scale is the Abbreviated Profile of Hearing Aid Benefit (APHAB).[103] This 24-item scale measures four aspects of communication ability, and values that correspond to minimally clinically important clinical change have also been established.[104] The Effectiveness of Auditory Rehabilitation (EAR) scale addresses comfort and cosmesis issues associated with hearing aids that are overlooked in many hearing aid scales. The EAR comprises two brief 10-item modules: the Inner EAR addresses intrinsic issues of hearing loss such as functional, physical, emotional, and social impairment; the Outer EAR covers extrinsic factors such as comfort, convenience, and cosmetic appearance.[105]

Effects of cochlear implantation on HRQOL have also recently begun to be measured. The Nijmegen Cochlear Implant Questionnaire (NCIQ) has been used for this purpose,[106] whereas the University of Washington Clinical Assessment of Musical Perception (CAMP) has been developed to assess perception of music in cochlear implant recipients.[107]

Individuals interested in pursuing research on hearing amplification should also be aware of a number of other validated scales; only a partial listing is referenced here.[108-112] In addition to these scales, several excellent validated scales assess other aspects of otologic disease, including dizziness (the Dizziness Handicap Inventory [DHI])[113] and tinnitus (the Tinnitus Handicap Inventory [THI]).[114]

Rhinologic Disease. The ability to assess outcomes in chronic rhinosinusitis has dramatically improved with the development of disease-specific scales. The two most widely used scales are the Sinonasal Outcome Test (SNOT-20)[115] and the Chronic Sinusitis Survey (CSS).[116] The SNOT-20 has 20 items, has been extensively validated, and is a shortened version of the 31-item Rhinosinusitis Outcome Measure (RSOM-31).[117] It is responsive to clinical change and has established scores that reflect minimal clinically important differences. The CSS is a shorter scale that consists of two components: the severity-based component has four items; the duration-based component covers duration of both symptoms and medication use. In addition to the SNOT-20 and CSS, a number of other excellent validated sinusitis scales are also available.[118,119] Some of these scales—the Mini Rhinoconjunctivitis Quality of Life Questionnaire (mRQLQ),[120] the Rhinitis Outcome Questionnaire (ROQ),[121] and the Nocturnal Rhinoconjunctivitis Quality of Life Questionnaire (NRQLQ)[122]— focus on rhinitis specifically, whereas others focus on rhinosinusitis specifically; the Rhinosinusitis Quality of Life (RhinoQOL) survey has been validated for both acute and chronic sinusitis.[123] In addition, new rhinologic scales continue to be developed.

In 2003, the American Academy of Otolaryngology–Head and Neck Surgery Foundation commissioned the National Center for the Promotion of Research in Otolaryngology to develop and validate a disease-specific instrument for patients with nasal obstruction for a national outcomes study. The Nasal Obstruction Symptom Evaluation (NOSE) scale is a five-item instrument that is valid, reliable, and responsive.[125]

Pediatric Diseases. An important difference between measuring outcomes in adults versus children is that younger children may be unable to complete the scales by themselves. In these cases, the instruments need to be completed by proxy, typically by a parent or other caregiver—a difference in perspective that must be kept in mind when interpreting the results of pediatric studies. A good generic scale, similar to the SF-36 in adults, is the Child Health Questionnaire (CHQ).[126] This widely used instrument has been extensively validated and translated into numerous languages. It is a health status measure designed for children 5 years of age and older, and it can be completed directly by children 10 and older. Other generic QOL assessments for children include the Pediatric Quality of Life Inventory (PedsQL) and the Child Health and Illness Profile–Child Edition (CHIP-CE).[127,128] The Glasgow Children's Benefit Inventory (GCBI) is a validated measure that evaluates the benefit a child receives from an intervention; it is a general measure developed with otolaryngologic disease in mind.[129] The Caregiver Impact Questionnaire (CIQ) has been used to evaluate the impact of disease on the child's caregivers.[130,131]

A number of excellent, validated, disease-specific scales for children are currently available. A number of instruments have been developed to assess the impact of otitis media (OM); the most widely used, OM-6, is a brief six-item scale useful for the evaluation of OM-related quality of life in children.[132] It has been shown to be reliable, valid, and responsive and has therefore been widely adopted. Two scales are pertinent to children who have an obstructive sleep disorder (OSD), such as OSA; the OSA-18[133]—found to be valid, reliable, and responsive—and the OSD-6.[134,135] A scale has also recently been developed that measures tonsil and adenoid health in children, the Tonsil and Adenoid Health Status Instrument (TAHSI).[136] Voice-related QOL has also been evaluated in children using the Pediatric Voice Outcomes Survey (PVOS) and the Pediatric Voice-Related Quality of Life (PVRQOL) survey.[137-139]

Voice. Several instruments have been developed to assess outcomes in voice, including the Voice Handicap Index (VHI)[140] and the Voice Outcome Survey (VOS).[141] The Voice Handicap Index is one of the most widely used instruments and has been well studied. It evaluates the psychosocial impact of dysphonia and has been validated by both classic test theory[108,142] and

IRT.[143] The Voice Symptom Scale (VoiSS),[144,145] the Vocal Performance Questionnaire (VPQ),[146] and the Voice-Related Quality of Life (V-RQOL)[147] instrument have all been well studied and well used also. These instruments provide independent useful data that complement clinician-performed perceptual evaluation.[148,149] In addition, the Singing Voice Handicap Index (SVHI) has been created and was found to be valid and reliable for assessing vocal problems specific to singers.[150]

Sleep. Several validated scales are in use to assess HRQOL in adults with OSA. The most widely used are the 30-item Functional Outcomes of Sleep Questionnaire (FOSQ)[151] and the 50-item Calgary Sleep Apnea Quality of Life Index (SAQLI).[152,153] In addition, the Quebec Sleep Questionnaire (QSQ) was recently validated as an additional OSA instrument.[154] Clinicians interested in a more brief inventory may wish to consider the Symptoms of Nocturnal Obstruction and Respiratory Events (SNORE-25) questionnaire.[155] The eight-item Epworth Sleepiness Scale (ESS) is commonly used to assess the degree of daytime sleepiness.[156] Although perhaps one of the most useful tools available, a recent study found that it was not clinically reproducible,[157] and a number of studies have shown wide variability in correlation between the ESS and objective measures of sleep apnea severity. Because sleepiness and fatigue can be difficult to differentiate on QOL instruments and in clinical practice, the Empirical Sleepiness and Fatigue scales were recently created. These utilized a number of items from the ESS and were found to have internal consistency and good test-retest reliability, and they will likely aid in the evaluation of patients with OSA, who are more likely to endorse sleepiness variables.[158]

