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- A. To urge the extension and improvement of measures for the control and prevention of oral disorders;
- B. To encourage qualified persons to consider a career in dentistry so that dental health services will be available to all, and to urge broad preparation for such a career at all educational levels;
- C. To encourage graduate studies and continuing educational efforts by dentists and auxiliaries;
- D. To encourage, stimulate, and promote research;
- E. To improve the public understanding and appreciation of oral health service and its importance to the optimum health of the patient;
- F. To encourage the free exchange of ideas and experiences in the interest of better service to the patient;
- G. To cooperate with other groups for the advancement of interprofessional relationships in the interest of the public;
- H. To make visible to professional persons the extent of their responsibilities to the community as well as to the field of health service and to urge the acceptance of them;
- I. To encourage individuals to further these objectives, and to recognize meritorious achievements and the potential for contributions to dental science, art, education, literature, human relations, or other areas which contribute to human welfare—by conferring Fellowship in the College on those persons properly selected for such honor.

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Cover photograph: What is the role of patients in contributing to dental knowledge?

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FROM THE EDITOR

DARWIN ON DENTISTRY

Let's imagine that dentistry is a species of oral health care existing in a complex environment. It has evolved nicely. Coach builders, phrenologists, alchemists, and denturist—by contrast—have not made the big cut.

What we call dentistry today, however, is vastly different and more complex than even a few decades ago. When CDT codes were introduced in 1969, there were 284 of them; today, there are 641. In the 1920s, some dental supply houses sold dental insurance; in the 1930s there were a few practitioners on salary mostly attending to oral health needs of workers in towns with large factories. Today, almost 60% of the dental bill is paid by someone other than the patient, more than 99% of dentists accept insurance, and the fastest-growing infusion of money into the profession is coming from the government. Those were forces widely predicted 50 years ago to be fatal to dentistry. We used to say that dental materials were not forgiving, but patients were.

Change is the only alternative to extinction. But I strongly suspect there is more to be said about that choice.

The causes, reactions to, and pace of change matter.

Darwin startled everybody by insisting that a fundamental requirement for survival of the species is regular replacement of individual members. The three necessary components of the system include: a replicator mechanism (dental schools and organized dentistry), a standard for fitness (public and professional definitions of good oral health), and random variation (research, technology, economics, and plain luck). Dropping or hobbling any of these will jeopardize the future.

Rather than talk about randomness, individual turnover, and the environment having the ultimate say in what thrives, however, we prefer our Darwinianism in a “survival of the fittest” garb. Those who are here now must have earned the right to brag about their way of doing things. This is an attractive myth, best reserved for graduations and ceremonial occasions honoring organizations. If it were really true, the smartest money managers would be lottery winners, all elected officials could claim to be born leaders, and professional athletes should be paid based on what they did last year.

I share the view of many modern evolutionists that Darwin was only approximately right. He left out memes and self-organizing systems.

Memes are like non-biological genes. They have replicator mechanisms and advance by disruptive repurposing that

better matches their environments. Cell phones, kick-em-off TV talent shows, EBD, the Tea Party, Facebook, and organized dentistry are memes. They survive by adapting to their environments just as genes do. Plants and animals are the replicator system for genes; dentists are the replicator system for organized dentistry. The organization continues and evolves precisely because it replaces its members.

Self-organizing systems are more complicated than they appear at first. If you put a hot rock in the swimming pool and come back a short time later, the temperature of the rock and all the water will be the same. This is called entropy—the second law of thermodynamics. It says that closed systems—ones that do not exchange energy with their environments—run down to sameness over time.

Self-organization is the reconfiguring of systems in response to the dynamic tension between the organization and its environment. It is constant, open-system redefinition. Dentistry going from an apprentice trade of self-proclaimed competent individuals to a protoprofession then to a science-based profession is an example of self-organization. The parts were not only rearranged, something new was created each time.

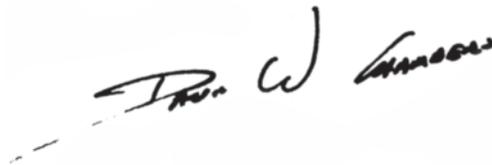
Here are some of the laws that govern self-organizing systems:

- Any system that has less complexity than its immediate environment or changes more slowly will be stunted.
- Optimization on current conditions is dumb.
- Pursuing a single, optimal strategy is riskier than allowing prudent, diverse experimentation.
- Growth occurs at the border between stability and chaos and between the organization and its environment.
- Thriving cannot be predicted.
- Control of information flow is delicate: tight control produces stagnation, loose control leads to chaos.
- Closed systems always run down over time.
- Systems become obsolete gradually, but grow in spurts caused by betting on options, only a few of which are big winners.
- As organizations approach optimality, each improvement is harder to make and more costly.
- Most innovation comes from the bottom or from outside the organization.
- All evaluation is coevolution. Most of my problems are caused by other people solving their problems.
- Large organizations are most efficient and most stable when goals and operating procedures are decentralized and even slightly divergent across units of moderate size.
- No system can see all of its environment—it has to feel its way.

Nobel Laureate Ronald Coase wrote what is perhaps the most widely cited paper in the field of economics, “The nature of the firm.” He asked a simple question. If top down, rational organizations are so efficient—and of course they are—why is there not just one organization in the whole world? The answer, as every brontosaurus knows, is that there is an optimal size dictated by the environment. Adaptability matters and that cannot be maximized by size or homogeneity of vision and operation.

Some of the current heavy hitter in management—James Brian Quinn in *Strategies for Change* and Henry Mintzberg, *The Rise and Fall of Strategic Planning*—caution that it is easier for organizations to respond nimbly into the future than to try to control it by planning.

Whether the choices of the leadership in organized dentistry turn out to be the right ones will be determined by the young men and women just coming into dental schools and starting their practices today. They and the public should be consulted.



Plants and animals are the replicator system for genes; dentists are the replicator system for organized dentistry. The organization continues and adapts precisely because it replaces its members.

THE BELMONT REPORT

ETHICAL PRINCIPLES AND GUIDELINES FOR THE PROTECTION OF HUMAN SUBJECTS OF RESEARCH

As the atrocities committed by some physicians during the Nazi regime came to light in the Nuremberg Trials, the international research community and governments recognized the potential conflict that may occur between science for the betterment of mankind and the inherent dignity of individuals. Two decades later, America was appalled by research on syphilis conducted at the Tuskegee Prison in Alabama where the natural progression of the disease was observed in inmates who were told they were receiving care when in fact they were not. The United States Department of Health, Education, and Welfare convened a panel of researchers, practitioners, and ethicists to develop standards to prevent such abuses in the future. The working group met for nearly four years and a final report was issued in 1979 based on a meeting at the Smithsonian Institute's Belmont Conference Center.

The Belmont Report is the touchstone statement of research ethics for studies involving biomedical and behavioral research. The report itself is advisory. But it carries the weight of regulation by virtue of being incorporated in the Code of Federal Regulations Title 45 (Public Welfare), Section 46 (Protection of Human Subjects). This document is known as 45 CFR 46. The policy establishes a requirement that research organizations create Institutional Review Boards (IRBs) charged with giving prior approval to all research project involving human subjects and monitoring ongoing research. The standard for all IRBs is the

Belmont Report. "Human subjects" or "clinical research" is defined in 45 CFR 46 as involving any person or anything produced by a person. Tissue samples, questionnaire responses, and photographs are "clinical research." The requirement for IRB approval and monitoring applies to any organization or individual that has formal dealings with the United States government in any capacity, regardless of whether the particular research is federally funded.

The Belmont Report is organized around three ethical principles: (a) respect for persons, (b) beneficence, and (c) justice. If these sound familiar, that is because the ADA Principles of Ethics and Code of Professional Conduct was developed shortly after the Belmont Report. Respect for persons was modified by the ADA to autonomy. Beneficence was expanded into two principles: nonmaleficence and beneficence. And veracity (which carries by far the largest load in the ADA code) was added. A powerful feature of the Belmont Report is its third section, applications. Each of the three principles is worked out in terms of a primary behavior that researchers must follow. Respect for persons is manifested through informed consent, and the Belmont Report is one of the clearest statements of what this means ethically (not legally). Beneficence enters the research world in terms of the requirements to balance risks and benefits. Finally, justice concerns the issue of whether one group is bearing the burdens of research risk for the benefit of other group.

Office of the Secretary
April 18, 1979

AGENCY:
Department of Health, Education,
and Welfare

ACTION:
Notice of Report for Public Comment

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

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SUMMARY

On July 12, 1974, the National Research Act (Pub. L. 93-348) was signed into law, thereby creating the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. One of the charges to the Commission was to identify the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles. In carrying out the above, the Commission was directed to consider: (a) the boundaries between biomedical and behavioral research and the accepted and routine practice of medicine, (b) the role of assessment of risk-benefit criteria in the determination of the appropriateness of research involving human subjects, (c) appropriate guidelines for the selection of human subjects for participation in such research and (d) the nature and definition of informed consent in various research settings.

