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### Dedication

This book is dedicated to Drs Daniel Green and Robert Amato, great mentors and educators who inspired our pursuit of excellence and love of evidence-based endodontics. May you all find your Drs Green and Amato.



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We are pleased to offer the second edition of what became known as "The Orange Book" in certain circles to those seeking a literature-based discussion of endodontics. Whether this book will supplement your predoctoral or postdoctoral endodontics curriculum or guide self-study in general dental or specialty practice, we are proud to share the evidence-based *why* behind the diagnosis and delivery of endodontic care.

Evidence-based endodontics evolves as the literature changes. As new literature is published, including updated position statements and guidelines, practitioners must adapt their clinical practice. Many important updates have occurred in the field of endodontics research and clinical practice since the first edition was published in 2016. These updates have been incorporated into this second edition. That said, as the literature continues to advance, we encourage readers to stay abreast of changes to ensure delivery of the most up-to-date, evidence-based clinical care. This text provides the foundation to pursue this necessary continued self-study.

# Evidence-Based Dentistry

The practice of evidence-based dentistry requires that providers make treatment decisions based on a comprehensive and constantly evolving evaluation of the bodies of research and literature in their field. Practitioners must sift through the available resources with a discerning eye.

They must be able to justify their decisions and recommendations based on the highest-quality evidence available. Research published in peerreviewed journals is considered to be unbiased and therefore most useful. Although textbooks and lectures are effective means of disseminating information, quality versions of these resources will refer back to primary resources in peer-reviewed journals. Consequently, it is imperative that providers familiarize themselves with the primary references cited in all examples. This chapter covers study design, measures of statistical significance and validity, and epidemiology. For a more in-depth review of research design and biostatistics, please refer to Hulley et al's *Designing Clinical Research* and Glaser's *High-Yield Biostatistics, Epidemiology, and Public Health*.

## **Study Design**

Beyond citing peer-reviewed journals as the ideal reference source, certain study designs are generally considered more scientifically sound. The Oxford Centre for Evidence-Based Medicine (OCEBM) outlines a hierarchy of levels of evidence by study design, illustrated in Fig 1-1.



Fig 1-1 OCEBM hierarchy of levels of evidence by study design.

Systematic reviews, including meta-analyses, are considered the highest level of evidence, and their quality improves based on the compiled levels of evidence of the studies reviewed. Systematic reviews involve a comprehensive search and review of all of the literature on a topic, whereas a meta-analysis delves deeper by doing statistical analyses to make direct comparisons between studies. Depending on the variability of the statistics reported in the literature available on a topic, a meta-analysis may not be achievable.

Further algorithm-based criteria exist for rating the quality of evidence compiled in a systematic review or meta-analysis. The strength of recommendation taxonomy (SORT) grading system evaluates and categorizes systematic reviews and evidence-based clinical guidelines based on the quality, quantity, and consistency of the evidence included (Newman et al). Similarly, the Grading of Recommendation, Assessment, Development, and Evaluation (GRADE) system aims to summarize evidence addressing a question for use in producing systematic reviews and guidelines (Guyatt et al). Whether or not one of the above algorithms is included in a systematic review, it behooves the reader to take into account the quality of literature reviewed.

The Cochrane Collaborative produces systematic reviews that can be considered the gold standard for evidence-based medicine. The reviews are constantly updated with post-publication peer review and a strong conflict of interest policy. They may contain meta-analysis when homogenous data is available for comparison among the studies reviewed. Efforts are made by the Cochrane authors to focus on randomized controlled trials when possible to reduce effects of known and unknown confounders as well as publication bias. If a Cochrane Review is available on a subject, its conclusions are considered the ultimate evidence-based take on a topic.

Beyond reviews, randomized controlled trials are considered the highest level of evidence when considering clinical research studies (OCEBM). Randomized controlled trials involve a planned intervention on a diseased population with matched controls. These studies are both resource- and time-intensive and are consequently difficult to perform. Furthermore, ethical concerns often arise in the discussion of this study type. Prior knowledge of superior intervention outcomes cannot be denied to a diseased population, and it is considered unethical to study certain populations, such as children or the disabled.

Cohort studies are considered next best among the levels of evidence hierarchy (OCEBM). Cohort studies are prospective and longitudinal, and they measure the incidence of new cases of a disease while assessing risk or protective factors. These types of studies can be resource-intensive and are not practical for rare outcomes.