Symptom Scales

Two scales specific to swallowing are available. The M.D. Anderson Dysphagia Inventory (MDADI)[159] is a brief 20-item scale intended to measure dysphagia in head and neck cancer patients. The SWAL-QOL is longer (44 items) but is validated for use in a more general population.[160] One instrument, the Quality of Life in Reflux and Dyspepsia (QOLRAD), was developed to assess QOL in patients with laryngopharyngeal reflux.[161] Finally, several instruments have been developed to assess outcomes in facial plastic surgery, such as the Blepharoplasty Outcomes Evaluation (BOE).[162]

SUMMARY AND FUTURE DIRECTIONS

Outcomes research is the scientific analysis of treatment effectiveness. In the past two decades, it has contributed substantially to the national debate on health resource allocation. Outcomes research provides insight into the value of otolaryngology treatments and into methods for quantifying important outcomes previously too “soft” to measure. Better appreciation for outcomes research will improve the level of evidence of important treatments and operations.

The impact of outcomes research is now beginning to extend into deliberations about quality of care, as the health care system moves to establish standards for patient safety. A coalition of the largest public and private organizations that provide health care benefits for their employees, the Leapfrog Group, uses its collective purchasing power to ensure that its employees have access to, and more informed choices about, quality health care. Policymakers will increasingly look to outcomes research for insight into how to measure quality and safety in addition to measuring effectiveness.

It is imperative that clinicians be familiar with these basic principles. Otolaryngologists should participate in local and national outcomes research efforts to improve the evidence supporting successful otolaryngology interventions and to provide informed physician perspective in a health care environment increasingly driven by third-party participants.

For a complete list of references, see expertconsult.com.

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2

Interpreting Medical Data

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Key Points

- Learning how to interpret medical data will make you a better clinician, researcher, and teacher.
- Interpreting data begins by assessing the investigation that produced it; low-quality data with a high risk of bias are of limited value, regardless of how appealing the results may seem.
- The presence or absence of a control or comparison group has a profound influence on data interpretation. An uncontrolled study is purely descriptive and cannot assess effectiveness or efficacy.
- Statistical tests often make assumptions about the underlying data. Unless these assumptions are met, the results are invalid.
- Uncertainty is present in all data because of the inherent variability in biologic systems and in our ability to assess them in a reproducible fashion. Results should be reported with 95% confidence intervals, which incorporate uncertainty by providing a zone of compatibility with the data.
- All statistical tests measure error. The *P* value is the likelihood of a type I error (false-positive conclusion), which occurs if a true null hypothesis is mistakenly rejected. Conversely, a type II error (false-negative conclusion) occurs when a real difference is missed and is related to statistical power and sample size.
- A study has internal validity when the data are analyzed and interpreted properly, but external validity (generalizability) requires that the study sample be representative of the larger population to which it is intended to apply.
- Confidence and common sense are needed to balance statistical significance with clinical importance.
- A single study is rarely definitive. Science is a cumulative process that requires a large body of consistent and reproducible evidence before conclusions can be formed.
- Effective data interpretation facilitates moving from observations to generalizations with predictable degrees of certainty and uncertainty.

In every chapter of this text, whether it relates to clinical medicine or basic science, the authors draw on their own experience and the experience of others to form valid and generalizable conclusions. Experience yields data, and interpreting data is the heart and soul of the cumulative process called *science*. Learning how to interpret medical data will make you a better clinician, researcher, and teacher.

Effective data interpretation is a habit: a combination of knowledge, skill, and desire.[1] By applying the seven habits shown in Table 2-1 and further outlined in this chapter, any otolaryngologist—regardless of his or her level of statistical knowledge or lack thereof—can interpret data. Practitioners can also improve their ability to understand and critically appraise the biomedical literature.[2] The numerous tables that accompany the text were designed as stand-alone reminders and often contain keywords with definitions endorsed by the International Epidemiological Association.[3]

This chapter also discusses the practice of data interpretation and includes specific hypothesis tests, sample size determinations, and common statistical deceptions encountered in the otolaryngology literature. You do not have to be a wizard with numbers to understand data; all you need are patience, persistence, and a few good habits that will help settle the dust that follows the clash of statistics with the human mind.

SEVEN HABITS OF HIGHLY EFFECTIVE DATA USERS

The seven habits that follow are the key to understanding data.[4] They embody fundamental principles of epidemiology and biostatistics developed in a logical and sequential fashion. Table 2-1 gives an overview of the seven habits and their corresponding principles and keywords.

HABIT 1: CHECK QUALITY BEFORE QUANTITY

Bias is a four-letter word that is easy to ignore but difficult to avoid.[5] Data collected specifically for research (Table 2-2) are likely to be unbiased—they reflect the true value of the attribute being measured. In contrast, data collected during routine clinical care will vary in quality depending on the specific methodology applied.

Experimental studies, such as randomized trials, often yield high-quality data, because they are performed under carefully controlled conditions. In observational studies, however, the investigator is simply a bystander who records the natural course of health events during clinical care. Although more

TABLE 2-1. Seven Habits of Highly Effective Data Users

Habit	Underlying Principles	Keywords
1. Check quality before quantity.	All data are not created equal; fancy statistics cannot salvage biased data from a poorly designed and executed study.	Bias, accuracy, research design, internal validity, confounding, causality
2. Describe before you analyze.	Special data require special tests; improper analysis of small samples or data with an asymmetric distribution gives deceptive results.	Measurement scale, frequency distribution, descriptive statistics
3. Accept the uncertainty of all data.	All observations have some degree of random error; interpretation requires estimating the associated level of precision or confidence.	Precision, random error, confidence intervals
4. Measure error with the right statistical test.	Uncertainty in observation implies certainty of error; positive results must be qualified by the chance of being wrong, negative results by the chance of having missed a true difference.	Statistical test, type I error, *P* value, type II error, power
5. Put clinical importance before statistical significance.	Statistical tests measure error, not importance; an appropriate measure of clinical importance must be checked.	Effect size, statistical significance, clinical importance
6. Seek the sample source.	Results from one dataset do not necessarily apply to another; findings can be generalized only for a random and representative sample.	Population, sample, selection criteria, external validity
7. View science as a cumulative process.	A single study is rarely definitive; data must be interpreted relative to past efforts and by their implications for future efforts.	Research integration, level of evidence, meta-analysis

reflective of "real life" than a contrived experiment, observational studies are more prone to bias. Comparing randomized trials with outcomes studies highlights the difference between experimental and observational research (Table 2-3).

