

# THE ETHICS OF EXPERIMENTING IN DENTAL PRACTICE

David W. Chambers, EdM, MBA, PhD

This article is not about the experiments dental researchers conduct in laboratories or controlled clinical trials. It is about the far more common experiments dentists conduct in their offices—for example, the first time a new procedure is performed following a continuing education course, using a material ordered as a sample, performing endodontics on a molar more complex than any attempted in recent years, proceeding with a large case in which several alternatives look equally attractive.

There is a very simple and well-known rule of ethics for performing procedures in which there is some attendant risk: *Primum non nocere*—above all, cause no harm. This injunction is often attributed to the Hippocratic Oath, and it has become famous among malpractice attorneys and writers of editorials.

The truth is that *primum non nocere* does not appear in the Hippocratic Oath, and it is doubtful advice.<sup>6</sup> It is a Latin gloss on the older Hippocratic admonition that might better be translated, “You have been given great power as a doctor; use it for good and not for evil.” It would be unwise to make avoiding harm the ultimate standard for a care provider. The only certain way to assure avoiding harm would be to avoid undertaking treatment altogether.

Attempting to do good for patients is attendant with risk. This article addresses the problem of treating patients in an ethical fashion when there is no way of guaranteeing success. Such situations are common and unavoidable in dental practice.

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From the Office of Academic Affairs and Scholarship, School of Dentistry, University of the Pacific, San Francisco, California

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DENTAL CLINICS OF NORTH AMERICA

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## GENERAL APPROACHES TO ETHICS

The recent interest in ethics in medicine and dentistry reflects the growing range of choices in the professions. One hundred years ago when dentists primarily treated pain caused by advanced caries, fast forceps were the measure of quality. As dentists began to understand caries and periodontal diseases, diagnostic acumen assumed importance, and a range of treatment skills was required. Still, the number of procedures available per condition was small, and patients were both unaware of alternatives and usually quite willing to follow the judgment of the dentist. Today, patients visit the dentist in the complete absence of symptoms for preventive reasons and to seek cosmetic enhancements. They often bring their own opinions with them. Disease entities have expanded to include malocclusions, temporomandibular joint considerations, and oral cancers, and the options for treating even the most basic of conditions—caries—have become bewilderingly vast. Once a condition needing intervention is identified, there are frequently many choices of methods and materials for treatment. Industry and continuing education speakers pressure dentists to consider the merits of the alternatives they favor.

As choices multiply, the opportunities for making right and wrong choices expand. The profession has recognized this situation and has turned to the field of ethics for guidance. The basic texts in dental ethics are those by Ozar and Sokol<sup>12</sup> and Rule and Veatch.<sup>15</sup> An organization known as PEDNET—Professional Ethics in Dentistry Network—is devoted to promoting awareness and discussion of dental ethics, and its members welcome contact at [dozar@luc.edu](mailto:dozar@luc.edu). Dental schools across the country are adding courses in ethics to their curricula. A national Alliance for Oral Health has been created, embracing 61 organizations involved in health care such as the American Dental Association (ADA), insurers, specialty groups, the military, public health groups, allied dental health professionals, examiners, schools, and so forth. The American College of Dentists, long concerned with ethics and professionalism, has an excellent, small handbook (available at [www.facd.org](http://www.facd.org)). The winter, 1996, issue of the *Journal of the American College of Dentists* contrasts multiple approaches to ethical analysis of a single case involving managed care.<sup>10</sup>

Of the many approaches to ethics, the most basic is grounded on ethical principles. Principles animated the revision of the ADA Code of Ethics and Professional Conduct completed in 1998. In this approach, a set of ethical principles (shown in Table 1) is used as a touchstone for reflection and conduct. Obtaining informed consent from patients, for example, is appropriate based on the principle of autonomy—the patients' right to decide what is to be done with their bodies. The principle of veracity can be cited as reason for explaining procedures and their consequences in clear, understandable language. Such principles offer general guidance, although conflicts can arise among the principles. For example, a patient may want veneers when what is needed is periodontal therapy. Autonomy and beneficence clash in this case. The issue