The Belmont Report attempts to summarize the basic ethical principles identified by the Commission in the course of its deliberations. It is the outgrowth of an intensive four-day period of discussions that were held in February 1976 at the Smithsonian Institution's Belmont Conference Center supplemented by the monthly deliberations of the Commission that were held over a period of nearly four years. It is a statement of basic ethical principles and guidelines that should assist in resolving the ethical problems that surround the conduct of research with human subjects. By publishing the Report in the Federal Register, and providing reprints upon request, the Secretary intends that it may be made readily available to scientists, members of Institutional Review Boards, and Federal employees. The two-volume Appendix, containing the lengthy reports of experts

and specialists who assisted the Commission in fulfilling this part of its charge, is available as DHEW Publication No. (OS) 78-0013 and No. (OS) 78-0014, for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

Unlike most other reports of the Commission, the Belmont Report does not make specific recommendations for administrative action by the Secretary of Health, Education, and Welfare. Rather, the Commission recommended that the Belmont Report be adopted in its entirety, as a statement of the Department's policy. The Department requests public comment on this recommendation.

Scientific research has produced substantial social benefits. It has also posed some troubling ethical questions. Public attention was drawn to these questions by reported abuses of human subjects in biomedical experiments, especially during the Second World War. During the Nuremberg War Crime Trials, the Nuremberg code was drafted as a set of standards for judging physicians and scientists who had conducted biomedical experiments on concentration camp prisoners. This code became the prototype of many later codes (Note 1) intended to assure that research involving human subjects would be carried out in an ethical manner.

The codes consist of rules, some general, others specific, that guide the investigators or the reviewers of

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research.

research in their work. Such rules often are inadequate to cover complex situations; at times they come into conflict, and they are frequently difficult to interpret or apply. Broader ethical principles will provide a basis on which specific rules may be formulated, criticized, and interpreted.

Three principles, or general prescriptive judgments, that are relevant to research involving human subjects are identified in this statement. Other principles may also be relevant. These three are comprehensive, however, and are stated at a level of generalization that should assist scientists, subjects, reviewers, and interested citizens to understand the ethical issues inherent in research involving human subjects. These principles cannot always be applied so as to resolve beyond dispute particular ethical problems. The objective is to provide an analytical framework that will guide the resolution of ethical problems arising from research involving human subjects.

This statement consists of a distinction between research and practice, a discussion of the three basic ethical principles, and remarks about the application of these principles.

PART A: BOUNDARIES BETWEEN PRACTICE & RESEARCH

It is important to distinguish between biomedical and behavioral research, on the one hand, and the practice of accepted therapy on the other, in order to know what activities ought to undergo review for the protection of human subjects of research. The distinction between research and

practice is blurred partly because both often occur together (as in research designed to evaluate a therapy) and partly because notable departures from standard practice are often called “experimental” when the terms “experimental” and “research” are not carefully defined.

For the most part, the term “practice” refers to interventions that are designed solely to enhance the well-being of an individual patient or client and that have a reasonable expectation of success. The purpose of medical or behavioral practice is to provide diagnosis, preventive treatment, or therapy to particular individuals (Note 2). By contrast, the term “research” designates an activity designed to test an hypothesis, permit conclusions to be drawn, and thereby to develop or contribute to generalizable knowledge (expressed, for example, in theories, principles, and statements of relationships). Research is usually described in a formal protocol that sets forth an objective and a set of procedures designed to reach that objective.

When a clinician departs in a significant way from standard or accepted practice, the innovation does not, in and of itself, constitute research. The fact that a procedure is “experimental,” in the sense of new, untested, or different, does not automatically place it in the category of research. Radically new procedures of this description should, however, be made the object of formal research at an early stage in order to determine whether they are safe and effective. Thus, it is the responsibility of medical practice committees, for example, to insist that a major innovation be incorporated into a formal research project (Note 3).

Research and practice may be carried on together when research is designed to evaluate the safety and efficacy of a therapy. This need not cause any confusion regarding whether

or not the activity requires review; the general rule is that if there is any element of research in an activity, that activity should undergo review for the protection of human subjects.

PART B: BASIC ETHICAL PRINCIPLES

The expression “basic ethical principles” refers to those general judgments that serve as a basic justification for the many particular ethical prescriptions and evaluations of human actions. Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect for persons, beneficence, and justice.

1. RESPECT FOR PERSONS

Respect for persons incorporates at least two ethical convictions: first, that individuals should be treated as autonomous agents, and second, that persons with diminished autonomy are entitled to protection. The principle of respect for persons thus divides into two separate moral requirements: the requirement to acknowledge autonomy and the requirement to protect those with diminished autonomy.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons’ considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. To show lack of respect for an autonomous agent is to repudiate that person’s considered judgments, to deny an individual the freedom to act on those considered judgments, or to withhold information necessary to make a considered

judgment, when there are no compelling reasons to do so.

However, not every human being is capable of self-determination. The capacity for self-determination matures during an individual's life, and some individuals lose this capacity wholly or in part because of illness, mental disability, or circumstances that severely restrict liberty. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

Some persons are in need of extensive protection, even to the point of excluding them from activities which may harm them; other persons require little protection beyond making sure they undertake activities freely and with awareness of possible adverse consequence. The extent of protection afforded should depend upon the risk of harm and the likelihood of benefit. The judgment that any individual lacks autonomy should be periodically reevaluated and will vary in different situations.

In most cases of research involving human subjects, respect for persons demands that subjects enter into the research voluntarily and with adequate information. In some situations, however, application of the principle is not obvious. The involvement of prisoners as subjects of research provides an instructive example. On the one hand, it would seem that the principle of respect for persons requires that prisoners not be deprived of the opportunity to volunteer for research. On the other hand, under prison conditions they may be subtly coerced or unduly influenced to engage in research activities for which they would not otherwise volunteer. Respect for persons would then dictate that prisoners be protected. Whether to allow prisoners to "volunteer" or to "protect" them presents a dilemma. Respecting persons, in

most hard cases, is often a matter of balancing competing claims urged by the principle of respect itself.

2. BENEFICENCE

Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense: (a) do not harm and (b) maximize possible benefits and minimize possible harms.

The Hippocratic maxim "do no harm" has long been a fundamental principle of medical ethics. Claude Bernard extended it to the realm of research, saying that one should not injure one person regardless of the benefits that might come to others. However, even avoiding harm requires learning what is harmful; and, in the process of obtaining this information, persons may be exposed to risk of harm. Further, the Hippocratic Oath requires physicians to benefit their patients "according to their best judgment." Learning what will in fact benefit may require exposing persons to risk. The problem posed by these imperatives is to decide when it is justifiable to seek certain benefits despite the risks involved, and when the benefits should be foregone because of the risks.

Three basic principles, among those generally accepted in our cultural tradition, are particularly relevant to the ethics of research involving human subjects: the principles of respect of persons, beneficence, and justice.

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of “fairness in distribution” or “what is deserved.” An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

The obligations of beneficence affect both individual investigators and society at large, because they extend both to particular research projects and to the entire enterprise of research. In the case of particular projects, investigators and members of their institutions are obliged to give forethought to the maximization of benefits and the reduction of risk that might occur from the research investigation. In the case of scientific research in general, members of the larger society are obliged to recognize the longer term benefits and risks that may result from the improvement of knowledge and from the development of novel medical, psychotherapeutic, and social procedures.

The principle of beneficence often occupies a well-defined justifying role in many areas of research involving human subjects. An example is found in research involving children. Effective ways of treating childhood diseases and fostering healthy development are benefits that serve to justify research involving children—even when individual research subjects are not direct beneficiaries. Research also makes it possible to avoid the harm that may result from the application of previously accepted routine practices that on closer investigation turn out to be dangerous. But the role of the principle of beneficence is not always so unambiguous. A difficult ethical problem remains, for example, about research that presents more than minimal risk without immediate prospect of direct benefit to the children involved. Some have argued that such research is inadmissible, while others have pointed out that this limit would rule out much research promising great benefit to children in the future. Here again, as with all hard cases, the different claims covered by the principle of beneficence may come into conflict and force difficult choices.

3. JUSTICE

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of “fairness in distribution” or “what is deserved.” An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution? Almost all commentators allow that distinctions based on experience, age, deprivation, competence, merit, and position do sometimes constitute criteria justifying differential treatment for certain purposes. It is necessary, then, to explain in what respects people should be treated equally.