The presence or absence of a control group has a profound influence on data interpretation. An uncontrolled study, no matter how elegant, is purely descriptive.[6] Case series, which appear frequently in the otolaryngology literature, cannot assess efficacy or effectiveness, but they can convey feasibility, experience, technical details of an intervention, and predictive factors associated with good outcomes or adverse events. The best case series 1) include a consecutive sample of subjects; 2) describe the sample fully and include details of interventions and adjunctive treatments; 3) account for all participants enrolled, including withdrawals and dropouts; and 4) ensure that follow-up duration is adequate to overcome random disease fluctuations.[7]

Without a control or comparison group, treatment effects cannot be distinguished from other causes of clinical change (Table 2-4).[8] Some of these causes are seen in Figure 2-1, which

TABLE 2-2. Effect of Study Design on Data Interpretation

Aspect of Study Design	Effect on Data Interpretation
How Were the Data Originally Collected?	
Specifically for research	Interpretation is facilitated by quality data collected according to an a priori protocol.
During routine clinical care	Interpretation is limited by consistency, accuracy, availability, and completeness of the source records.
Database or data registry	Interpretation is limited by representativeness of the sample and the quality and completeness of data fields.
Is the Study Experimental or Observational?	
Experimental study with conditions under direct control of the investigator	Low potential for systematic error (*bias*); bias can be reduced further by randomization and masking (*blinding*).
Observational study without intervention other than to record, classify, analyze	High potential for bias in sample selection, treatment assignment, measurement of exposures, and outcomes.
Is There a Comparison or Control Group?	
Comparative or controlled study with two or more groups	Permits analytic statements concerning efficacy, effectiveness, and association.
No comparison group present	Permits descriptive statements only because of improvements from natural history and placebo effect.
What is the Direction of Study Inquiry?	
Subjects identified before an outcome or disease; future events recorded	Prospective design measures incidence (new events) and causality (if a comparison group included).
Subjects identified after an outcome or disease; past histories examined	Retrospective design measures prevalence (existing events) and causality (if a comparison group is included).
Subjects identified at a single time point, regardless of outcome or disease	Cross-sectional design measures prevalence (existing events) and association (if a comparison group is included).

TABLE 2-3. Comparison of Randomized Controlled Trials and Outcomes Studies

Characteristic	Randomized Controlled Trial	Outcomes Study
Level of investigator control	Experimental	Observational
Treatment allocation	Random assignment	Routine clinical care
Patient selection criteria	Restrictive	Broad
Typical setting	Hospital or university based	Community based
End point definition	Objective health status	Subjective quality of life
End point assessment	Masked (blinded)	Unmasked
Statistical analysis	Comparison of groups	Multivariate regression
Potential for bias	Low	Very high
Generalizability	Potentially low	Potentially high

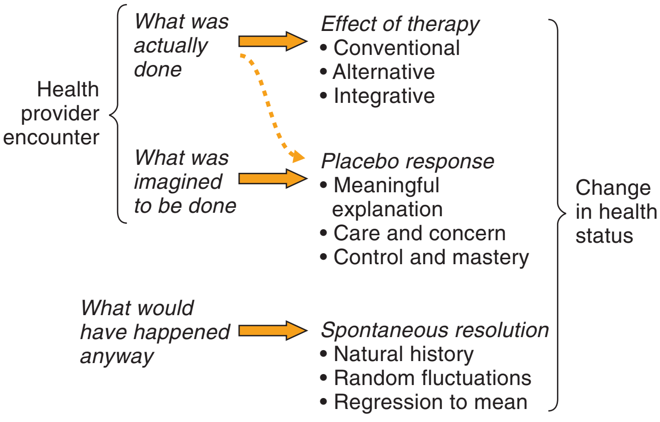

FIGURE 2-1. Model depicting change in health status after a healing encounter. Dashed arrow shows that a placebo response may occur from symbolic significance of the specific therapy given or from interpersonal aspects of the encounter.

depicts change in health status after a healing encounter as a complex interaction of three primary factors.[9, 10]

1. *What was actually done.* Specific effects of therapy, which include medications, surgery, physical manipulations, and alternative or integrative approaches.
2. *What was imagined to be done.* Placebo response, defined as a change in health status resulting from the symbolic significance attributed by the patient (or proxy) to the encounter itself. A placebo response is most likely to occur when the patient receives a meaningful and personalized explanation, feels care and concern expressed by the practitioner, and achieves control and mastery over the illness or believes that the practitioner can control the illness.[11]
3. *What would have happened anyway.* Spontaneous resolution, which includes natural history, random fluctuations in disease status, and regression to a mean symptom state.