**Table 1.** COMMON ETHICAL PRINCIPLES

Principle	Definition
Autonomy	The right of the patient, the dentist, and any other competent individual who is involved to determine what should be done by and to them
Beneficence	An obligation to help others, normally assumed in exchange for privileges granted a group such as professionals
Competence	The capacity to perform as one promises or as expected
Integrity	Consistency throughout one's actions and language; being guided by core values
Justice	Fairness in the distribution of rewards and obligations and in the processes by which distribution is made; sometimes tested by a willingness to trade places with others one deals with
Nonmaleficence	Avoiding unnecessary harm to others
Veracity	Telling the truth and creating environments where honest views are expressed

addressed in this article—experimenting in dental practice—can be framed as a conflict between beneficence (helping the patient and other patients in the future) and nonmaleficence (not harming the patient).

Some dental ethicists are pushing beyond the principles approach. Their work is prompted by questions such as, “How does a person recognize when he or she is dealing with an ethical issue?”, “What happens when principles are in conflict?”, and “Shouldn’t ethics lead to right action as well as right thought?” Murial Bebeau has applied the work of Rest and Narvaez<sup>14</sup> to dentistry in proposing an approach to ethical issues in terms of moral sensitivity, moral reasoning and judgment, moral motivation and commitment, and (at the highest level) moral character and competence. Ozar and Sokol<sup>12</sup> and Rule and Veatch<sup>15</sup> have worked through many cases in dentistry, offering some thoughts on how competing claims can be addressed and which values take precedence. Bruce Peltier has written about the difficulties of taking ethical action and has offered practical advice.<sup>13</sup>

## A Discursive Approach to Ethics

The discursive approach to ethics builds on the traditional methods presented previously.<sup>4</sup> This approach sets a context that places greater emphasis on people than on principles, and it favors ethical behavior over reflection. Attention is paid to how language is used to create ethical communities.

Dentistry takes place in a social context.<sup>8</sup> There is an understanding on the patients’ part that dentists are well trained, perform only those procedures they have high confidence will be successful, value the patients’ welfare and their own reputation, are part of a network of professionals available for backup, and will not take advantage of patients by performing unnecessary work or charging more than is fair.

Patients also realize that they are expected to be present and prompt for appointments, to pay their bills, to answer honestly when asked about their health, and to comply with reasonable requests for home care and postoperative recommendations. This general therapeutic alliance is understood by reasonable adults. It is the background for the jury system, and it makes health care possible and efficient. No book contains these rules, and they are normally discussed only when something unexpected happens. Patients participating in insurance fraud or dentists who performs unnecessary work generally understand that they are acting outside the normal bounds of right and wrong.

In other cases, the therapeutic alliance is ambiguous. The patient knows a damaged tooth must be fixed. But there are choices: considerations of function, appearance, and cost must be understood and weighed. Or the patient may be uncertain whether to remain with the current dentist. The hours are inconvenient, the staff may not show respect, and the dentist is abstemious with explanations. Again, an understanding must be reached. These are not cases of universal expectations that form a treatment alliance. They represent alternatives in a range of variation that contains individuality. Some dentists are known to be expensive or to focus on esthetics. Others are known to take a holistic approach. Some patients have personal traits that make them difficult to deal with; others require an inordinate amount of attention. As long as the office team and the patient can come to an understanding about what is mutually acceptable, the treatment alliance can be preserved across a wide range of individual variation. Of course, there is a limit to individual agreements that exceed public acceptability. Dentists cannot perform medicine even if the patient agrees to medical procedures, and insurance fraud is unacceptable, even with patients' collusion.

Discursive ethicists are concerned with ethical communities and agreements that promote civil good. Making and keeping promises is central to a discursive view of ethics.<sup>7</sup> A definition that is used in this article is *Ethics is the creation, adjustment, and maintenance of communities in which participants can reach their potentials.*