There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are (a) to each person an equal share, (b) to each person according to individual need, (c) to each person according to individual effort, (d) to each person according to societal contribution, and (e) to each person according to merit.

Questions of justice have long been associated with social practices such as punishment, taxation, and political representation. Until recently these questions have not generally been associated with scientific research. However, they are foreshadowed even

in the earliest reflections on the ethics of research involving human subjects. For example, during the 19th and early 20th centuries the burdens of serving as research subjects fell largely upon poor ward patients, while the benefits of improved medical care flowed primarily to private patients. Subsequently, the exploitation of unwilling prisoners as research subjects in Nazi concentration camps was condemned as a particularly flagrant injustice. In this country, in the 1940s, the Tuskegee syphilis study used disadvantaged, rural black men to study the untreated course of a disease that is by no means confined to that population. These subjects were deprived of demonstrably effective treatment in order not to interrupt the project, long after such treatment became generally available.

Against this historical background, it can be seen how conceptions of justice are relevant to research involving human subjects. For example, the selection of research subjects needs to be scrutinized in order to determine whether some classes (e.g., welfare patients, particular racial and ethnic minorities, or persons confined to institutions) are being systematically selected simply because of their easy availability, their compromised position, or their manipulability, rather than for reasons directly related to the problem being studied. Finally, whenever research supported by public funds leads to the development of therapeutic devices and procedures, justice demands both that these not provide advantages only to those who can afford them and that such research should not unduly involve persons from groups unlikely to be among the beneficiaries of subsequent applications of the research.

PART C: Applications

Applications of the general principles to the conduct of research leads to consideration of the following require-

ments: informed consent, risk/benefit assessment, and the selection of subjects of research.

1. INFORMED CONSENT

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While the importance of informed consent is unquestioned, controversy prevails over the nature and possibility of an informed consent. Nonetheless, there is widespread agreement that the consent process can be analyzed as containing three elements: information, comprehension, and voluntariness.

Information: Most codes of research establish specific items for disclosure intended to assure that subjects are given sufficient information. These items generally include: the research procedure, their purposes, risks and anticipated benefits, alternative procedures (where therapy is involved), and a statement offering the subject the opportunity to ask questions and to withdraw at any time from the research. Additional items have been proposed, including how subjects are selected, the person responsible for the research, etc.

However, a simple listing of items does not answer the question of what the standard should be for judging how much and what sort of information should be provided. One standard frequently invoked in medical practice, namely the information commonly provided by practitioners in the field or in the locale, is inadequate since research takes place precisely when a common understanding does not exist.

Another standard, currently popular in malpractice law, requires the practitioner to reveal the information that reasonable persons would wish to know in order to make a decision regarding their care. This, too, seems insufficient since the research subject, being in essence a volunteer, may wish to know considerably more about risks gratuitously undertaken than do patients who deliver themselves into the hand of a clinician for needed care. It may be that a standard of "the reasonable volunteer" should be proposed: the extent and nature of information should be such that persons, knowing that the procedure is neither necessary for their care nor perhaps fully understood, can decide whether they wish to participate in the furthering of knowledge. Even when some direct benefit to them is anticipated, the subjects should understand clearly the range of risk and the voluntary nature of participation.

A special problem of consent arises where informing subjects of some pertinent aspect of the research is likely to impair the validity of the research. In many cases, it is sufficient to indicate to subjects that they are being invited to participate in research of which some features will not be revealed until the research is concluded. In all cases of research involving incomplete disclosure, such research is justified only if it is clear that (a) incomplete disclosure is truly necessary to accomplish the goals of the research, (b) there are no undisclosed risks to subjects that are more than minimal, and (c) there is an adequate

plan for debriefing subjects, when appropriate, and for dissemination of research results to them. Information about risks should never be withheld for the purpose of eliciting the cooperation of subjects, and truthful answers should always be given to direct questions about the research. Care should be taken to distinguish cases in which disclosure would destroy or invalidate the research from cases in which disclosure would simply inconvenience the investigator.

Comprehension: The manner and context in which information is conveyed is as important as the information itself. For example, presenting information in a disorganized and rapid fashion, allowing too little time for consideration, or curtailing opportunities for questioning, all may adversely affect a subject's ability to make an informed choice.

Because the subject's ability to understand is a function of intelligence, rationality, maturity, and language, it is necessary to adapt the presentation of the information to the subject's capacities. Investigators are responsible for ascertaining that the subject has comprehended the information. While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Special provision may need to be made when comprehension is severely limited—for example, by conditions of

immaturity or mental disability. Each class of subjects that one might consider as incompetent (e.g., infants and young children, mentally disable patients, the terminally ill, and the comatose) should be considered on its own terms. Even for these persons, however, respect requires giving them the opportunity to choose to the extent they are able, whether or not to participate in research. The objections of these subjects to involvement should be honored, unless the research entails providing them a therapy unavailable elsewhere. Respect for persons also requires seeking the permission of other parties in order to protect the subjects from harm. Such persons are thus respected both by acknowledging their own wishes and by the use of third parties to protect them from harm.

The third parties chosen should be those who are most likely to understand the incompetent subject's situation and to act in that person's best interest. The person authorized to act on behalf of the subject should be given an opportunity to observe the research as it proceeds in order to be able to withdraw the subject from the research, if such action appears in the subject's best interest.

Voluntariness: An agreement to participate in research constitutes a valid consent only if voluntarily given. This element of informed consent requires conditions free of coercion and undue influence. Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance. Undue influence, by contrast, occurs through an offer of an excessive, unwarranted, inappropriate, or improper reward, or other overture in order to obtain compliance. Also, inducements that would ordinarily be acceptable may become undue influences if the subject is especially vulnerable.

Unjustifiable pressures usually occur when persons in positions of authority or commanding influence—especially where possible sanctions are involved—urge a course of action for a subject. A continuum of such influencing factors exists, however, and it is impossible to state precisely where justifiable persuasion ends and undue influence begins. But undue influence would include actions such as manipulating a person's choice through the controlling influence of a close relative and threatening to withdraw health services to which an individual would otherwise be entitled.

2. ASSESSMENT OF RISKS AND BENEFITS

The assessment of risks and benefits requires a careful array of relevant data, including, in some cases, alternative ways of obtaining the benefits sought in the research. Thus, the assessment presents both an opportunity and a responsibility to gather systematic and comprehensive information about proposed research. For the investigator, it is a means to examine whether the proposed research is properly designed. For a review committee, it is a method for determining whether the risks that will be presented to subjects are justified. For prospective subjects, the assessment will assist the determination whether or not to participate.

The Nature and Scope of Risks and Benefits: The requirement that research be justified on the basis of a favorable risk/benefit assessment bears a close relation to the principle of beneficence, just as the moral requirement that informed consent be obtained is derived primarily from the principle of respect for persons. The term "risk" refers to a possibility that harm may occur. However, when expressions such

as “small risk” or “high risk” are used, they usually refer (often ambiguously) both to the chance (probability) of experiencing a harm and the severity (magnitude) of the envisioned harm.

The term “benefit” is used in the research context to refer to something of positive value related to health or welfare. Unlike, “risk,” “benefit” is not a term that expresses probabilities. Risk is properly contrasted to probability of benefits, and benefits are properly contrasted with harms rather than risks of harm. Accordingly, so-called risk/benefit assessments are concerned with the probabilities and magnitudes of possible harm and anticipated benefits. Many kinds of possible harms and benefits need to be taken into account. There are, for example, risks of psychological harm, physical harm, legal harm, social harm, and economic harm and the corresponding benefits. While the most likely types of harms to research subjects are those of psychological or physical pain or injury, other possible kinds should not be overlooked.

Risks and benefits of research may affect the individual subjects, the families of the individual subjects, and society at large (or special groups of subjects in society). Previous codes and Federal regulations have required that risks to subjects be outweighed by the sum of both the anticipated benefit to the subject, if any, and the anticipated benefit to society in the form of knowledge to be gained from the research. In balancing these different elements, the risks and benefits affecting the immediate research subject will normally carry special weight. On the other hand, interests other than those of the subject may on some occasions be sufficient by themselves to justify the risks involved in the research, so long as the subjects’ rights have been protected. Beneficence thus requires that we protect against risk of harm to subjects

and also that we be concerned about the loss of the substantial benefits that might be gained from research.