The placebo response differs from the traditional definition of placebo as an inactive medical substance. Whereas a placebo can elicit a placebo response, the latter can occur without the former. A placebo response results from the psychologic or symbolic importance attributed by the patient to any nonspecific event in a healing environment. These events include touch, words, gestures, local ambience, and social interactions.[12] Many of these factors are encompassed in the term *caring effects,*[13] which have been central to medical practice in all cultures throughout history. Caring and placebo effects are so important that they have been deliberately used to achieve positive outcomes in clinical practice.[14]

Questionnaires and quality of life surveys are particularly prone to bias (see Table 2-4) if they have not been assessed for reliability, validity, and responsiveness. Unless the authors used

TABLE 2-4. Explanations Other than "Efficacy" for Outcomes in Treatment Studies

Explanation	Definition	Solution
Bias	Systematic deviation of results or inferences from truth; may be intentional or unintentional	Accurate, protocol-driven data collection
Chance	Random variation without apparent relation to other measurements or variables (e.g., luck)	Control or comparison group
Natural history	Course of a disease from onset to resolution; may include relapse, remission, and spontaneous recovery	Control or comparison group
Regression to the mean	Symptom improvement independent of therapy, as sick patients return to a mean level after seeking care	Control or comparison group
Placebo effect	Beneficial effect caused by the expectation that the regimen will have an effect (e.g., power of suggestion)	Control or comparison group with placebo
Halo effect	Beneficial effect caused by treatment novelty or by the provider's manner, attention, and caring	Control or comparison group treated similarly
Hawthorne effect	Beneficial effect caused by the participant's knowledge of being evaluated and observed in a study	Control or comparison group treated similarly
Confounding	Distortion of a measure of the effect of an exposure on an outcome by other prognostic factors or variables that influence the occurrence of the outcome	Randomization or multivariate analysis
Allocation (susceptibility) bias	Beneficial effect caused by allocating subjects with less severe disease or better prognosis to the treatment group	Randomization or comorbidity analysis
Ascertainment (detection) bias	Favoring the treatment group during outcome analysis (e.g., rounding numbers up for treated subjects and rounding them down for controls)	Masked (blinded) outcome assessment

TABLE 2-5. **Relationship of Study Type to Study Methodology**

Study Type	How Were the Data Originally Collected?	Was a Control or Comparison Group Included?	What Is the Direction of the Study Inquiry?
Experimental Studies			
Basic science study	Research	Yes or no	Prospective or cross-sectional
Clinical trial	Research	Yes or no	Prospective or cross-sectional
Randomized trial	Research	Yes	Prospective
Observational Studies			
Cohort study	Clinical care or research	Yes or no	Prospective
Historical cohort study*	Clinical care	Yes	Prospective
Outcomes research	Clinical care or research	Yes or no	Prospective
Case-control study	Clinical care	Yes	Retrospective
Case series	Clinical care	Yes or no	Retrospective or prospective
Survey study	Clinical care or research	Yes or no	Cross-sectional
Diagnostic test study	Clinical care or research	Yes or no	Cross-sectional

*Also called a retrospective cohort study or nonconcurrent cohort study.

a "validated" measure, the results are suspect; but problems may also arise if a validated instrument is used in an inappropriate way. For example, some surveys are developed specifically to compare individuals at a point in time (discriminative surveys) and may not be valid when used to measure change in status within individuals before and after intervention (evaluative surveys). Additional bias may arise in survey research related to sampling the population, administering the questionnaire, and managing the resultant data.[15]

When data from a comparison or control group are available, inferential statistics may be used to test hypotheses and measure associations. Causality may also be assessed when the study has a time-span component, either retrospective or prospective (see Table 2-2). Prospective studies measure incidence (new events), whereas retrospective studies measure prevalence (existing events). Unlike time-span studies, cross-sectional inquiries measure association, not causality. Examples include surveys, screening programs, and evaluation of diagnostic tests. Experimentally planned interventions are ideal for assessing cause-effect relationships, because observational studies are prone to innate distortions or biases caused by individual judgments and other selective decisions.[16]

Another clue to data quality is study type,[17] but this cannot replace the four questions in Table 2-2. Note the variability in data quality for the study types listed in Table 2-5, particularly the observational designs. Randomization balances baseline prognostic factors, both known and unknown, among groups; this includes factors such as severity of illness and the presence of comorbid conditions. Because these factors also influence a clinician's decision to offer treatment, nonrandomized studies are prone to allocation (susceptibility) bias (see Table 2-4) and false-positive results.[18] For example, when the survival of surgically treated cancer patients is compared with the survival of nonsurgical controls (e.g., patients treated with radiation or chemotherapy) without randomization, the surgical group will generally have a more favorable prognosis independent of therapy, because the customary criteria for operability—special anatomic conditions and no major comorbidity—also predispose to favorable results.

The relationship between data quality and interpretation is illustrated in Table 2-6 using hypothetical studies to determine whether tonsillectomy causes baldness. Note how a case series (examples 1 and 2) can have either a prospective or retrospective direction of inquiry, depending on how subjects are identified; contrary to common usage, all cases series are not "retrospective reviews." Only the controlled studies (examples 3 through 7) can measure associations, and only the controlled studies with a time-span component (examples 4 through 7) can assess causality. The nonrandomized studies (examples 3 through 6), however, require adjustment for potential confounding variables—baseline prognostic factors that may be associated with both tonsillectomy and baldness and may therefore influence results. As noted previously, adequate randomization ensures balanced allocation of prognostic factors among groups, thereby avoiding the issue of confounding.

HABIT 2: DESCRIBE BEFORE YOU ANALYZE

Statistical tests often make assumptions about the underlying data. Unless these assumptions are met, the test will be invalid. Describing before you analyze avoids trying to unlock the mysteries of square data with a round key.

Describing data begins by defining the measurement scale that best suits the observations. Categorical (qualitative) observations fall into one or more categories and include dichotomous, nominal, and ordinal scales (Table 2-7). Numeric (quantitative) observations are measured on a continuous scale and are further classified by the underlying frequency distribution, a plot of observed values versus the frequency of each value. Numeric data with a symmetric (normal) distribution are symmetrically placed around a central crest or trough (bell-shaped curve). Numeric data with an asymmetric distribution

TABLE 2-6. **Determining Whether Tonsillectomy Causes Baldness: Study Design vs. Interpretation**