Several aspects of this definition go beyond the traditional concept of ethics. First, ethics is a community activity; it concerns the relationships among people. There are no private ethics. Ethics is something people do together. Second, ethical understandings are created. This is different from some traditional notions that there are abstract ethical principles that must be discovered or with which all people would agree. Discursive ethics is not ethical relativism; some actions such as lying, murder, and seeking to avoid the penalties of violating agreements are universally abhorred. The general treatment alliance mentioned previously contains such examples. Discursive ethics also recognizes that there can be ethical violations within specific communities. A husband can cheat on his wife in ways that might not bother other couples. A dentist can violate the confidence of a patient without violating the ADA Code or any generally accepted set of ethical rules. Third, discursive ethics is concerned with the obligation to create ethical communities and

to adjust them when necessary, as well as with avoiding breaches of established codes. Creating systems that put people in ethical jeopardy is as wrong as violating the rules of such a system. Some dentists have argued, for example, that the conditions of some reimbursement mechanisms are unethical. (They are probably wrong, however, in pleading that it is ethical to violate these conditions if they have voluntarily agreed to a contract that contains them.)

Discursive ethics uses all the methods of traditional ethical theories to create ethical communities. Ethics is often defined as the study of right and wrong, and some ethical theories seem to accept that distinguishing right from wrong is the entirety of the ethical problem. Other theories use the determination of right and wrong as a step in the ethical process. In traditional ethical theory, judgments of right and wrong are often made by third parties. In discursive ethics, however, the number of categories is broader than the right/wrong dichotomy, judgment plays a smaller role, and the perspective is entirely from within the community.

It may be too crude to categorize people or actions as only ethical and unethical. Some people are ethically insensitive. They just do not understand ethical issues; they are surprised when others call ethical lapses to their attention. They do not pay as close attention to what is expected as others would like. Some people are ethically awkward. They try to do good, but they are unskilled. A colleague once described a situation in which the dentist prescribed narcotics for the same patient four times in a single day. He said he knew he was doing wrong but he just could not be assertive with this particular patient.

A third category is ethical abuse. Ethical abuse is more than breaking the rules. Abusers want the rules to remain in place precisely so they can take advantage of others who follow the values of the community. Scam artists take advantage of the expectation that trust will be part of relationships. Insurance frauds defend the insurance system. Patients who fail to honor their financial obligations steadfastly profess a relationship with the dentist. Ethical abusers want the benefits of participation in an ethical community without the obligations of such participation. (Civil disobedience, by contrast, is a willingness to step outside a community whose ethics the conscientious objector finds offensive. It is an open disobeying of the community's norms.) The response to ethical insensitivity or awkwardness is normally to increase group concern and to try to help the individual. In the case of abuse, the community distances the person from the group to preserve the group. Dentists with addiction problems and those with poor clinical judgment or skill receive remedial treatment or training. Those who refuse remediation or engage in purposeful deception lose the privileges of dental practice. Those who embarrass the profession are shunned.

## The Ethics Test

Dentists are in partnership with three ethical communities. The first partnership is with each individual patient. Dentists operate within the

general treatment alliance, as modified by individual circumstances. The second relationship is with the profession. It is inherent in professionalism that the acts of individual members affect the reputation of all colleagues, and the reputation of the profession is an asset available for use by the individual practitioner. Regardless of participation in organized dentistry, any who call themselves dentists are part of the community, precisely because patients and the public see it this way. The third relationship is with the public at large. Customs in a community, laws, and general civil expectations apply in all cases.

Being aware of the three communities and the mutual ethical expectations placed on all members of these communities is useful in creating the ethics test. It is helpful to know when one is in an ethical situation. Academics can always create a hypothetical context that would make a particular act of a dentist an ethical issue, but dentists need a more practical way of identifying, from an internal perspective, situations in which the community is suffering from tension and abuse. If the test is to be useful, it must work from the point of view of those in the community. Here is the guideline: *An ethical situation exists whenever members of the community are compromised in their potentials.* If the dentist makes money by overtreating or undertreating or mistreating a patient, it is an ethical situation. If an associate receives less compensation than promised or a poorer mix of patients than promised, it is an ethical issue. If a group of patients has less access to care than contracted for in their insurance coverage or care that is limited, it is an ethical issue.

From the discursive perspective, it is possible to fashion an ethics test. The test is oriented to the communities involved and not toward abstract principles or personal feelings of right or wrong. The test has two parts:

- If you believe members of the community (patients, colleagues, or society generally) would be offended or outraged by an action on your part provided that they knew all the relevant details—do not do it!
- If you believe members of the community would be concerned by an action on your part provided they knew all the relevant details—discuss it with them.