The Systematic Assessment of Risks and Benefits: It is commonly said that benefits and risks must be “balanced” and shown to be “in a favorable ratio.” The metaphorical character of these terms draws attention to the difficulty of making precise judgments. Only on rare occasions will quantitative techniques be available for the scrutiny of research protocols. However, the idea of systematic, nonarbitrary analysis of risks and benefits should be emulated insofar as possible. This ideal requires those making decisions about the justifiability of research to be thorough in the accumulation and assessment of information about all aspects of the research and to consider alternatives systematically. This procedure renders the assessment of research more rigorous and precise, while making communication between review board members and investigators less subject to misinterpretation, misinformation, and conflicting judgments. Thus, there should first be a determination of the validity of the presuppositions of the research; then the nature, probability, and magnitude of risk should be distinguished with as much clarity as possible. The method of ascertaining risks should be explicit, especially where there is no alternative to the use of such vague categories as small or slight risk. It should also be determined whether an investigator’s estimates of the probability of harm or benefits are reasonable, as judged by known facts or other available studies.

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them. This opportunity is provided when adequate standards for informed consent are satisfied.

While there is always an obligation to ascertain that the information about risk to subjects is complete and adequately comprehended, when the risks are more serious, that obligation increases. On occasion, it may be suitable to give some oral or written tests of comprehension.

Finally, assessment of the justifiability of research should reflect at least the following considerations:

- (a) Brutal or inhumane treatment of human subjects is never morally justified.
- (b) Risks should be reduced to those necessary to achieve the research objective. It should be determined whether it is in fact necessary to use human subjects at all. Risk can perhaps never be entirely eliminated, but it can often be reduced by careful attention to alternative procedures.
- (c) When research involves significant risk of serious impairment, review committees should be extraordinarily insistent on the justification of the risk (looking usually to the likelihood of benefit to the subject—or, in some rare cases, to the manifest voluntariness of the participation).
- (d) When vulnerable populations are involved in research, the appropriateness of involving them should itself be demonstrated. A number of variables go into such judgments, including the nature and degree of risk, the condition of the particular population involved, and the nature and level of the anticipated benefits.
- (e) Relevant risks and benefits must be thoroughly arrayed in documents and procedures used in the informed consent process.

3. SELECTION OF SUBJECTS

Just as the principle of respect for persons finds expression in the requirements for consent, and the

principle of beneficence in risk/benefit assessment, the principle of justice gives rise to moral requirements that there be fair procedures and outcomes in the selection of research subjects.

Justice is relevant to the selection of subjects of research at two levels: the social and the individual. Individual justice in the selection of subjects would require that researchers exhibit fairness: thus, they should not offer potentially beneficial research only to some patients who are in their favor or select only “undesirable” persons for risky research. Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons. Thus, it can be considered a matter of social justice that there is an order of preference in the selection of classes of subjects (e.g., adults before children) and that some classes of potential subjects (e.g., the institutionalized mentally infirm or prisoners) may be involved as research subjects, if at all, only on certain conditions.

Injustice may appear in the selection of subjects, even if individual subjects are selected fairly by investigators and treated fairly in the course of research. Thus injustice arises from social, racial, sexual, and cultural biases institutionalized in society. Thus, even if individual researchers are treating their research subjects fairly, and even if IRBs are taking care to assure that subjects are selected fairly within a particular institution, unjust social patterns may nevertheless appear in the overall distribution of the burdens and benefits of research. Although individual institutions or investigators may not be able to resolve a problem that is pervasive in their social setting, they

can consider distributive justice in selecting research subjects.

Some populations, especially institutionalized ones, are already burdened in many ways by their infirmities and environments. When research is proposed that involves risks and does not include a therapeutic component, other less burdened classes of persons should be called upon first to accept these risks of research, except where the research is directly related to the specific conditions of the class involved. Also, even though public funds for research may often flow in the same directions as public funds for health care, it seems unfair that populations dependent on public health care constitute a pool of preferred research subjects if more advantaged populations are likely to be the recipients of the benefits.

One special instance of injustice results from the involvement of vulnerable subjects. Certain groups, such as racial minorities, the economically disadvantaged, the very sick, and the institutionalized may continually be sought as research subjects, owing to their ready availability in settings where research is conducted. Given their dependent status and their frequently compromised capacity for free consent, they should be protected against the danger of being involved in research solely for administrative convenience, or because they are easy to manipulate as a result of their illness or socioeconomic condition.

NOTES:

(1) Since 1945, various codes for the proper and responsible conduct of human experimentation in medical research have been adopted by different organizations. The best known of these

codes are the Nuremberg Code of 1947, the Helsinki Declaration of 1964 (revised in 1975), and the 1971 Guidelines (codified into Federal Regulations in 1974) issued by the U.S. Department of Health, Education, and Welfare. Codes for the conduct of social and behavioral research have also been adopted, the best known being that of the American Psychological Association, published in 1973.

(2) Although practice usually involves interventions designed solely to enhance the well-being of a particular individual, interventions are sometimes applied to one individual for the enhancement of the well-being of another (e.g., blood donation, skin grafts, organ transplants) or an intervention may have the dual purpose of enhancing the well-being of a particular individual, and, at the same time, providing some benefit to others (e.g., vaccination, which protects both the person who is vaccinated and society generally). The fact that some forms of practice have elements other than immediate benefit to the individual receiving an intervention, however, should not confuse the general distinction between research and practice. Even when a procedure applied in practice may benefit some other person, it remains an intervention designed to enhance the well-being of a particular individual or groups of individuals; thus, it is practice and need not be reviewed as research.

(3) Because the problems related to social experimentation may differ substantially from those of biomedical and behavioral research, the Commission specifically declines to make any policy determination regarding such research at this time. Rather, the Commission believes that the problem ought to be addressed by one of its successor bodies. ■

Social justice requires that distinction be drawn between classes of subjects that ought, and ought not, to participate in any particular kind of research, based on the ability of members of that class to bear burdens and on the appropriateness of placing further burdens on already burdened persons.

World Medical Association Declaration of Helsinki

ETHICAL PRINCIPLES FOR MEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

Published research in English-language journals are increasingly required to carry a statement that the study has been approved and monitored by an Institutional Review Board in conformance with 45 CFR 46 standards if the study was conducted in the United States. Alternative language attesting conformity with the Helsinki Declaration is often included when the research was conducted in Europe or elsewhere. The Helsinki Declaration was created by the World Medical Association in 1964 (ten years before the Belmont Report) and has been amended several times.

The Helsinki Declaration differs from its American version in several respects, the most significant of which is that it was developed by and for physicians. The term "patient" appears in many places where we would expect to see "subject." It is stated in several places that physicians must either conduct or have supervisory control of the research. The dual role of the physician-researcher is acknowledged, but it is made clear that the role of healer takes precedence over that of scientist. In the United States, the federal government developed and enforces regulations on researcher; in the rest of the world, the profession, or

a significant part of it, took the initiative in defining and promoting good research practice, and governments in many countries have worked to harmonize their standards along these lines.

The Helsinki Declaration is based less on key philosophical principles and more on prescriptive statements. Although there is significant overlap between the Belmont and the Helsinki guidelines, the latter extends much further into research design and publication. Elements in a research protocol, use of placebos, and obligation to enroll trials in public registries (to ensure that negative findings are not buried), and requirements to share findings with the research and professional communities are included in the Helsinki Declaration. As a practical matter, these are often part of the work of American IRBs, but not always as a formal requirement. Reflecting the socialist nature of many European countries, there is a requirement that provision be made for patients to be made whole regardless of the outcomes of the trial or if they happened to have been randomized to a control group that did not enjoy the benefits of a successful experimental intervention.

General Assembly of the World
Medical Association

PREAMBLE

1. The World Medical Association (WMA) has developed the Declaration of Helsinki as a statement of ethical principles for medical research involving human subjects, including research on identifiable human material and data.
The Declaration is intended to be read as a whole and each of its constituent paragraphs should be applied with consideration of all other relevant paragraphs.
2. Consistent with the mandate of the WMA, the Declaration is addressed primarily to physicians. The WMA encourages others who are involved in medical research involving human subjects to adopt these principles.

GENERAL PRINCIPLES

3. The Declaration of Geneva of the WMA binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that, "A physician shall act in the patient's best interest when providing medical care."
4. It is the duty of the physician to

promote and safeguard the health, well-being and rights of patients, including those who are involved in medical research. The physician's knowledge and conscience are dedicated to the fulfilment of this duty.