Study Design*	Study Execution	Interpretation
1. Retrospective case series	A group of bald subjects are questioned as to whether or not they had a tonsillectomy.	Measures prevalence of tonsillectomy in bald subjects; cannot assess association or causality
2. Prospective case series	A group of subjects who had or who are about to have tonsillectomy are examined later for baldness.	Measures incidence of baldness after tonsillectomy; cannot assess association or causality
3. Cross-sectional study	A group of subjects are examined for baldness and for presence or absence of tonsils at the same time.	Measures prevalence of baldness and tonsillectomy and their association; cannot assess causality
4. Case-control study	A group of bald subjects and a group of nonbald subjects are questioned about prior tonsillectomy.	Measures prevalence of baldness and association with tonsillectomy; limited ability to assess causality
5. Historical (retrospective) cohort study	A group of subjects who had prior tonsillectomy and a comparison group with intact tonsils are examined later for baldness.	Measures incidence of baldness and association with tonsillectomy; can assess causality when adjusted for confounding variables
6. Cohort study (longitudinal)	A group of nonbald subjects about to have tonsillectomy and a nonbald comparison group with intact tonsils are examined later for baldness.	Measures incidence of baldness and association with tonsillectomy; can assess causality when adjusted for confounding variables
7. Randomized controlled trial	A group of nonbald subjects with intact tonsils are randomly assigned to tonsillectomy or observation and are examined later for baldness.	Measures incidence of baldness and association with tonsillectomy; can assess causality despite baseline confounding variables

*Studies are listed in order of increasing ability to establish causal relationship.

are skewed (shifted) to one side of the center, have a sloping "exponential" shape that resembles a forward or backward *J*, or contain some unusually high or low outlier values.

Depending on the measurement scale, data may be summarized using one or more of the descriptive statistics given in Table 2-8. Note that when summarizing numeric data, the descriptive method varies according to the underlying distribution. Numeric data with a symmetric distribution are best summarized with the mean and standard deviation (SD), because 68% of the observations fall within the mean ± 1 SD, and 95% fall within the mean ± 2 SD. In contrast, asymmetric numeric data are best summarized with the median, because even a single outlier can strongly influence the mean. If a series of five patients are followed after sinus surgery for 10, 12, 15, 16, and 48 months, the mean duration of follow-up is 20 months, but the median is only 15 months. In this case, a single outlier, 48 months, distorts the mean.

TABLE 2-7. **Measurement Scales for Describing and Analyzing Data**

Scale	Definition	Examples
Dichotomous	Classification into either of two mutually exclusive categories	Breastfeeding (yes/no), sex (male/female)
Nominal	Classification into unordered qualitative categories	Race, religion, country of origin
Ordinal	Classification into ordered qualitative categories but with no natural (numeric) distance between their possible values	Hearing loss (none, mild, moderate), patient satisfaction (low, medium, high), age group
Numeric	Measurements with a continuous scale or a large number of discrete, ordered values	Temperature, age in years, hearing level in decibels
Numeric (censored)	Measurements on subjects lost to follow-up or in whom a specified event has not yet occurred at the end of a study	Survival rate, recurrence rate, or any time-to-event outcome in a prospective study

Although the mean is appropriate only for numeric data with a symmetric distribution, it is often applied regardless of the underlying symmetry. An easy way to determine whether the mean or median is appropriate for numeric data is to calculate both; if they differ significantly, the median should be used. Another way is to examine the SD; when it is very large (e.g., larger than the mean value with which it is associated), the data often have an asymmetric distribution and should be described by the median and interquartile range. When in doubt, the median should always be used over the mean.[19]

A special form of numeric data is called *censored* (see Table 2-7). Data are censored when three conditions apply: 1) the direction of study inquiry is prospective; 2) the outcome of interest is time related; and 3) some subjects die, are lost, or have not yet had the outcome of interest when the study ends. Interpreting censored data is called *survival analysis* because of its use in cancer studies, in which survival is the outcome of interest. Survival analysis permits full use of censored observations (e.g., patients with less than 1 year of follow-up) by including them in the analysis up to the time the censoring occurred. Results of cancer studies are often reported with *Kaplan-Meier curves*, which may describe overall survival, disease-free survival, disease-specific survival, or progression-free survival.[20] Survival data at the far right of the curves should be interpreted cautiously, because fewer patients remain, which yields less precise estimates.

A survival curve starts with 100% of the study sample alive and shows the percentage still surviving at successive times for as long as information is available. The curve may be applied not only to survival as such but also to the persistence of freedom from a disease or complication or some other end point. For example, the 3-, 5-, or 10-year rates for cholesteatoma

TABLE 2-8. **Descriptive Statistics**

Descriptive Measure	Definition	Application
Central Tendency		
Mean	Arithmetic average	Numeric data that are symmetric
Median	Middle observation; half the values are smaller, and half are larger	Ordinal data; numeric data with an asymmetric distribution
Mode	Most frequent value	Nominal data; bimodal distribution
Dispersion		
Range	Largest value minus smallest value	Emphasizes extreme values
Standard deviation	Spread of data about their mean	Numeric data that are symmetric
Percentile	Percentage of values equal to or below that number	Ordinal data; numeric data with an asymmetric distribution
Interquartile range	Difference between the twenty-fifth and seventy-fifth percentiles	Ordinal data; numeric data with an asymmetric distribution
Outcome		
Survival rate	Proportion of subjects surviving, or with some other outcome, after a time interval (e.g., 1 year, 5 years)	Numeric (censored) data in a prospective study; can be overall, cause specific, or progression free
Odds ratio	Odds of a disease or outcome in subjects; risk factor divided by odds in controls	Dichotomous data in a retrospective or prospective controlled study
Relative risk	Incidence of a disease or outcome in subjects; risk factor divided by incidence in controls	Dichotomous data in a prospective controlled study
Rate difference*	Event rate in treatment group minus event rate in control group	Compares success or failure rates in clinical trial groups
Correlation coefficient	Degree to which two variables have a linear relationship	Numeric or ordinal data

*Also called the absolute risk reduction.

recurrence or the future "survival" of tonsils (i.e., no need for tonsillectomy) could be estimated in a cohort of children after adenoidectomy alone. Several statistical methods are available for analyzing survival data. The Kaplan-Meier (product-limit) method records events by exact dates and is suitable for small and large samples. Conversely, the life-table (actuarial) method records events by time interval (e.g., every month, every year) and is most commonly used for large samples in epidemiologic studies.