Notice that both parts of the rule directly connect the ethical community to actions. The admonition, “Don’t do anything that would outrage those with whom you have a relationship,” is obvious. The injunction to discuss actions that might be of concern is more novel. It speaks directly of ethics being the creation and adjustment of communities. Talking about ethical concerns goes to the point of clarifying and renegotiating relationships. One of the conditions for membership in a group is giving others the right to withdraw from the relationship if one intends to change it. The principle of autonomy is important in this concept. Veracity, another ethical principle, is also important. When discussing an ethical concern one must be honest—as one certainly expects of others in the community. Informed consent is largely a process

of establishing and adjusting mutual expectations in an ethical community limited to the dentist and patient in a specific situation. The concept can be generalized.

## EXPERIMENTS IN DENTAL PRACTICE

Dental practice makes use of science in several ways. Fundamental principles are learned in dental school and updated through reading, discussions with friends, and continuing education. Manufacturers also provide information of varying degrees of accuracy and usefulness. By far the most common way dentists learn is through observing the outcomes of their work in their own practices on their patients in their own hands.<sup>9</sup> This information is potentially of great value; whether it does in fact improve practice depends on how each practitioner responds.

A common understanding of the word *experiment* is a carefully designed and controlled attempt to reveal truth in a research context. In his classic *The Reflective Practitioner*,<sup>16</sup> however, Donald Schon shows that there are other common uses of the term.

An ethical issue is involved in the translation of research findings into practice. Ethical issues are also involved in the experiments that are conducted on a regular basis in practice. Most dental experiments involving patients are performed in offices by dentists who are not trained as researchers and normally do not think of themselves as experimenting. Experimenting is what takes place, however, when a dentist performs his or her first bonding case or first posterior composite. It is an experiment when the dentist says "Let's keep a watch on that tooth." The first injection in dental school or the first endodontics case falls into the same category. The dental profession even experiments on a wholesale basis in initial licensure examinations when unlicensed dentists perform independent care on patients with a national success rate approximating 80% (one in five state board experiments fails<sup>11</sup>).

An experiment is any planned and purposeful action where the results can be observed and the outcomes contain risk. Table 2 shows several categories of experiments. Two of these are discussed along with the rules of ethical experimentation in practice, and the final two are then considered briefly.

### Scientific Investigation

There may be a reluctance to accept the idea that practitioners perform experiments in their practices because of the dominant concept of experimentation that comes from science. The characteristics of strict experimental design, randomized control groups, precisely defined parameters, and sophisticated statistical analyses are not possible in dental practice. Dentists who are interested in this type of experimentation



**Table 2.** TAXONOMY OF EXPERIMENTS

Type	Characteristics
Scientific investigation	Extreme uncertainty regarding outcomes, rigorous control, nonpractice context, purpose to discover general principles, results in publications
Experimental practice	High probability of success, careful observation rather than control, realistic settings, purpose to discover more effective methods, results in improved practice
Heroic measures	High probability of failure, little control, all else has failed
Doing nothing	Unknown outcomes, no control, changes in practice unrelated to outcomes

normally associate themselves with universities or other research programs.

**Experimental Practice**

Experimenting in practice is more common than it might sound. It occurs regularly following continuing education programs, reading the literature, or talking with colleagues. A visit from a supplier or to the annual convention is another stimulus. Any new class of procedures is an experiment. There is a common misconception that the ADA seal of approval, publications in peer-reviewed journals, Food and Drug Administration (FDA) endorsement, and other scientific validation protects a practitioner from experimenting. Unproven products, materials, procedures, and equipment are only one source of risk in therapy. Another source contributing to risk is the dentist. There is risk in a technique when it is tried for the first time, regardless of how much scientific research has been conducted or how many other dentists have used the technique successfully. The third major source of risk comes from the patient. To the extent that the patient in the chair is exactly the same as the average patient in the research studies, the risk is reduced, but it is never eliminated. Even a generally established procedure performed by an experienced practitioner can present risk if the patient has unusual conditions, systemic complications, or idiopathic expectations. Of course, there are also interactions among the three primary categories of risk—between therapy and dentist, therapy and patient, and patient and dentist, and the interaction of all three factors.