5. Medical progress is based on research that ultimately must include studies involving human subjects.
6. The primary purpose of medical research involving human subjects is to understand the causes, development, and effects of diseases and improve preventive, diagnostic, and therapeutic interventions (methods, procedures, and treatments). Even the best proven interventions must be evaluated continually through research for their safety, effectiveness, efficiency, accessibility, and quality.
7. Medical research is subject to ethical standards that promote and ensure respect for all human subjects and protect their health and rights.
8. While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.
9. It is the duty of physicians who are involved in medical research to protect the life, health, dignity, integrity, right to self-determination, privacy, and confidentiality of personal information of research subjects. The responsibility for the protection of research subjects must always rest with the physician or other healthcare professionals and never with the research subjects, even though they have given consent.
10. Physicians must consider the ethical, legal, and regulatory norms and standards for research involving human subjects in their own countries as well as applicable international norms and standards. No national or international ethical, legal, or regulatory requirement should reduce or eliminate any of the protections for research subjects set forth in this Declaration.
11. Medical research should be conducted in a manner that minimizes possible harm to the environment.
12. Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training, and qualifications. Research on patients or healthy volunteers requires the supervision of a competent and appropriately qualified physician or other healthcare professional.
13. Groups that are underrepresented in medical research should be provided appropriate access to participation in research.
14. Physicians who combine medical research with medical care should involve their patients in research only to the extent that this is justified by its potential preventive,

While the primary purpose of medical research is to generate new knowledge, this goal can never take precedence over the rights and interests of individual research subjects.

Medical research involving human subjects must be conducted only by individuals with the appropriate ethics and scientific education, training, and qualifications.

diagnostic, or therapeutic value and if the physician has good reason to believe that participation in the research study will not adversely affect the health of the patients who serve as research subjects.

15. Appropriate compensation and treatment for subjects who are harmed as a result of participating in research must be ensured.

Risks, BURDENS, AND BENEFITS

16. In medical practice and in medical research, most interventions involve risks and burdens.

Medical research involving human subjects may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.

17. All medical research involving human subjects must be preceded by careful assessment of predictable risks and burdens to the individuals and groups involved in the research in comparison with foreseeable benefits to them and to other individuals or groups affected by the condition under investigation.

Measures to minimize the risks must be implemented. The risks must be continuously monitored, assessed and documented by the researcher.

18. Physicians may not be involved in a research study involving human subjects unless they are confident that the risks have been adequately assessed and can be satisfactorily managed.

When the risks are found to outweigh the potential benefits or when there is conclusive proof of

definitive outcomes, physicians must assess whether to continue, modify or immediately stop the study.

VULNERABLE GROUPS AND INDIVIDUALS

19. Some groups and individuals are particularly vulnerable and may have an increased likelihood of being wronged or of incurring additional harm.

All vulnerable groups and individuals should receive specifically considered protection.

20. Medical research with a vulnerable group is only justified if the research is responsive to the health needs or priorities of this group and the research cannot be carried out in a non-vulnerable group. In addition, this group should stand to benefit from the knowledge, practices, or interventions that result from the research.

SCIENTIFIC REQUIREMENTS AND RESEARCH PROTOCOLS

21. Medical research involving human subjects must conform to generally accepted scientific principles, be based on a thorough knowledge of the scientific literature, other relevant sources of information, and adequate laboratory and, as appropriate, animal experimentation. The welfare of animals used for research must be respected.
22. The design and performance of each research study involving human subjects must be clearly described and justified in a research protocol.

The protocol should contain a statement of the ethical considerations involved and should indicate how the principles in this Declaration have been addressed. The protocol should include information regarding funding,

sponsors, institutional affiliations, potential conflicts of interest, incentives for subjects, and information regarding provisions for treating and/or compensating subjects who are harmed as a consequence of participation in the research study.

In clinical trials, the protocol must also describe appropriate arrangements for post-trial provisions.

RESEARCH ETHICS COMMITTEES

23. The research protocol must be submitted for consideration, comment, guidance, and approval to the concerned research ethics committee before the study begins. This committee must be transparent in its functioning, must be independent of the researcher, the sponsor, and any other undue influence, and must be duly qualified. It must take into consideration the laws and regulations of the country or countries in which the research is to be performed as well as applicable international norms and standards, but these must not be allowed to reduce or eliminate any of the protections for research subjects set forth in this Declaration.

The committee must have the right to monitor ongoing studies. The researcher must provide monitoring information to the committee, especially information about any serious adverse events. No amendment to the protocol may be made without consideration and approval by the committee. After the end of the study, the researchers must submit a final report to the committee containing a summary of the study's findings and conclusions.

PRIVACY AND CONFIDENTIALITY

24. Every precaution must be taken to protect the privacy of research subjects and the confidentiality of their personal information.

INFORMED CONSENT

25. Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary. Although it may be appropriate to consult family members or community leaders, no individual capable of giving informed consent may be enrolled in a research study unless he or she freely agrees.

26. In medical research involving human subjects capable of giving informed consent, each potential subject must be adequately informed of the aims, methods, sources of funding, any possible conflicts of interest, institutional affiliations of the researcher, the anticipated benefits and potential risks of the study and the discomfort it may entail, post-study provisions, and any other relevant aspects of the study. The potential subject must be informed of the right to refuse to participate in the study or to withdraw consent to participate at any time without reprisal. Special attention should be given to the specific information needs of individual potential subjects as well as to the methods used to deliver the information.

After ensuring that the potential subject has understood the information, the physician or another appropriately qualified individual must then seek the potential subject's freely-given informed consent, preferably in writing. If the consent cannot be expressed in writing, the non-

written consent must be formally documented and witnessed.

All medical research subjects should be given the option of being informed about the general outcome and results of the study.

27. When seeking informed consent for participation in a research study the physician must be particularly cautious if the potential subject is in a dependent relationship with the physician or may consent under duress. In such situations the informed consent must be sought by an appropriately qualified individual who is completely independent of this relationship.
28. For a potential research subject who is incapable of giving informed consent, the physician must seek informed consent from the legally authorized representative. These individuals must not be included in a research study that has no likelihood of benefit for them unless it is intended to promote the health of the group represented by the potential subject, the research cannot instead be performed with persons capable of providing informed consent, and the research entails only minimal risk and minimal burden.
29. When a potential research subject who is deemed incapable of giving informed consent is able to give assent to decisions about participation in research, the physician must seek that assent in addition to the consent of the legally authorized representative. The potential subject's dissent should be respected.

30. Research involving subjects who are physically or mentally incapable of giving consent, for example, unconscious patients, may be done only if the physical or mental condition that prevents giving informed consent is a necessary characteristic of the research group. In such circumstances the physician must seek informed consent from the legally authorized representative. If no such representative is available and if the research cannot be delayed, the study may proceed without informed consent provided that the specific reasons for involving subjects with a condition that renders them unable to give informed consent have been stated in the research protocol and the study has been approved by a research ethics committee. Consent to remain in the research must be obtained as soon as possible from the subject or a legally authorized representative.
31. The physician must fully inform the patient which aspects of their care are related to the research. The refusal of a patient to participate in a study or the patient's decision to withdraw from the study must never adversely affect the patient-physician relationship.
32. For medical research using identifiable human material or data, such as research on material or data contained in biobanks or similar repositories, physicians must seek informed consent for its collection, storage, and/or reuse. There may be exceptional situations where consent would be impossible or impracticable to obtain for such

research. In such situations the research may be done only after consideration and approval of a research ethics committee.

USE OF PLACEBO

33. The benefits, risks, burdens, and effectiveness of a new intervention must be tested against those of the best proven intervention(s), except in the following circumstances:
- Where no proven intervention exists, the use of placebo, or no intervention, is acceptable; or where for compelling and scientifically sound methodological reasons the use of any intervention less effective than the best proven one, the use of placebo, or no intervention is necessary to determine the efficacy or safety of an intervention and the patients who receive any intervention less effective than the best proven one, placebo, or no intervention will not be subject to additional risks of serious or irreversible harm as a result of not receiving the best proven intervention.
- Extreme care must be taken to avoid abuse of this option.

POST-TRIAL PROVISIONS

34. In advance of a clinical trial, sponsors, researchers, and host country governments should make provisions for post-trial access for all participants who still need an intervention identified as beneficial in the trial. This information must also be disclosed to participants during the informed consent process.

RESEARCH REGISTRATION AND PUBLICATION AND DISSEMINATION OF RESULTS

35. Every research study involving human subjects must be registered in a publicly accessible database before

recruitment of the first subject.

36. Researchers, authors, sponsors, editors, and publishers all have ethical obligations with regard to the publication and dissemination of the results of research. Researchers have a duty to make publicly available the results of their research on human subjects and are accountable for the completeness and accuracy of their reports. All parties should adhere to accepted guidelines for ethical reporting. Negative and inconclusive as well as positive results must be published or otherwise made publicly available. Sources of funding, institutional affiliations, and conflicts of interest must be declared in the publication. Reports of research not in accordance with the principles of this Declaration should not be accepted for publication.