The odds ratio, relative risk, and rate difference (see Table 2-8) are useful ways of comparing two groups of dichotomous data.[21] A retrospective (case-control) study of tonsillectomy and baldness might report an odds ratio of 1.6, indicating that bald subjects were 1.6 times more likely to have had tonsillectomy than were nonbald controls. In contrast, a prospective study would report results using relative risk. A relative risk of 1.6 means that baldness was 1.6 times more likely to develop in tonsillectomy subjects than in nonsurgical controls. Finally, a rate difference of 30% in a prospective trial or experiment reflects the increase in baldness caused by tonsillectomy above and beyond what occurred in controls. No association exists between groups when the rate difference equals zero or the odds ratio or relative risk equals one (unity).

Two groups of ordinal or numeric data are compared with a correlation coefficient (see Table 2-8). A coefficient (r) from 0 to 0.25 indicates little or no relationship, from 0.25 to 0.49 a fair relationship, from 0.50 to 0.74 a moderate to good relationship, and greater than 0.75 a good to excellent relationship. A perfect linear relationship would yield a coefficient of 1.00. When one variable varies directly with the other, the coefficient is positive; a negative coefficient implies an inverse association. Sometimes the correlation coefficient is squared (r^2) to form the coefficient of determination, which estimates the percentage of variability in one measure that is predicted by the other.

HABIT 3: ACCEPT THE UNCERTAINTY OF ALL DATA

Uncertainty is present in all data because of the inherent variability in biologic systems, and it is present in our ability to assess data in a reproducible fashion.[22] If we were to measure hearing in 20 healthy volunteers on five different days, it would be very unlikely for us to get the same mean result each time; this is because audiometry has a variable behavioral component that depends on the subject's response to a stimulus and the examiner's perception of that response. Similarly, if hearing were to be measured in five groups of 20 healthy volunteers each, it would be very unlikely for us to get the same mean hearing level in each group; again, it would be unlikely because of variations among individuals. A range of similar results would be obtained, but rarely would the exact same result be obtained on repetitive trials.

Uncertainty must be dealt with when interpreting data, unless the results are meant to apply only to the particular group of patients, animals, cell cultures, and DNA strands in which the observations were initially made. Recognizing this uncertainty, each of the descriptive measures in Table 2-8 is called a *point estimate*, which is specific to the data that generated it. In medicine, however, the clinician seeks to pass from observations to generalizations and from point estimates to estimates about other populations. When this process occurs with calculated degrees of uncertainty, it is called *inference*.

The following is a brief example of clinical inference. After treating five vertiginous patients with vitamin C, you remark to a colleague that four had excellent relief of their vertigo. She asks, "How confident are you of your results?"

"Quite confident," you reply. "There were five patients, four got better, and that's 80%."

"Maybe I wasn't clear," she interjects. "How confident are you that 80% of vertiginous patients you see in the next few weeks will respond favorably, or that 80% of similar patients in my practice will do well with vitamin C? In other words, can you infer anything about the real effect of vitamin C on vertigo from only five patients?"

Hesitatingly you retort, "I'm pretty confident about that number, 80%, but maybe I'll have to see a few more patients to be sure."

The real issue, of course, is that a sample of only five patients offers low precision (repeatability). How likely is it that the same results would be found if five new patients were studied? Actually, it can be stated with 95% confidence that four out of five successes in a single trial is consistent with a range of results from 28% to 99% in future trials. This 95% confidence interval may be calculated manually or with a statistical program; it reveals the range values considered plausible for the population. Another useful way to understand confidence intervals (CIs) is as providing a zone of compatibility with the data.[23] A point estimate summarizes findings for the sample, but extrapolation to the large population introduces error and uncertainty, which makes a range of plausible values more appropriate.

Precision may be increased, or uncertainty may be decreased, by 1) using a more reproducible measure, 2) increasing the number of observations (sample size), or 3) decreasing the variability among the observations. The most common method is to increase the sample size, because the variability inherent in the subjects studied can rarely be reduced. Even a huge sample of perhaps 50,000 subjects still has some degree of uncertainty, but the 95% CI will be quite small. Realizing that uncertainty can never completely be avoided, statistics are used to estimate precision. Thus when data are described using the summary measures listed in Table 2-8, a corresponding 95% CI should accompany each point estimate.

Precision differs from accuracy. Precision relates to random error and measures repeatability; accuracy relates to systematic error (bias) and measures nearness to the truth. A precise otologist may always perform a superb mastoidectomy, but an accurate otologist performs it on the correct ear. A precise surgeon cuts on the exact center of the line, but an accurate surgeon first checks the line to be sure its placement is correct. Succinctly put, precision is doing things right, and accuracy is doing the right thing. Precise data include a large enough sample of carefully measured observations to yield repeatable estimates; accurate data are measured in an unbiased manner and reflect what is truly purported to be measured. When we interpret data, we must estimate both precision and accuracy.

To summarize habits 1, 2, and 3: "Check quality before quantity" determines whether or not the data are worth interpreting (habit 1). Assuming they are, "describe before you analyze," and summarize the data using appropriate measures of central tendency, dispersion, and outcome for the particular measurement scales involved (habit 2). Next, "accept the uncertainty of all data" as noted in habit 3, and qualify the point estimates in habit 2 with 95% CIs to measure precision. When precision is low (e.g., the CI is wide), proceed with caution. Otherwise, proceed with habits 4, 5, and 6, which deal with errors and inference.

HABIT 4: MEASURE ERROR WITH THE RIGHT STATISTICAL TEST

To err is human—and statistical. When comparing two or more groups of uncertain data, errors in inference are inevitable. If it can be concluded that the groups are different, they may actually be equivalent. If the conclusion is that they are the same, a true difference may have been missed. Data interpretation is an exercise in modesty, not pretense—any conclusion we reach may be wrong. The ignorant data analyst ignores the possibility of error; the savvy analyst estimates this possibility by using the right statistical test.[24]

Now that we have stated the problem in English, let us restate it in thoroughly confusing statistical jargon (Table 2-9). We begin with some testable hypotheses about the groups we are studying, such as "Gibberish levels in group A differ from those in group B." Rather than keep it simple, we now invert this to form a null hypothesis: "Gibberish levels in group A are equal to those in group B." Next we fire up our personal computer, enter the gibberish levels for the subjects in both groups, choose an appropriate statistical test, and wait for the omnipotent *P* value to emerge.