Previous success involving any one or two of the categories of risk does not eliminate risk in the others. A dentist who fails in treatment using a product well-tested in the literature is not immune from questioning about whether he or she was properly trained and experienced in the use of the product or whether the use of the product was appro-



priate in the particular circumstance. The recent concern over peer-reviewed literature is in many ways unfortunate. It creates an impression that only the product or procedure risk matters. The proliferation of journals that focus on products and procedures and the small number devoted to differences among dentists or among patients creates a misperception that therapy is the major or even the only important source of experimental risk in practice.

## THE ETHICS OF PRACTICE EXPERIMENTS

The fundamental rule for experimentation in practice is if your patients or colleagues would be shocked to learn that you had tried the treatment, do not do it; if they would be concerned, discuss it with them; if there would be no concern, proceed. Discussing treatments one uses with patients is a matter of informed consent. Discussions with colleagues are often informal, such as case discussions at component society meetings, but they could be formalized as literature searches or seeking the advice of known experts.

An experiment is not necessarily a failure because it does not go as planned; it is always a failure when it should not have been attempted in the first place. A motorcyclist who weaves between lanes of automobile traffic may sustain injury or worse because he or she is a poor rider or because an automobile driver makes an unexpected maneuver. The risk lies not so much the cyclist's skill as the poor judgment in being between the cars. Discursive ethics is concerned with creating ethical circumstances as well as with acting ethically. There are four ethical standards for experimentation in practice:

1. The action is undertaken for improving patient oral health.
2. The action is within standard of care.
3. There is a probable expectation of success based on evidence.
4. The action is performed reflectively, systematically, and with measured outcomes.

### Patients' Interests First

The patient's interests must always be the primary concern, and the reasons for experimentation must always be to improve patient oral health. Placing patients at risk in hopes of finding a faster or more profitable way of delivering care is unethical. It is true that all three parties (dentist, profession, and patient) are at risk in most practice experiments, but patients cannot be co-opted into endeavors in which they bear risk for the sake of other's potential gain. It is insufficient to argue that patients tacitly agree to general experimentation by agreeing to care. (Treatment in dental schools is a possible exception to the rule.)

A special challenge to the principle of patients first involves the

difference between the interests of patients individually and collectively. Can an individual patient be expected to bear the risk for improvements that will benefit patients generally? This problem is handled in research by informing patients that they are participating in an experiment, that they may receive either a standard treatment or an experimental one, and the expected outcomes of each. In such circumstances, patients must consent to participate in a set of therapies that include uncertain alternatives.

As a general practice, informed consent is vital when attempting a novel treatment. Consent has the following advantages: (1) it forces the dentist to think through what is being done in a rigorous fashion; (2) it offers some legal protection; and (3) it clarifies exactly what is in the patient's interests. Sometimes dentists undertake heroic or innovative treatments on the assumption that patients would prefer these courses of action. (Certainly, dentists would prefer the successful outcomes if the odds were not an issue.) Sometimes, a conversation with the patient about the risks involved reveals that the risks are acceptable but the proposed outcome is not what the patient prefers. Certainly, honest, informed consent serves as a check that the innovative treatment is being done for the patient's benefit and not the dentist's. If the dentist must disclose that a novel treatment is being undertaken primarily for his or her benefit, the ethical rule "if there is a concern, discuss it with those involved" will preserve the dentist's integrity (or the dentist will lie, most often through incomplete disclosure).

## **Standard of Care**

The second criterion for ethical experimentation is grounded in the standard of care. The standard of care is a legal concept and one that is rather fuzzy at the edges—precisely where office experimentation is involved. In an important sense, the standard of care is an operational form of the ethical rule "if one's colleagues would be shocked at what was done, do not do it." The normal form of the argument in the standard of care is that a particular example of therapy for a given patient and performed by a dentist of certain qualifications falls into a class that other practitioners would accept. LaForte resections are reserved for specialists, often those with specific training. Surgical extractions can be done by general dentists, but there will be some question about what other surgical experience the practitioner has and what protocols were followed. The standard of care does allow for experimentation, but what constitutes acceptable innovation is subject to review by the standard of what one's professional peers are doing.

