

WHAT IS EVIDENCE BASED DENTISTRY?

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The volume of literature and lectures directed at the modern dental practitioner has created some problems. How does one resolve the often contradictory information? How does one determine what is a cutting-edge technique and what is useless? In resolving a clinical decision, evidence rather than empiricism should dictate treatment. Evidence based dentistry (EBD), based on the concepts developed at MacMaster University,^{13, 14, 17-22} presents guidelines to determine the validity of study results and whether they can be applied to clinical practice.

The foundation for evidence based practice was laid by David Sackett who has defined it as "integrating individual clinical expertise with the best available external clinical evidence from systematic research."²³

Evidence based dentistry supplies guidelines to help the clinician make an intelligent decision. In and of itself, EBD does not give definitive answers. It does not exchange the tyranny of the expert for the tyranny of the literature. As Sackett's definition states, EBD relies first on clinical expertise. This expertise is especially critical in dentistry, where the number of randomized, controlled clinical trials and prospective cohort studies is limited. In a perfect world, full of quality prospective studies, one would only have to pull up a well-performed meta-analysis or systematic review of the evidence on the clinical question to solve the problem at hand. Unfortunately, these studies are too few, and clinicians must apply the best available evidence to make a decision.

The Cochrane Collaboration, an international nonprofit organization whose goal is to make up-to-date, accurate information on the effects of health care available worldwide, has an Oral Health Group that has produced some systematic reviews. Their web site (<http://hiru.mcmaster.ca/cochrane/default/htm>) is an excellent place to see what the evidence based dental practice in the future will be like.

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The internet has made it easy to initiate an evidence based practice (see article by Felton on page 45 of this issue). Guidelines for EBD are applicable to peer-reviewed literature and also to publications and lectures that provide a case report or, at best, a case series done under conditions that may not be similar to those seen in the average dental office. Armed with the tools of EBD, the clinician can readily evaluate the mass of data and choose, in an educated manner, what to use and what to discard.

Unfortunately, most of what is seen in dentistry is product testing done in laboratories, not operatories. The studies are usually univariate analyses, because the researcher has been trained to homogenize the study so that only one variable is tested. Clinicians, however, live in a multivariate environment. For example, an in vitro study on a dental cement might deal with retention of castings on extracted teeth. Retention, however, is not the only variable that a clinician evaluates in choosing a cement. A clinician must also be concerned with postoperative sensitivity, film thickness, setting time, working time, longevity, ability to clean up, setting expansion, and so forth. One might also wonder how good the retention would be in a clinical milieu where isolation, crevicular fluid, saliva, and intraoral humidity become confounding variables. Clinicians, seeing only one variable tested, should be reluctant to change their cement based on the limited laboratory study. Needed instead are controlled, long-term clinical trials to help clinicians make decisions, but such studies are expensive and require a long time to supply the information. Chambers questioned whether "there is clinical evidence showing that this restorative material will last longer in patient's mouths then it will be on the market" (see article by Chambers on page 29 of this issue).

Using EBD is quite simple:³

1. Create an answerable question.
2. Track down the best evidence to answer the question.
3. Critically appraise the information.
4. Apply the results to one's patients.
5. Evaluate one's performance.

The *Journal of Prosthetic Dentistry* has published a series similar to the *User's Guide to the Medical Literature*,^{13, 14, 17-22} specific to dentistry, to help appraise the information.^{1, 2, 5, 6, 8, 11, 12, 15, 16} Although the guidelines differ for the different clinical question being asked, certain characteristics pertain to all studies.

THE USE OF EVIDENCE BASED DENTISTRY IN DETERMINING THERAPY

Was the Assignment of Patients to Treatment Randomized?

Randomization eliminates allocation bias. In theory, randomization ensures that variables, over which the study has control and the un-

known variables that come in to play in all studies, are equally distributed among the test groups. To ensure equal distribution, the study population (N) must be sufficiently large. A randomized controlled trial (RCTs) is considered the optimal research design and is the reference standard for most clinical questions. Not all RCTs, however, are properly planned and carried out. The reader must still examine the methodology. Also, as Sackett concluded, "some questions about therapy do not require randomized trials (successful interventions for otherwise fatal interventions) or cannot wait for the trials to be conducted. And if no randomized trial has been carried out for our patient's predicament, we follow the trail to the next best external evidence and work from there."²³

Feinstein⁹ has questioned the blind faith often put in randomized trials and has suggested that prognostic stratification is critical to the utilization of the data. He maintains that if data are to be evaluated in prognostic subgroups, those subgroups should be identified, where possible, before the study starts, and that subjects should be allocated to those subgroups before they are randomly allocated to treatment.¹⁰ For example, in a study on implants in which the site (anterior mandible versus posterior maxilla) is a major variable, it would be sensible to identify the site before randomizing to ensure that chance alone does not place most of the anterior mandibles in one group and most of the posterior maxillae in the other. Another potential confounder would be smoking. Although it would be unwieldy, if not impossible, to identify every possible variable, certain dominant ones known to affect the outcome of the therapy should be identified at the start of the project.