The *P* value gives the probability of making a type I error: rejection of a true null hypothesis. In other words, if $P = .10$, there is a 10% chance of being wrong when we declare that group A differs from group B based on the observed data. Alternatively, there is a 10% probability that the difference in gibberish levels is explainable by random error—we cannot be certain that uncertainty is not the cause. In medicine, $P < .05$ is generally considered low enough to safely reject the null hypothesis. Conversely, when $P > .05$, the null hypothesis of equivalent gibberish levels is accepted. Nonetheless, one might be making a type II error by accepting a false null hypothesis.

TABLE 2-9. **Glossary of Statistical Terms Encountered when Testing Hypotheses**

Term	Definition
Central tendency	A supposition arrived at from observation or reflection that leads to predictions that can be tested and refuted
Null hypothesis	Results observed in a study, experiment, or test that are no different from what might have occurred because of chance alone
Statistical test	Procedure used to reject or accept a null hypothesis; statistical tests may be parametric, nonparametric (distribution free), or exact
Type I (alpha) error	Wrongly rejecting a null hypothesis (false-positive error); declaring that a difference exists, when in fact it does not
P value	Probability of making a type I error; $P < .05$ indicates a statistically significant result that is unlikely to have been caused by chance
Confidence interval	A zone of compatibility with the data, which also indicates a range of values considered plausible for the population from which the study sample was selected
Type II (beta) error	Failing to reject a false null hypothesis (false-negative error); declaring that a difference does not exist, when in fact it does
Power	Probability that the null hypothesis will be rejected if it is indeed false; mathematically, power is 1.00 minus type II error

Rather than state the probability of a type II error directly, it is stated indirectly by specifying power (see Table 2-9).

Moving from principles to practice, two hypothetical studies are presented. The first is an observational prospective study to determine whether tonsillectomy causes baldness: 20 patients who underwent tonsillectomy and 20 controls are examined 40 years later, and the incidence of baldness is compared. The second study will use the same groups but will determine whether tonsillectomy causes hearing loss. This allows exploration of statistical error from the perspective of a dichotomous outcome (bald vs. nonbald) and a numeric outcome (hearing level in decibels).

Suppose that baldness develops in 80% of tonsillectomy patients (16/20) but in only 50% of controls (10/20). If we infer, based on these results in 40 specific patients, that tonsillectomy predisposes to baldness in general, what is the probability of being wrong (i.e., a type I error)? Because $P = .10$ (Fisher exact test), a 10% chance of type I error exists, so we should be reluctant to associate tonsillectomy with baldness based on this single study; the strength of the evidence against the null hypothesis is simply too much to ignore.

Intuitively, however, a rate difference of 30% seems significant; so what is the chance of being wrong when we conclude that it is not (i.e., a type II error)? The probability of a type II error (false-negative result) is actually 48%, the same as saying 52% power, which means we may indeed be wrong in accepting the null hypothesis; therefore a larger study is needed before any definitive conclusions can be drawn.

Intrigued by the initial findings, we repeat the tonsillectomy study with twice as many patients in each group. Suppose that baldness again develops in 80% of tonsillectomy patients (32/40) but in only 50% of controls (20/40). The rate difference is still 30%, but now $P = .01$ (Fisher exact test). The conclusion is that tonsillectomy is associated with baldness, with only a 1% chance of making a type I error (false-positive result). By increasing the number of subjects studied, the precision is increased to a level that could move from observation to generalization with a tolerable level of uncertainty. Similarly, the strength of the evidence against the null hypothesis is now much higher.

Returning to the earlier study of 20 tonsillectomy patients and 20 controls, the hearing levels for the groups are 25 ± 9 decibels (dB) and 20 ± 9 dB, respectively (mean value ± SD). What is the chance of being wrong if we infer that posttonsillectomy patients have hearing levels 5 dB lower than controls? Because $P = .09$ (t test), the probability of a type I error is 9%. If, however, we conclude that no true difference exists between the groups, the chance of making a type II error is 58%. Thus, little can be said about the impact of tonsillectomy on hearing based on this study, because power is only 42%.

In general, studies with "negative" findings should be interpreted by power, not P values. The difference is significant between observing nothing in a study and proving nothing really happened. Most often, not enough patients were studied to offer a reasonable chance of not missing differences of up to 50% between groups. Even randomized trials in otolaryngology journals, with a median samples size of only about 50 patients, suffer from low statistical power and potential false-negative results.[25]

When making inferences about numeric data, precision may be increased by studying more subjects or by studying subjects with less variability in their responses. For example, suppose again that there are 20 tonsillectomy patients and 20 controls, but this time the hearing levels are 25 ± 3 dB and 20 ± 3 dB. Although the difference remains 5 dB, the SD is only 3 for this study, compared with 9 in the preceding example. For whatever reason, the second set of subjects had more consistent (less variable) responses. What effect does this reduced variability have on the ability to make inferences? The P value is now less than .001 (t test), indicating less than a 1 : 1000 probability of a type I error if we conclude that the hearing levels truly differ.

All statistical tests measure error. Choosing the right test for a particular situation (Tables 2-10 and 2-11) is determined by 1) whether the observations come from independent or related samples, 2) whether the purpose is to compare groups or to associate an outcome with one or more predictor variables, and 3) the measurement scale of the variables.[26] Despite the myriad tests available, the principles that underlie each remain constant.

Two events are independent if the occurrence of one is in no way predictable from the occurrence of the other. A common example of independent samples is two or more parallel (concurrent) groups in a clinical trial or observational study. Conversely, related samples include paired organ studies, subjects matched by age and sex, and repeated measures on the same subjects (e.g., before and after treatment). Measurement scales were discussed previously, but the issue of frequency distribution deserves reemphasis. The tests in Tables 2-10 and 2-11 labeled as "parametric" assume an underlying symmetric distribution for data. If the data are sparse, asymmetric, or plagued with outliers, a "nonparametric" test must be used.