## **Grounds for Expecting Success**

Third, there must be probable reason to expect success with the new product or procedure or patient. This baseline of probable success can

be established by studying its scientific basis, in conversations with people who have first-hand knowledge and experience, or through the dentist's own experience with similar situations. In a highly abstract sense, every treatment is a novel application of product and process, dentist experience, and patient characteristics. Practically, each case is an example from a class of similar factors. With extensive experience with similar products or procedures, with dental experience in similar cases, and familiarity with given categories of patients, the risk goes down. There are no sharp categories regarding grounded experimentation. The burden of proof increases rather sharply, however, when the dentist has to answer that he or she has never used this therapy or any like it, has little or no experience in such treatment, or has never done such work on this type of patient. Before trying something new, dentists must ask themselves, "On what grounds am I willing to justify taking this risk?"

### **Systematic Approach**

The final criterion dictates that unusual treatments require unusual care in their execution. Experimentation cannot be capricious. Dentists are expected to reflect on alternatives and their benefits and risks and to share the results of their reflections. The treatment also must be delivered in a careful fashion, and the results must be recorded. It is valuable in some cases to prepare a written protocol for innovative treatments. At an absolute minimum, the reasons for performing experimental work must be entered in the chart.

Recording the outcomes of experimental procedures is critical. There is much to be gained from recording outcomes on a routine basis for all treatment, but experimental procedures are a special case. When exposing patients, one's self, and the profession to risk, it is imperative to learn as much from the experience as possible. Recording outcomes is necessary to reduce the exposure of further patients and others to similar risk. If a treatment seems reasonable based on the patient's interests, standard of care, and available evidence but results differ from expectations, the dentist will need to have good information about the outcomes. Saying that, "It just didn't turn out as planned," or, "We'll have to do more such experiments to clarify the situation," are signals of ethical jeopardy.

The preceding discussion has focused on office experiments that realistically have a high probability of success. The experiment is ethical, provided that it meets the criteria of aiming to improve patient care within the standard of care, is based on treatment that is known to have a reasonable basis for successful outcomes, and is undertaken in a reflective fashion. When some of the criteria approach the borderline, honest communication with the patient will resolve the matter. If any criteria are not met, office experimentation is unwise. Patients cannot consent to risks others would regard as foolish.

## Heroic Experiments

Heroic experiments are high risk. Although they may be undertaken in the patient's best interests, they normally fail two other tests: being within the standard of care and having evidence of probable success. Normally, heroic efforts are considered only when there is no other valid alternative. Professional groups and the public at large normally frown on such interventions because they expose both the individual patient and the system for deciding what is appropriate behavior to risk. Dentists who may be attracted to such interventions are well counseled to investigate the standard of care carefully.

The fundamental justification for heroic effort is that all other conventional alternatives have been exhausted and that great risks are justified to protect the patient from grave harm. There are presumed trade-offs between the criterion for evidence of probable success and the criterion for improving the patient's well being. For such trade-offs to be considered valid, there is a greatly heightened requirement for informed consent. The patient's true interests must be carefully explored, and there must be overwhelming evidence that the patient understands the risks associated with various outcomes (including no treatment) and that the patient has made a completely uncoerced decision. The criteria are written in capital letters when cases of experimentation in the dental office deviate from standard circumstances. There may also be cases in which the patient agrees to heroic treatment that would shock the profession or the public. A private agreement between the patient and the dentist—for example, to practice outside legal limits—is still unethical because there are communities to consider other than the patient.

## The Invisible Experiment

Doing nothing is quite literally impossible. Sins of omission are still sins, as anyone who has been sued for failure to diagnosis periodontal disease will verify. Doing nothing in the context of this article means adopting a hyperconservative approach and seeking to avoid experimentation in the office by doing only what has been done successfully in the past. As long as patients do not change, as long as their expectations remain unaffected by media or reimbursement plans, and as long as no other dentists innovate, this is a sound strategy. Professionals, however, have an ethical responsibility to their colleagues to practice to an evolving standard of care. Technically speaking, a dentist should reveal as part of informed consent that therapies being offered are behind the times or that a definitive diagnosis is not being made because of outdated knowledge.

## READING THE LITERATURE

This article has explored the ethics of experimentation in dental practice. There is also a well-developed literature on the ethics of re-

search.<sup>17</sup> An area between these two raises some interesting ethical questions. What is the right or wrong in moving knowledge from the scientific literature to the office practice?