UNPROVEN INTERVENTIONS IN CLINICAL PRACTICE

37. In the treatment of an individual patient, where proven interventions do not exist or other known interventions have been ineffective, the physician, after seeking expert advice, with informed consent from the patient or a legally authorized representative, may use an unproven intervention if in the physician's judgment it offers hope of saving life, reestablishing health, or alleviating suffering. This intervention should subsequently be made the object of research, designed to evaluate its safety and efficacy. In all cases, new information must be recorded and, where appropriate, made publicly available. ■

Code of ETHICS for DENTAL RESEARCHERS

The International Association for Dental Research, in 2009, adopted a code of ethics. The code applies to members of the association and is enforceable by sanction, with the stated requirement that members are expected to inform the association in cases where they believe misconduct has occurred.

The IADR code goes beyond the Belmont and Helsinki statements by virtue of covering animal research. It also addresses issues of sponsorship of research and conflicts of interest, international collaborative research, duty of researchers to be informed about applicable norms, standards of publication (including plagiarism), and the obligation of “whistleblowing” for the sake of maintaining the integrity of the dental research enterprise as a whole.

The code is organized, like the ADA code, into two sections. The IADR principles are stated, but not defined, and number 12, instead of the ADA’s five. The second section consists of “best practices,” which are specific statements of expected or interdicted activities. The short list of definitions is useful.

International Association for Dental Research

The purpose of the Code of Ethics is to provide a set of guiding principles to promote exemplary ethical standards in research and scholarship by investigators and the International Association for Dental Research (IADR).

The Code of Ethics is predicated on well-established international guidelines, such as the Declaration of Helsinki, and does not take the place of or supersede any rules, agreements, or Bylaws of the Association.

The IADR expects its members to be guided in their professional conduct by this Code.

The IADR, through its Committee on Ethics in Dental Research, advises its members regarding interpretation of the Code.

The ability of the scientific community to regulate itself is critical to the maintenance of the public trust. Adherence to the Code is basic to one’s professional responsibility and commitment to an ethical pursuit of knowledge.

Members are expected to cooperate in the implementation of the Code. Misconduct casts doubt on the integrity of individuals and their institutions. It is incumbent upon IADR members to take adequate measures to discourage, prevent, expose, and correct unethical conduct. Members deemed to be in violation of the Code will be sanctioned by the Association.

STATEMENT of Principles

All members of the IADR shall:

1. Act with **honor** and in accordance with the highest standards of professional integrity.
2. Conduct work with **objectivity**.
3. Communicate in an **honest** and **responsible** manner.
4. Show **consideration** and **respect** for all components of and individuals associated with the research process.
5. Cultivate an environment whereby differences in perspective, experience, and culture are **recognized** and **valued**.
6. Maintain appropriate standards of accuracy, reliability, credit, candor, and **confidentiality** in all research and scholarship activities.
7. Use all resources **prudently**, taking into account appropriate laws and regulations.

BEST PRACTICE IN RESEARCH AND SCHOLARSHIP

The prevention of misconduct in research is best achieved through the education of all individuals involved in research. It is a recommendation that all researchers should participate in appropriate educational activities, which is mandatory in some institutions. Of critical importance is maintaining up to date knowledge of best practices and the mentoring of colleagues and students.

The appearance of a conflict of interest, such as the potential for financial and personal gain, can often be as damaging as an actual act of conflict of interest. Full disclosure of any potential conflict of interest must be made to the investigator's institution or to the Associations as applicable.

HUMAN RESEARCH

The Declaration of Helsinki is a statement of ethical principles for research involving human participants, including research on identifiable human material and data, which is subject to ethical standards that promote respect for all human participants and protect their health and rights (www.wma.net/en/30publications/10policies/b3/).

Research must adhere to the fundamental principles that respect the needs for autonomy, beneficence, and justice, as well as veracity, fidelity, anonymity, and nonmaleficence. Human participant research comprises, but is not limited to, investigative clinical research, clinical trials, studies using tissue samples and records. Biogenetics, using stem cells and utilizing tissue banks requires complete transparency in all aspects of consenting and confidentiality. It is imperative that investigators remain up to date as these areas are more likely to be subject to legislative change.

ANIMAL RESEARCH

By definition, animal research committees provide and approve the informed consent by proxy. An investigator using animals in research should strive to advance understanding of basic principles and/or to contribute to the improvement of human or animal health and welfare. Laws and regulations notwithstanding, an animal's overall protection depends upon the scientist's appropriate stewardship.

Every effort must be made: (a) to replace the use of live animals by non-

animal alternatives; (b) to reduce the number of animals used in research to the minimum required for meaningful results; and (c) to refine the procedures so that the degree of suffering is kept to a minimum (<http://royalsociety.org/landing.asp?id=1222>).

INTERNATIONAL COLLABORATIVE RESEARCH

It is incumbent on all participating investigators and their colleagues to conduct any research to the highest standards of ethical practice, with due consideration of any local legislation and regulations. Ethical committee approval must be obtained for all sites and written informed consent provided by study participants in the language of each participating site.

Where the population may be vulnerable to exploitation it is important to respect their human rights and ensure that the research has relevance and potential benefit to their well-being (Shapiro & Meslin, 2001).

CONFLICTS OF INTEREST

Each individual is expected to behave in an ethical way to avoid conflict in terms of decision making, publication of data, and post-study investigator responsibility. The appearance of a conflict of interest, such as the potential for financial and personal gain, can often be as damaging as an actual act of conflict of interest. Full disclosure of any potential conflict of interest must be made to the investigator's institution or to the Associations as applicable (www.charitycommission.gov.uk/Charity_requirements_guidance/Charity_governance/Good_governance/conflicts.aspx).

The intellectual property rights of all participating researchers should be protected by giving proper credit for

the origin of the new ideas. Intellectual property rights apply to any potential commercial gain and must be agreed at the outset of the project by the investigators, their institutions, and/or any other external body, such as a sponsoring company.

DISSEMINATION OF INFORMATION

Most scientific journals ask authors to make declarations at submission about the integrity of their research. Many journals have experienced plagiarism (Smith, 2008), so that editors of journals need to develop policies to minimize the publication of articles containing evidence of scientific misconduct.

It is expected that authors, in any communication, such as manuscripts or abstracts, whether in paper or electronic format, representing a body of research should:

- Not inappropriately fragment data into several different publications;
- Credit sources of funding;
- Adhere to predetermined guidelines regarding qualification and order of authorship;
- Read the final manuscript and agree to its submission for review and publication.
- Emphasis should be on quality rather than quantity of research as a criterion for recognition of scholarship.
- Appropriate written permission must be obtained to publish any type of image, which should not identify the participant.

REPORTING MISCONDUCT AND SANCTIONS

The IADR reserves the right to sanction members for scientific misconduct. In the event of any observed or perceived episodes of research misconduct, it is a professional obligation to inform the appropriate authority. IADR membership

may be suspended or terminated “for proven scientific misconduct” (IADR Constitution, Article VI, Section 3(B), 1992). Any reporting on violations of the Code of Ethics will be kept confidential by the administrators and staff of the IADR, and by the Editors of IADR’s publications, except as otherwise provided in this document. Sanctions will not be implemented without prior approval of the IADR Board of Directors.

All officers*, administrators, and staff of the IADR shall:

1. **Respect** the rights and reputation of the IADR and the privacy of the membership;
2. Hold Association information in **confidence**;
3. Communicate in an **honest** and **responsible** manner regarding sponsorship or certification by the IADR;
4. Not solicit or use recommendations or testimonials from agents nor use their relationships with agents to promote commercial expertise of any kind;
5. Seek approval of the appropriate authority of IADR to communicate advertisement to the public by written or audiovisual means; and
6. State **accurately, objectively**, and without misrepresentation their professional qualifications, affiliations, and functions as well as those of the IADR with which they or their statements are associated. They shall correct the misrepresentations of others with respect to those matters.

DEFINITIONS

- a. **Conflict of interest** is any situation in which personal interest or interests which an individual owes

to another body and those of the organization arise simultaneously or appear to clash.

- b. **Error**: The inadvertent or unrecognized omission of a result or experimental detail or the misinterpretation of data. (A clear distinction must be made between error and fraud. The former can be tolerated, but once recognized must be corrected. The latter cannot be condoned under any circumstances.)
- c. **Fraud** indicates deliberate fabrication, falsification, or omission of data. It constitutes deception and therefore undermines the scientific enterprise from every aspect.
- d. **Plagiarism** is the representation of another’s work in any form as one’s own without appropriate acknowledgment.
- e. **Misconduct** is the fabrication, falsification, plagiarism, or other serious deviation from accepted practices in proposing, carrying out, or reporting results from research. It is the failure to comply with international, national, local, and institutional requirements for the protection of researchers, human participants and the public and also to ensure the welfare of laboratory

* *Officers of IADR include individuals with responsibility from headquarters, federations, divisions, sections, and groups.*

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animals. It is also the failure to meet other legal requirements governing research.