Case-control studies follow cohort studies in the OCEBM hierarchy. This type of study compares past risk factors and exposures of cases with disease and controls without disease in a retrospective fashion. These studies are often less expensive to perform, less time-intensive, and can be useful to study rare outcomes. They are considered lower quality due to recall bias, difficulties with misdiagnosis, and assignment of controls.

Publications of case series or case reports represent the second-lowest level of evidence for observational studies (OCEBM). They involve a simple presentation of an outcome without provision of a control. Their importance comes from the introduction of novel disease presentations or treatments for further investigation.

Lastly, expert opinions offer the lowest level of evidence. Their utility is limited in the justification of evidence-based diagnosis and treatment. Rather, they serve to introduce innovation and new techniques, as clinical empiricism is oftentimes the starting point for further higher-level research.

### **Statistics**

Although a comprehensive review of biostatistics will not be addressed in this textbook, a review of the more commonly encountered concepts in biostatistics, particularly those encountered in later parts of this text, is presented here. Readers are encouraged to seek out further resources, particularly if questions arise during the reading of primary references.

### Measures of statistical significance

The ultimate goal of research is to test a hypothesis. Although absolute statements regarding proof or disproof of a hypothesis cannot be made based on limited populations and study parameters, researchers look to determine the likelihood that results support the hypothesis. Similarly, determination of cause and effect is extremely difficult to prove, requiring large-scale randomized controlled trials with longitudinal follow-ups. Most studies fall short of determining causation but can identify associations or relationships between two factors. It is important in quoting literature to never overstate results.

One way researchers can increase the odds of obtaining statistically significant results is to ensure that the sample population under study is both large and diverse enough to demonstrate outcomes. Although successful endodontic practice does not require an intimate understanding of the methods researchers use to determine the adequacy of sample sizes, familiarity with the concept of power to rule out errors in hypothesis testing is imperative. Well-designed research studies involve power calculations to ensure adequate sample sizes, and in critical review of literature articles, one should note if appropriate power calculations were made to justify the use of a particular sample size.

It is clear that the best means of measuring any parameter would be to draw data from every possible member of a population. As this is not realistic, study designs aim to draw a random sample that will be representative of the whole population. The larger the sample size, the more representative it will be of the varying parameters of the whole population. Sample size is inversely related to the likelihood for error (Glaser). Confidence limits, oftentimes described as a range between values called the *confidence interval*, are a means of inferring the likely range of a parameter factoring in possible errors related to a sample not being truly random and therefore representative of the whole population. The narrower the confidence interval, the more likely results are accurate, and the only way to narrow this is to increase sample size.

With samples selected and the experiment performed, results must be analyzed to determine their statistical relevance. The most common measure of statistical

significance encountered in the endodontic literature is the *P value*. The *P* value refers to the likelihood of the outcome having occurred by chance. A *P* value less than or equal to .05 generally indicates statistical significance (Fig 1-2). In other words, with a *P* value of less than .05, the probability that the study results were obtained by chance is less than 5%. For example, in a retrospective case-control study performed by Spili et al investigating the outcomes of teeth with and without fractured nickel-titanium instruments, success was found in 91.8% of cases with retained fractured instruments compared with 94.5% success in controls. Statistical analysis using the Fisher



**Fig 1-2** The relationship between *P* value and statistical significance. The *P* value describes the probability that results occurred by chance.

exact test, a tool used to determine deviation from a null hypothesis, resulted in a P value of .49. This corresponds to a 49% chance that the difference in healing rates was due to chance. As the authors set the significance value at P = .05, the difference in healing rates obtained from the study was deemed statistically insignificant. In other words, the authors cannot prove that instrument separation led to a worse outcome.

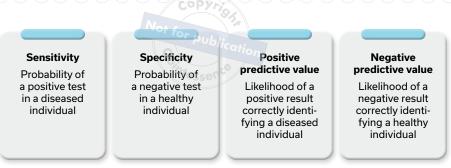


Fig 1-3 The validity measures often encountered in the endodontic literature.