As much as practitioners might wish it were otherwise, responsibility for using the scientific literature in dentistry rests almost entirely with the dentist. Certainly, there is bad science, and some of it is published in peer-reviewed journals or other sources that attempt to present themselves as authoritative. The ADA and the FDA perform a valued service in establishing standards for products and materials, but many products do not seek this approval, including some effective products that fall outside the FDA's mandate. There are also some sound products whose developers choose not to list with the ADA because of the length of time required for approval or the restrictions on advertising that the ADA places on products. Further, these organizations review only products, materials, and devices that make therapeutic and some cosmetic claims; supplements, for example, fall outside their purview. When a clinically proven product fails to perform in a particular dentist's hands, manufacturers reflexively argue that the failure results from the dentist's technique.

Even peer review is not a sufficient standard. In 1998, the *Journal of the American Medical Association* published an entire issue on the medical literature. Included in the publication were a number of papers that examined the uses and impact of peer review. In several respected medical journals, the agreement among reviews was low, and there were even cases in which, over the entire period studied, the consistency between peer reviewers and the decision to publish was negative—the higher the rating by reviewers, the less likely the manuscript was to be published.<sup>3</sup> The situation in dentistry is unknown. The only dental journal that annually publishes the acceptance rate of manuscripts and the concordance between reviewers and decision to publish is the *Journal of the American College of Dentists*. The rate of concordance in that journal is moderately high, between 0.60 and 0.80.

The credibility of published research findings cannot be assured even by the best external reviewers. Three problems cannot be resolved through the review process: (1) internal versus external validity, (2) generalizability, and (3) the baseline problem. Because the individual dentist cannot transfer responsibility for any of these problems to the research or the journalistic communities, the practitioner must exercise ethical practices in these areas as well. In fact, the solution to this problem has already been addressed—dentists must perform reasonable experiments in their own practices using the ethical standards discussed previously.

### **Internal versus External Validity**

Steady advances in the theory and practice of experimental design and hypothesis testing have brought both basic science and clinical

dental research to a high level of sophistication. The standards for judging the scientific rigor of research are well understood and are fairly consistently applied by reviewers. The problem is inherent in the theory of research design itself.<sup>2</sup> The rigor that has been developed is largely in the area known as internal validity. Controls, placebos, cross-overs, statistical tests, and so forth all work to increase the likelihood of valid conclusions in the context in which the research was conducted. A well-designed study of patients in a nursing home tells about that nursing home; a clinical trial of a new material conducted at a university applies to that university. Scientific rigor is important, and reviewers are customarily sensitive to the fine points of experimental design. External validity—accuracy in general circumstances such as various dental practices—requires high internal validity in the research, but internal validity does not guarantee external validity.

### **Generalizability**

External validity is commonly discussed under the heading of generalizability,<sup>1</sup> that is, whether the results of a clinical trial on a certain product in specific conditions can be generalized to other settings, particularly to the office of the dentist who is reading the study and may wish to use the product. Generalizability is a gradient. The more similar the study conditions described in the literature are to the office where the results will be applied, the greater the external validity and the less likely the practitioner will be surprised. External validity, however, will always be lower in an application than in the study on which the application is based. An appropriate analogy is shipping cookies across country: sometimes they arrive only slightly damaged and stale, but they never improve during the trip.

Responsibility for estimating generalizability of research results does not rest with the research community; it rests with individual practitioners. There is no way for the researcher to know all of the circumstances in which results might be applied. Only the individual dentist knows the difference between his or her practice and the circumstances described in the literature. In this sense, all dental research consists of two experiments—one conducted by the researcher, and another conducted by the dentist. The dentist is responsible for the second experiment, and the ethical nature of the second experiment should follow the rules already developed.