Were All Patients Who Entered the Trial Properly Accounted For and Attributed For at its Conclusion?

It is critical that all patients who enter a trial are properly accounted for at its conclusion. It is not enough to say that a certain number of patients dropped out. One must include the dropouts in the statistical analysis (see article by Clive on page 137 of this issue). The most common reason patients drop out of a therapy trial is because they are unhappy with the therapy. Some subjects die, and some move out of the area, but the number in these categories should be relatively equal in the control and test groups. If the drop-out rate exceeds 20%, the clinician should be concerned about the external validity or generalizability of the project.

Were Patients, Their Clinicians, and Study Personnel Blinded to Treatment?

Blinding means that someone was not aware of the treatment being rendered. *Double-blinded* means that both the evaluators and the patients

were unaware of the therapy being rendered. Blinding is easily done in a drug trial in which the pills look and taste the same and the patient is identified only by a code number unknown to the evaluator looking at the outcome. Blinding can also be easily done in a study of toothpastes or mouthwashes. It is not always possible to blind a clinical trial. For example, in a study comparing implant-retained overdentures with either two or four fixtures in place, it would be impossible to blind the patient or the researcher if intraoral examinations were necessary. Although a nonblinded trial is not ideal, it can still be an excellent experiment that can generate usable, reliable data.

Were the Groups Similar at the Start of the Trial?

To ensure validity, it is critical that the cohorts (groups) be similar in all pertinent demographic, medical, and dental factors. Although in a large study randomization should ensure equivalence, it is the investigators responsibility to assess equivalence among cohorts in detail.

Aside From the Experimental Intervention, Were the Groups Treated Equally?

Anything one studies, one alters. Patients who agree to participate in a study tend to be more compliant than the average. Knowing they are to be examined may cause them to exercise better home care before presenting in an effort to please the investigator. It is tempting for investigators to recall a test group more often when the outcome is uncertain or side effects are suspected. Co-interventions, such as an extra prophylaxis, can affect the primary outcome being examined and the validity of the study. All groups need be treated equally.

Were All Clinically Important Outcomes Considered?

The reader must decide whether all clinically important outcomes have been considered. If, for example, in evaluating a new cement for ceramic restorations, the investigator reports only that the restoration was in place after the time of the study, it is obvious that other important considerations have been ignored. If the investigator also evaluates postoperative sensitivity, film thickness, setting time, working time, longevity, ability to clean up, setting expansion, and so forth, the important clinical factors have been evaluated. More commonly, the investigation might evaluate only two of the factors. Some clinicians would find the study adequate; other readers might not. An implant study, for example, might speak of prosthesis stability and neglect the number of implants

remaining. If six implants were placed and three were lost, the prosthesis might be stable, but the clinician has cause to question the data.

Was Follow-up Sufficiently Long and Complete?

Too often a study is not long enough to be valid to the clinician (chronology bias). Although a 1-year follow-up may be sufficient in a study of the efficacy of tetracycline-impregnated cord, the same follow-up time is not adequate in a study on a new composite resin restoration. For restorative procedures, a minimum of 3 to 5 years may be necessary to convince a dentist to change therapy.

Were Objective and Unbiased Outcome Criteria Used?

Outcome criteria are chosen by the investigator, and it is easy to err by choosing an assessment that best serves the theory of the investigator. The adage, "I would not have seen it if I didn't believe it," readily comes into play. Picture a study that compares a Lexus with a Yugo and chooses the following criteria for the study:

- Does it have an engine?
- Does it have a radio?
- Does it have four wheels?
- Does it have windshield?
- Does it have seat belts?

Using these criteria, one concludes that the Lexus and Yugo are similar. Any rational person, however, clearly sees that results based on questionable outcome assessments are useless. In more sophisticated studies, such a flaw may not be so obvious.

Will the Results help Clinicians in Caring for Their Patients?

The critical question for clinicians is whether the results will help them provide better care for their patients, because that question involves all the others. If the methodology is good, if the statistically significant results have clinical relevance, and if the data interpretation is rational, one would lean towards accepting the study. If, however, the population is not representative of a clinician's practice or if the inclusion and exclusion criteria do not match the practice population, clinicians should be hesitant about applying the results to the population they are treating.³

USING EVIDENCE BASED DENTISTRY TO EVALUATE THE NEED FOR A DIAGNOSTIC TEST

Was There an Independent, Blind Comparison with a Reference Standard?