Examples of misconduct:

1. Submission of the same article simultaneously to more than one journal without informing the editors concerned;
 2. A lack of consent by co-authors (co-authorship of an article indicates that all individuals who have genuinely participated in research, in either a conceptual or practical sense, have full knowledge of, and are in total agreement with, the content of the article);
 3. A lack of acknowledgments of financial support; and
 4. Premature release of scientific data prior to presentation or publication in a peer-reviewed forum.
- f. **“Whistleblowing”** is the disclosure by an individual of confidential information, which relates to some fraud, danger, or other illegal or unethical conduct connected with research. A “whistleblower” is a person who alleges misconduct. Whistleblowing may be seen as a means to deter wrongdoing, promote transparency and good governance, underpin regulation, and maintain professional and public confidence. ■

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UNIFORM REQUIREMENTS FOR MANUSCRIPTS SUBMITTED TO BIOMEDICAL JOURNALS (EXCERPTS)

The Vancouver Convention is renowned among editors who publish dental and related research. It is the standard for what content goes in the Methods section, how tables and figures are to be laid out, and how references are to be cited, among many other particulars. Almost no biomedical research journals follow the Vancouver Convention in every detail; virtually all come very close.

In addition to the mechanics of manuscript submission and formatting for publication, the Vancouver Convention is looked to as the standard for the ethics of publication. Common practice is defined for who counts as an author to what constitutes an acceptable republication. Very clear language is included regarding conformity with the Belmont Report or Helsinki Declaration and other requirements for ethical treatment of subjects. Conflicts of interest, confusion of advertising with research, relations with the popular press, and sponsorship of supplements are addressed.

The Vancouver Convention makes a special point of emphasizing the responsibility of journal editors as having the final check in the chain of research ethics that begins with scientists pursuing a line of inquiry and ends when the results are reported. The *Journal of the American College of Dentists* endorses and honors the Vancouver Convention. In 2000, the Board of Regents of the American College of Dentists and the officers of the American Association of Dental Editors approved a joint Code of Ethics for Dental Editors. The code is based on the Vancouver Convention, but also addresses journal content beyond reports of research findings. The joint ACD-AADE code can be accessed at <http://acd.org/codefordentaleditors.htm>.

International Committee of Medical Journal Editors

A small group of editors of general medical journals met informally in Vancouver, British Columbia, in 1978 to establish guidelines for the format of manuscripts submitted to their journals. The group became known as the Vancouver Group. Its requirements for manuscripts, including formats for bibliographic references developed by the National Library of Medicine, were first published in 1979. The Vancouver Group expanded and evolved into the International Committee of Medical Journal Editors (ICMJE), which meets annually; gradually it has broadened its concerns.

The committee has produced five editions of the Uniform Requirements for Manuscripts Submitted to Biomedical Journals. Over the years, issues have arisen that go beyond manuscript preparation. Some of these issues are now covered in the Uniform Requirements; others are addressed in separate statements. Each statement has been published in a scientific journal.

The fifth edition (1997) is an effort to reorganize and reword the fourth edition to increase clarity and address concerns about rights, privacy, descriptions of methods, and other matters. The total content of Uniform Requirements for Manuscripts Submitted to Biomedical Journals may be reproduced for educational, not-for-profit purposes without regard for copyright; the committee encourages distribution of the material.

Journals that agree to use the Uniform Requirements (over 500 do so) are asked to cite the 1997 document in their instructions to authors.

It is important to emphasize what these requirements do and do not imply.

First, the Uniform Requirements are instructions to authors on how to prepare manuscripts, not to editors on publication style. (But many journals have drawn on them for elements of their publication styles.)

Second, if authors prepare their manuscripts in the style specified in these requirements, editors of the participating journals will not return the manuscripts for changes in style before considering them for publication. In the publishing process, however, the journals may alter accepted manuscripts to conform with details of their publication style.

Third, authors sending manuscripts to a participating journal should not try to prepare them in accordance with the publication style of that journal but should follow the Uniform Requirements.

Authors must also follow the instructions to authors in the journal as to what topics are suitable for that journal and the types of papers that may be submitted—for example, original articles, reviews, or case reports. In addition, the journal's instructions are likely to contain other requirements

unique to that journal, such as the number of copies of a manuscript that are required, acceptable languages, length of articles, and approved abbreviations.

Participating journals are expected to state in their instructions to authors that their requirements are in accordance with the Uniform Requirements for Manuscripts Submitted to Biomedical Journals and to cite a published version.

ISSUES TO CONSIDER BEFORE SUBMITTING A MANUSCRIPT

REDUNDANT OR DUPLICATE PUBLICATION

Readers of primary source periodicals deserve to be able to trust that what they are reading is original unless there is a clear statement that the article is being republished by the choice of the author and editor. The bases of this position are international copyright laws, ethical conduct, and cost-effective use of resources.

Most journals do not wish to receive papers on work that has already been reported in large part in a published article or is contained in another paper that has been submitted or accepted for publication elsewhere, in print or in electronic media. This policy does not preclude the journal considering a paper that has been rejected by another journal, or a complete report that follows publication of a preliminary report, such as an abstract or poster displayed for colleagues at a professional meeting. Nor does it prevent journals considering a paper that has been presented at a scientific meeting but not published in full or that is being

considered for publication in a proceedings or similar format. Press reports of scheduled meetings will not usually be regarded as breaches of this rule, but such reports should not be amplified by additional data or copies of tables and illustrations.

When submitting a paper, the author should always make a full statement to the editor about all submissions and previous reports that might be regarded as redundant or duplicate publication of the same or very similar work. The author should alert the editor if the work includes subjects about which a previous report has been published. Any such work should be referred to and referenced in the new paper. Copies of such material should be included with the submitted paper to help the editor decide how to handle the matter.

If redundant or duplicate publication is attempted or occurs without such notification, authors should expect editorial action to be taken. At the least, prompt rejection of the submitted manuscript should be expected. If the editor was not aware of the violations and the article has already been published, then a notice of redundant or duplicate publication will probably be published with or without the author's explanation or approval.

Preliminary release, usually to public media, of scientific information described in a paper that has been accepted but not yet published violates the policies of many journals. In a few cases, and only by arrangement with the editor, preliminary release of data may be acceptable—for example, if there is a public health emergency.

ACCEPTABLE SECONDARY PUBLICATION

Secondary publication in the same or another language, especially in other countries, is justifiable, and can be beneficial, provided all of the following conditions are met.

1. The authors have received approval from the editors of both journals; the editor concerned with secondary publication must have a photocopy, reprint, or manuscript of the primary version.
2. The priority of the primary publication is respected by a publication interval of at least one week (unless specifically negotiated otherwise by both editors).
3. The paper for secondary publication is intended for a different group of readers; an abbreviated version could be sufficient.
4. The secondary version faithfully reflects the data and interpretations of the primary version.
5. The footnote on the title page of the secondary version informs readers, peers, and documenting agencies that the paper has been published in whole or in part and states the primary reference. A suitable footnote might read: "This article is based on a study first reported in the [title of journal, with full reference]." Permission for such secondary publication should be free of charge.

PROTECTION OF PATIENTS' RIGHTS TO PRIVACY

Patients have a right to privacy that should not be infringed without informed consent. Identifying information should not be published in written descriptions, photographs, and pedigrees unless the information is essential for scientific purposes and the patient (or parent or guardian) gives written informed consent for publication. Informed consent for this purpose requires that the patient be shown the manuscript to be published.

Identifying details should be omitted if they are not essential, but patient data should never be altered or falsified in an

attempt to attain anonymity. Complete anonymity is difficult to achieve, and informed consent should be obtained if there is any doubt. For example, masking the eye region in photographs of patients is inadequate protection of anonymity.

The requirement for informed consent should be included in the journal's instructions for authors. When informed consent has been obtained it should be indicated in the published article.

REQUIREMENTS FOR SUBMISSION OF MANUSCRIPTS

[Items other than the sections on authorship, ethics, and statistics have been omitted.]

AUTHORSHIP

All persons designated as authors should qualify for authorship. Each author should have participated sufficiently in the work to take public responsibility for the content.

Authorship credit should be based only on substantial contributions to (a) conception and design or analysis and interpretation of data; and to (b) drafting the article or revising it critically for important intellectual content; and on (c) final approval of the version to be published. Conditions (a), (b), and (c) must all be met. Participation solely in the acquisition of funding or the collection of data does not justify authorship. General supervision of the research group is not sufficient for authorship. Any part of an article critical to its main conclusions must be the responsibility of at least one author.

Editors may ask authors to describe what each contributed; this information may be published.

Increasingly, multicenter trials are attributed to a corporate author. All members of the group who are named as authors, either in the authorship position below the title or in a footnote,

should fully meet the above criteria for authorship. Group members who do not meet these criteria should be listed, with their permission, in the acknowledgments or in an appendix.