### Measures of validity

When new testing modalities are compared to the current standard, the validity or accuracy of the new approach must be verified. Sensitivity, specificity, and predictive values provide the means by which validity can be confirmed (Fig 1-3). These values are often encountered in descriptions of pulp sensitivity tests. Mainkar and Kim's systematic review and meta-analysis on the diagnostic accuracy of varying pulp sensitivity and vitality testing methodologies provides an excellent example in the discussion of validity measures.

Understanding validity measures requires familiarity with the concepts of both true positive and negative results and false positive and negative results (Table 1-1). True positive and negative results correctly identify individuals as diseased or healthy. False positive and negative results incorrectly identify the individual's disease status.

*Sensitivity* is defined as the ability of a test to detect diseased individuals. It is calculated by comparing the number of true positives detected by the test with the total number of diseased subjects, including the true positives plus false negatives. In Mainkar and Kim's meta-analysis, they found that laser Doppler flowmetry (LDF) was the most accurate means of diagnostic testing, whereas heat testing was the least accurate means. Pooled sensitivity was 0.98 for LDF and 0.78 for heat testing. In other words, LDF correctly identified teeth with pulp necrosis 98% of the time, whereas heat testing only did so 78% of the time (Mainkar and Kim).

*Specificity* is defined as the ability of a test to correctly identify a healthy individual. It is calculated by comparing the number of true negatives detected by the test with the total number of nondiseased subjects, including the true negatives and false positives. In Mainkar and Kim's meta-analysis, pooled specificity was 0.95 for LDF and 0.67 for heat testing. In other words, LDF correctly identified vital teeth 95% of the time, whereas heat testing only did so 67% of the time (Mainkar and Kim).

Table 1-1	The possible outcomes of a test	
Test result	Disease present	Disease absent
Positive	True positive	False positive
Negative	False negative	True negative

Statistics

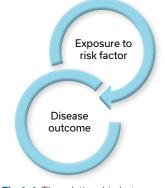
Predictive values describe the likelihood of the test to correctly identify health or disease. The *positive predictive value* is calculated as the proportion of true positives compared with positive results. The *negative predictive value* is calculated as the proportion of true negatives compared with negative results. Mainkar and Kim found positive predictive values of 0.94 versus 0.62 and negative predictive values of 1.00 versus 0.79 for LDF and heat testing, respectively. In other words, with LDF, a positive result (ie, no flow) corresponded to pulp necrosis 94% of the time, and a negative result (ie, flow) indicated the presence of vital pulp tissue 100% of the time, whereas with heat testing, a positive result (ie, no response to heat) correctly identified pulp necrosis only 62% of the time, and a negative result (ie, a response to heat) correctly identified pulp identified vital pulp tissue only 79% of the time (Mainkar and Kim).

### **Measures of risk**

Development of evidence to support any particular practice in medicine and dentistry relies largely on the determination of certain risk factors for a disease or outcome

(Fig 1-4). Knowledge of a risk factor can aid practitioners in diagnosing disease, preventing disease, predicting future incidence and prevalence of a disease, and even establishing the cause of a disease (Glaser) (Fig 1-5). The measures of risk—including relative risk, attributable risk, and odds ratio—all measure the effect of being exposed to a risk factor on the risk of experiencing a particular outcome. The particular type of risk measurement used is study dependent.

*Relative risk* states how many times exposure to the risk factor itself increases the chance of a particular outcome (Glaser). Numbers needed to treat (NNT) is a derivative of rela-



**Fig 1-4** The relationship between risk factors and disease.

tive risk, measuring risk reduction by an intervention, and allows for comparison of different treatments. As an example, the Oxford Pain Group League table showed that 800 mg ibuprofen provided demonstrably superior pain relief in the treatment of acute apical abscess or symptomatic apical periodontitis compared to other oral analgesics (Richards). In a meta-analysis compiling high-quality data from numerous other studies, they reported an NNT of 1.6 for 800 mg ibuprofen versus 2.2 for both combinations of 60 mg codeine per 1,000 mg acetaminophen and 5 mg oxycodone per 500 mg acetaminophen. In other words, 1.6 patients needed to be treated with 800 mg ibuprofen to achieve 50% pain reduction, whereas 2.2 patients needed to be treated with the narcotic preparations to achieve the same results (Richards). Ibuprofen is therefore a better drug for reducing the risk of endodontic pain. *Attributable risk* states the additional incidence of an outcome that is attributable to the risk factor in question and is determined by subtracting the incidence of disease in



Fig 1-5 The importance of establishing risk factors.

nonexposed patients from that in exposed patients. It is equivalent to the difference in *absolute risk* between the two groups.