### **The Baseline Problem**

There is much discussion today regarding evidence based dentistry. Although the term has been used to describe a variety of activities, the basic approach seems to be a concern that dental practice be based more securely on evidence from scientific studies. Certainly, the issues of

internal validity and generalizability must be considered as tempering the widespread use of this approach. Another issue is also troublesome. The concept of evidence based dentistry was borrowed from medicine, and the concept may not carry over effectively to dentistry. Physicians spend a substantial amount of their practice time diagnosing a broad range of conditions, but treatment is delegated to nurses, other physicians, therapists, and even to patients using prescribed medications. Dentists diagnose a much smaller number of more conditions, and they treat those conditions themselves. Problem-solving is a smaller part of a dentist's role than treatment, and dentists develop intimate, intuitive experience of the outcomes of treatment because of their direct involvement in it. In other words, dentists have a rich baseline understanding of patient conditions.

The baseline problem is a sophisticated issue in scientific decision making.<sup>5</sup> The most basic explanation of the baseline problem is that valid decisions are made based on what is known in a general sort of way about classes of conditions (the baseline knowledge) *and* on what can be found out by inquiry (the evidence). When trying to determine a value, such as pocket depth readings or the expected rate of decay observed in an incipient carious lesion, the best strategy is to combine the baseline knowledge and the evidence. Dentists do so intuitively when they shade the probing depth reading based on other probings in the area or modify their estimate of expected rate of caries advancement based on both the lesion itself and baseline factors such as the age of the patient, other evidence of caries in the mouth, and an assessment of home care.

When the decision involves a course of action rather than a value estimate, a different logic applies. The rule is always go with either the baseline *or* with the evaluation evidence, whichever has a higher probability of being accurate. To extract or to treat endodontically, to bleach or not to bleach, to use an implant or a crown are decisions that are mutually exclusive—one action excludes the other. Most carious lesions are best treated based on the individual practitioner's experience in the practice (baseline) rather than the literature (external evidence). The same is true, to varying degrees, for many other treatment decisions in practice. It must be remembered, however, that whether the dentist follows practice patterns or the literature in a particular case, if there is any probability for surprise, a practice experiment is being conducted, and the appropriate ethics must be observed.

## References

1. Brennan RL: (Mis)Conceptions about generalizability theory. *Educational Measurement: Issues, Practice* 19:5–10, 2000
2. Brunette DM: *Critical Thinking: Understanding and Evaluating Dental Research*. Carol Stream, IL, Quintessence, 1996
3. Callaham ML, Baxt WG, Waeckerle JF, et al: Reliability of editors' subjective quality ratings of peer reviews of manuscripts. *JAMA* 280:229–231, 1998



4. Chambers DW: Looking for virtue in a virtuous society – discursive ethics and dental managed care. *J Am Coll Dent* 63:39–42, 1996
5. Chambers DW: The roles of evidence and the baseline in dental decision making. *J Am Coll Dent* 66:60–68, 1999
6. Chambers DW: Above all, check your references. *J Am Coll Dent* 67:2–3, 2000
7. Chambers DW: Promises. *J Am Coll Dent* 67:51–55, 2000
8. Chambers DW, Abrams RG: *Dental Communication*. Sonoma, CA, The Ohana Group, 1986
9. Chambers DW, Eng WRL Jr: Practice profile: The first twelve years. *Journal of the California Dental Association* 12:25–32, 1994
10. Ethics of managed care. *J Am Coll Dent* 63: entire issue, 1996
11. Licensure Results. *News & Views* [the newsletter of the American College of Dentists] 26:5, 1998
12. Ozar D, Sokol D: *Dental Ethics at Chairside: Professional Principles and Practical Applications*. Washington, DC, Georgetown University Press, 1999
13. Peltier B: Reflection, introspection, and communication: A psychologist's view of dental ethics. *J Am Coll Dent* 67:33–38, 2000
14. Rest JR, Narvaez D: *Moral Development in the Professions: Psychology and Applied Ethics*. Hillsdale, NJ, Lawrence Erlbaum, 1994
15. Rule J, Veatch R: *Ethical Questions in Dentistry*. Chicago, Quintessence, 1993
16. Schon DA: *The Reflective Practitioner: How Professionals Think in Action*. New York, Basic Books 1983
17. Toward responsible research conduct: The role of scientific societies. *J Dent Res* 75:823–860, 1996

*Address reprint requests to*

David W. Chambers, EdM, MBA, PhD  
University of the Pacific  
2155 Webster Street  
San Francisco, CA 94115

e-mail: dchambers@uop.edu