A gold (reference) standard is important. In histopathology, the biopsy is considered the gold standard, but even the biopsy does not result in 100% agreement among pathologists. The disagreement is magnified when the pathologists are deprived of the clinical findings supplied by the surgeon. If a reference standard exists, one might question the need for the new test. If the test cannot offer the advantages of being less expensive, or less invasive, or easier to perform, one should question its use. Unfortunately, often there is no reference standard, or the reference may be controversial. Lack of a suitable reference standard does not mean that the new test is not useful, but a heavier burden of proof is demanded from the investigator, and the clinician must exercise more caution.

Were the Methods for Performing the Test Described in Sufficient Detail to Permit Replication?

If the reader cannot perform the test, it is of no use.

Were Sensitivity, Specificity, Positive Predictive Value, Negative Predictive Value, and Likelihood Ratios Presented?

It is not the reader's responsibility to undertake statistical analysis when reading an article. Rather, it is the researchers' obligation to supply the appropriate data (see article by Brunette on page 87 of this issue). Because EBD puts the onus of decision making on the clinician, readers must be familiar with the terms so they can determine if the new test would have merit in their practices.

Will the Patient be Better Off as a Result of the Test?

Routine testing, if it does not affect the diagnosis, prognosis, or treatment, has questionable value. If the results do not potentially change the course of treatment, the test is unnecessary. A patient who fell and knocked out the coronal portion of a tooth would benefit from a radiograph to determine the extent of the fracture but not from a pulp test to determine vitality. An adolescent with an ulceration from biting the cheek would be better served by a reexamination in a week rather than by a biopsy.

Evidence based dentistry will surely be abused.⁴ Insurance compa-

nies have already developed evidence based care policies that require dentists to prove that patients need the services.³ The possibility of abuse does not mean that dentistry should reject EBD. Indeed, dentists have been practicing EBD, in part, for many years. When clinicians tell patients to brush and floss, they do so because the evidence supports the efficacy of these interventions. When dentists advocate fluoride, they do so because the evidence supports its efficacy. Although many areas of dental practice are supported by numerous high-quality research projects, many more areas are supported only by anecdotal data. Hence, the validity of the data and who evaluates it become critical. Aurbach⁴ has questioned:

"Who will be the anointed one or group that determines which evidence is valid? Who will set the research agenda and determine where the results will be maintained? Who will validate the research? Who will maintain the data base to make sure that it is up to date? How will the results be used?"³

It is obvious that to control the data, clinicians need to own it. If clinicians are not sophisticated enough to force good research practices by their ability to evaluate and reject poor science, they will be at the hands of third parties who can use dubious research as justification to control clinicians' practices. The sooner dentistry as a profession universally embraces EBD, the sooner the profession will command the use of research and prevent its misuse.

WHAT EVIDENCE BASED DENTISTRY IS NOT

Evidence based dentistry is not a veil to mask the same old, inadequate research. It is disturbing to see lecturers invoke EBD and present the same anecdotal lectures they gave before, with different slide titles. As the profession of dentistry becomes more sophisticated, researchers and lecturers will be forced to grow also. Evidence based dentistry does not take the clinical decisions out of clinicians hands and put them into the hands of the literature. In fact, the opposite is true. Evidence based dentistry gives guidelines for the clinician and relies first on clinical expertise.

Evidence based dentistry does not mean that third parties will control dental practices. In fact, educated dentists, understanding the literature, will be able to prevent the misrepresentation of data by commercial interests.

Evidence based dentistry does not mean the clinician need not study basic and dental material sciences. In fact, the opposite is true. To evaluate the research presented, clinicians need a solid background on which to base their evaluations and decisions.

Evidence based dentistry does not mean clinicians abandon everything they learned in dental school. It does not force clinicians to go backwards to justify things the profession universally accepts.

WHO BENEFITS FROM EVIDENCE BASED DENTISTRY

- The ultimate beneficiaries of EBD are members of the public, who will reap the rewards of better care. The internet allows patients, as well as professionals, access to health care information. The public, however, does not have the tools to evaluate the data adequately and must rely on their educated dentists to help sort fact from fiction. Patients will be more educated, more involved in their treatment decisions, and more appreciative of quality care.
- Dentists, who will also benefit from EBD. Instead of conducting free product testing for dental product manufacturers, practitioners will have at their disposal more valid research on which to predicate their clinical decisions.
- Researchers, who will benefit by being called upon to do the clinical testing necessary before new products are placed on the market.

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