Both relative risk and attributable risk can be determined utilizing prospective cohort studies (Glaser). As previously discussed, these studies are not always feasible due to cost, time required, and their inefficiency in looking at rare outcomes. Therefore, retrospective case-control studies, wherein subjects with disease are compared to matched subjects without, are oftentimes more feasible. If a higher proportion of subjects with disease were exposed to a certain risk factor than those without disease, that risk factor can be associated with the disease.

*Odds ratio* is the measure of this proportional risk, comparing the odds that a case was exposed to the risk factor to the odds that a control was exposed to the same risk factor. An odds ratio of 1 indicates that a case is no more likely to have been exposed to the risk factor than a control and suggests that the risk factor is not associated with the disease. An odds ratio of greater than 1 suggests that the risk factor is associated, and an odds ratio of less than 1 suggests that the factor may, in fact, be protective. As an example, Sim et al found that pulpal floor fractures were associated with tooth loss. They reported an odds ratio of 11, meaning that teeth with pulpal floor fractures were 11 times more likely to be lost in the 5 years following treatment than teeth without identifiable pulpal floor fractures.

### Epidemiology

Epidemiology involves the study of health and disease in populations. Descriptive statistics are used in epidemiology to determine the impact of health or disease measures on the population under study. Commonly reported descriptive statistics include both prevalence and incidence (Fig 1-6). *Prevalence* refers to the total number of people affected by a disease at a particular time point. *Incidence* refers to the number of new disease cases arising during a defined period of time.



Fig 1-6 Descriptive statistics often encountered in the endodontic literature.

For example, Eriksen et al reviewed several European studies that reported the prevalence of apical periodontitis with a range from 26% to 70%. In other words, screening via periapical radiographs found that between 26% and 70% of patients sampled at one point in time had apical periodontitis. An additional example is found in a study by Lipton et al, which reported a 12% incidence of toothache in the US population in the preceding 6 months. Prevalence is a good measure for apical periodontitis because it develops slowly over a long time period, wherein it might be difficult to truly detect new cases. Incidence is a better measure for toothache because it generally has a rapid onset and decline, so a point-in-time assessment might miss many cases.

Epidemiologic methods can be used to measure the economic burden of a disease. Rampa et al investigated the economics of hospital visits related to periapical abscess (PA) via a retrospective analysis of the Nationwide Emergency Department Sample, a stratified database of hospital emergency department (ED) discharges in the United States. They found that the incidence of ED visits increased from 460,260 in 2008 to 545,693 in 2014. The mean charge for each patient discharged directly from the ED was \$1,080.50, totaling \$3.4 billion across the United States. When these patients were hospitalized following their PA-related ED visit, the mean hospitalization charges were \$34,245, totaling \$5.7 billion across the United States. The majority of these patients were uninsured (40%) or insured by state-run Medicaid (30%). Following this trend, Roberts et al reported a 2% incidence of dental diagnostic codes in patients visiting EDs in the United States, higher among patients with Medicaid than commercial insurance and highest among those aged 18 to 34 years.

### **Prognosis**

Success rates of therapy are frequently utilized to justify treatment choices. Chapter 12 presents an in-depth discussion of endodontic success rates. Success can have multiple definitions depending on the context, and it is important to understand how each study defines success. Oftentimes, a distinction can be made between *success*, defined as the absence of symptoms and periapical pathology found on radiographic examination, and *survival*, referring to the absolute presence or absence of the tooth in the mouth without consideration of symptoms or pathology. When

examining primary sources, it is important to understand the authors' definition of success, as results will vary accordingly. Furthermore, the advent of newer imaging modalities like CBCT may alter our future definitions. Wu et al suggested that the lines between success and survival may be blurred once prognosis studies utilizing CBCT imaging become available because CBCT images will inevitably detect more lesions than traditional radiography. Of course, one must recognize that the above discussion, as well as most published research to date, relates to clinician and biology-based outcomes. Newer research in the field of patient-centered outcomes focuses on symptoms and economic factors rather than radiographic or histologic measures of healing (Montero et al, Riordain et al). All considerations are important for a comprehensive understanding of prognosis.

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