Using the wrong statistical test to estimate error invalidates results. For example, suppose intelligence quotient (IQ) is measured in 20 subjects before and after tonsillectomy, and the mean IQ increases from 125 to 128. For this three-point increase, $P = .29$ (t test, independent samples) suggests a high probability (29%) of reaching a false-positive conclusion. However, the observations in this example are related before and after IQ tests in the same subjects. What is really of interest is the mean change in IQ for each subject (related samples), not how the mean IQ of all subjects before surgery compares with the mean IQ of all subjects postoperatively (independent samples). When the proper statistical test is used (t test, paired samples), $P = .05$ suggests a true association. Related (matched) samples are common in biomedical studies and should never be analyzed as though they were independent.

HABIT 5: PUT CLINICAL IMPORTANCE BEFORE STATISTICAL SIGNIFICANCE

Results are statistically significant when the probability of a type I error is low enough ($P < .05$) to safely reject the null hypothesis. If the statistical test compared two groups, we can conclude that the groups differ. If the statistical test compared three or more groups, we can conclude that global differences exist among them. If the statistical test related predictor and outcome variables (regression analysis), we can conclude that the predictor variables explain more variation in the outcome than would be expected by chance alone. These generalizations apply to all the statistical tests in Tables 2-10 and 2-11.

The next logical question after "Is there a difference?" (statistical significance) is "How big a difference is there?" (clinical importance). Unfortunately, most data interpretation stops with the P value, and the second question is never asked. For example, a clinical trial of nonsevere acute otitis media found amoxicillin superior to placebo as an initial treatment ($P = .009$).[27] Before we agree with the author's recommendation for routine amoxicillin therapy, let us look more closely at the magnitude of clinical effect. Initial treatment success occurred in 96% of amoxicillin-treated children versus 92% of controls, yielding a 4% rate difference that favored drug therapy. Alternatively, 25 subjects (100/4) must be treated with amoxicillin to increase the success rate by one subject over what would occur from placebo alone. Is this clinically important? Possibly not.

TABLE 2-10. Statistical Tests for Independent Samples

Situation	Parametric Test	Nonparametric Test
Comparing Two Groups of Data		
Numeric scale	*t* test	Mann-Whitney *U*,* median
Numeric (censored) scale	Mantel-Haenszel life table	Log rank, Mantel-Cox
Ordinal scale	—	Mann-Whitney *U*,* median test; chi-squared test for trend
Nominal scale	—	Chi-squared, log-likelihood ratio
Dichotomous scale	—	Chi-squared, Fisher exact, odds ratio, relative risk
Comparing Three or More Groups of Data		
Numeric scale	One-way ANOVA	Kruskal-Wallis ANOVA
Ordinal scale	—	Kruskal-Wallis ANOVA; chi-squared test for trend
Dichotomous or nominal scale	—	Chi-squared, log-likelihood ratio
Associating an Outcome with Predictor Variables		
Numeric outcome, one predictor	Pearson correlation	Spearman rank correlation
Numeric outcome, two or more predictor variables	Multiple linear regression, two-way ANOVA	—
Numeric (censored) outcome	Proportional hazards (Cox) regression	—
Dichotomous outcome	Discriminant analysis	Multiple logistic regression
Nominal or ordinal outcome	Discriminant analysis	Log-linear model

ANOVA, analysis of variance.
*The Mann-Whitney *U* test is equivalent to the Wilcoxon rank-sum test.

Statistically significant results must be accompanied by a measure of effect size that reflects the magnitude of difference between groups.[28] Otherwise, findings with minimal clinical importance may become statistically significant when a large number of subjects are studied. In the above example, the 4% difference in success rates was highly statistically significant, because more than 1000 episodes of otitis media contributed to this finding. Large numbers provide high precision (repeatability), which in turn reduces the likelihood of error. The final result, however, is a hypnotically tiny *P* value, which may reflect a clinical difference of trivial importance.

When comparing groups, common measures of effect size include the odds ratio, relative risk, and rate difference (see Table 2-8). For example, in the hypothetical study of tonsillectomy and baldness noted earlier, the rate difference was 30% ($P = .01$) with a 95% CI of 10% to 50%. Therefore we can be 95% confident that tonsillectomy increases the rate of baldness between 10% and 50%, with only a 1% chance of a type I error (false-positive). Alternatively, results could be expressed in terms of relative risk. For the tonsillectomy study, *relative risk* is 1.6 (the incidence of baldness was 1.6 times higher after surgery) with a 95% CI of 1.1 to 2.3. Effect size and 95% confidence limits may be calculated manually[29] or with a computer program.

Effect size is measured by the correlation coefficient (r) when an outcome variable is associated with one or more predictor variables in a regression analysis (see Table 2-10). Suppose that a study of thyroid surgery reports that shoe size had a statistically significant association with intraoperative blood loss (multiple linear regression, $P = .04$, $r = .10$). A correlation of only .10 implies little or no relationship (see habit 2), and an r^2 of .01 means that only 1% of the variance in survival is explainable by shoe size. Who cares if the results are "significant" when the effect size is clinically irrelevant, not to mention nonsensical? Besides, when $P = .04$, there is a 4% chance of being wrong when the null hypothesis is rejected, which may in fact be the case here. A nonsensical result should prompt a search for confounding factors that may not have been included in the regression, such as tumor-node-metastasis (TNM) stage, comorbid conditions, or duration of surgery.

Confidence intervals are more appropriate measures of clinical importance than are *P* values, because CIs reflect both magnitude and precision.[30] When a study reports "significant" results, the lower limit of the 95% CI should be scrutinized; a value of minimal clinical importance suggests low precision (inadequate sample size). When a study reports "nonsignificant" results, the upper limit of the 95% CI should be scrutinized; a value indicating a potentially important clinical effect suggests low statistical power (false-negative finding). CIs are

TABLE 2-11. Statistical Tests for Related (Matched, Paired, or Repeated) Samples

Situation	Parametric Test	Nonparametric Test
Comparing Two Groups of Data		
Dichotomous scale	—	McNemar
Ordinal scale	—	Sign, Wilcoxon signed rank
Numeric scale	Paired *t* test	Sign, Wilcoxon signed rank
Comparing Three or More Groups of Data		
Dichotomous scale	—	Cochran *Q*, Mantel-Haenszel chi-squared
Ordinal scale	—	Friedman ANOVA
Numeric scale	Repeated measures ANOVA	Friedman ANOVA

ANOVA, analysis of variance.