The order of authorship should be a joint decision of the coauthors. Because the order is assigned in different ways, its meaning cannot be inferred accurately unless it is stated by the authors. Authors may wish to explain the order of authorship in a footnote. In deciding on the order, authors should be aware that many journals limit the number of authors listed in the table of contents and that the U.S. National Library of Medicine (NLM) lists in MEDLINE only the first 24 plus the last author when there are more than 25 authors.

ETHICS

When reporting experiments on human subjects, indicate whether the procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional or regional) and with the Helsinki Declaration of 1975, as revised in 1983. Do not use patients' names, initials, or hospital numbers, especially in illustrative material. When reporting experiments on animals, indicate whether the institution's or a national research council's guide for, or any national law on, the care and use of laboratory animals was followed.

STATISTICS

Describe statistical methods with enough detail to enable a knowledgeable reader with access to the original data to verify the reported results. When possible, quantify findings and present

If redundant or duplicate publication is attempted or occurs without such notification, authors should expect editorial action to be taken. At the least, prompt rejection of the submitted manuscript should be expected.

Editors must have full authority for determining the editorial content of the journal. This concept of editorial freedom should be resolutely defended by editors even to the extent of their placing their positions at stake. To secure this freedom in practice, the editor should have direct access to the highest level of ownership, not only to a delegated manager.

them with appropriate indicators of measurement error or uncertainty (such as confidence intervals). Avoid relying solely on statistical hypothesis testing, such as the use of P values, which fails to convey important quantitative information. Discuss the eligibility of experimental subjects. Give details about randomization. Describe the methods for and success of any blinding of observations. Report complications of treatment. Give numbers of observations. Report losses to observation (such as dropouts from a clinical trial). References for the design of the study and statistical methods should be to standard works when possible (with pages stated) rather than to papers in which the designs or methods were originally reported. Specify any general-use computer programs used.

Put a general description of methods in the Methods section. When data are summarized in the Results section, specify the statistical methods used to analyze them. Restrict tables and figures to those needed to explain the argument of the paper and to assess its support. Use graphs as an alternative to tables with many entries; do not duplicate data in graphs and tables. Avoid non-technical uses of technical terms in statistics, such as “random” (which implies a randomizing device), “normal,” “significant,” “correlations,” and “sample.” Define statistical terms, abbreviations, and most symbols.

SEPARATE STATEMENTS

DEFINITION OF A PEER-REVIEWED JOURNAL

A peer-reviewed journal is one that has submitted most of its published articles

for review by experts who are not part of the editorial staff. The number and kind of manuscripts sent for review, the number of reviewers, the reviewing procedures, and the use made of the reviewers' opinions may vary, and therefore each journal should publicly disclose its policies in its instructions to authors for the benefit of readers and potential authors.

EDITORIAL FREEDOM AND INTEGRITY

Owners and editors of medical journals have a common endeavor—the publication of a reliable and readable journal, produced with due respect for the stated aims of the journal and for costs. The functions of owners and editors, however, are different. Owners have the right to appoint and dismiss editors and to make important business decisions in which editors should be involved to the fullest extent possible. Editors must have full authority for determining the editorial content of the journal. This concept of editorial freedom should be resolutely defended by editors even to the extent of their placing their positions at stake. To secure this freedom in practice, the editor should have direct access to the highest level of ownership, not only to a delegated manager.

Editors of medical journals should have a contract that clearly states the editor's rights and duties in addition to the general terms of the appointment and that defines mechanisms for resolving conflict.

An independent editorial advisory board may be useful in helping the editor establish and maintain editorial policy.

All editors and editors' organizations have the obligation to support the concept of editorial freedom and to draw major transgressions of such freedom to the attention of the international medical community.

CONFLICT OF INTEREST

Conflict of interest for a given manuscript exists when a participant in the peer review and publication process—author, reviewer, and editor—has ties to activities that could inappropriately influence his or her judgment, whether or not judgment is in fact affected. Financial relationships with industry (for example, through employment, consultancies, stock ownership, honoraria, expert testimony), either directly or through immediate family, are usually considered to be the most important conflicts of interest. However, conflicts can occur for other reasons, such as personal relationships, academic competition, and intellectual passion.

Public trust in the peer review process and the credibility of published articles depend in part on how well conflict of interest is handled during writing, peer review, and editorial decision making. Bias can often be identified and eliminated by careful attention to the scientific methods and conclusions of the work. Financial relationships and their effects are less easily detected than other conflicts of interest. Participants in peer review and publication should disclose their conflicting interests, and the information should be made available so that others can judge their effects for themselves. Because readers may be less able to detect bias in review articles and editorials than in reports of original research, some journals do not accept reviews and editorials from authors with a conflict of interest.

Authors: When they submit a manuscript, whether an article or a letter, authors are responsible for recognizing and disclosing financial and other conflicts of interest that might bias their work. They should acknowledge in

the manuscript all financial support for the work and other financial or personal connections to the work.

Reviewers: External peer reviewers should disclose to editors any conflicts of interest that could bias their opinions of the manuscript, and they should disqualify themselves from reviewing specific manuscripts if they believe it to be appropriate. The editors must be made aware of reviewers' conflicts of interest to interpret the reviews and judge for themselves whether the reviewer should be disqualified. Reviewers should not use knowledge of the work, before its publication, to further their own interests.

Editors and Staff: Editors who make final decisions about manuscripts should have no personal financial involvement in any of the issues they might judge. Other members of the editorial staff, if they participate in editorial decisions, should provide editors with a current description of their financial interests (as they might relate to editorial judgments) and disqualify themselves from any decisions where they have a conflict of interest. Published articles and letters should include a description of all financial support and any conflict of interest that, in the editors' judgment, readers should know about. Editorial staff should not use the information gained through working with manuscripts for private gain.

CORRECTIONS, RETRACTIONS, AND "EXPRESSIONS OF CONCERN" ABOUT RESEARCH FINDINGS

Editors must assume initially that authors are reporting work based on honest observations. Nevertheless, two types of difficulty may arise.

First, errors may be noted in published articles that require the publication of a correction or erratum of part of the work. It is conceivable that an error could be so serious as to vitiate the entire body of the work, but this is

unlikely and should be handled by editors and authors on an individual basis. Such an error should not be confused with inadequacies exposed by the emergence of new scientific information in the normal course of research. The latter require no corrections or withdrawals.

The second type of difficulty is scientific fraud. If substantial doubts arise about the honesty of work, either submitted or published, it is the editor's responsibility to ensure that the question is appropriately pursued (including possible consultation with the authors). However, it is not the task of editors to conduct a full investigation or to make a determination; that responsibility lies with the institution where the work was done or with the funding agency. The editor should be promptly informed of the final decision, and if a fraudulent paper has been published, the journal must print a retraction. If this method of investigation does not result in a satisfactory conclusion, the editor may choose to publish an expression of concern with an explanation.

The retraction or expression of concern, so labeled, should appear on a numbered page in a prominent section of the journal, be listed in the contents page, and include in its heading the title of the original article. It should not simply be a letter to the editor. Ideally, the first author should be the same in the retraction as in the article, although under certain circumstances the editor may accept retractions by other responsible people. The text of the retraction should explain why the article is being retracted and include a bibliographic reference to it.

The validity of previous work by the author of a fraudulent paper cannot be

assumed. Editors may ask the author's institution to assure them of the validity of earlier work published in their journals or to retract it. If this is not done, they may choose to publish an announcement to the effect that the validity of previously published work is not assured.

CONFIDENTIALITY

Manuscripts should be reviewed with due respect for authors' confidentiality. In submitting their manuscripts for review, authors entrust editors with the results of their scientific work and creative effort, on which their reputation and career may depend. Authors' rights may be violated by disclosure of the confidential details of the review of their manuscript. Reviewers also have rights to confidentiality, which must be respected by the editor. Confidentiality may have to be breached if dishonesty or fraud is alleged but otherwise must be honored.

Editors should not disclose information about manuscripts (including their receipt, their content, their status in the reviewing process, their criticism by reviewers, or their ultimate fate) to anyone other than the authors themselves and reviewers.

Editors should make clear to their reviewers that manuscripts sent for review are privileged communications and are the private property of the authors. Therefore, reviewers and members of the editorial staff should respect the authors' rights by not publicly discussing the authors' work or appropriating their ideas before the manuscript is published. Reviewers should not be allowed to make copies of

the manuscript for their files and should be prohibited from sharing it with others, except with the permission of the editor. Editors should not keep copies of rejected manuscripts.

Opinions differ on whether reviewers should remain anonymous. Some editors require their reviewers to sign the comments returned to authors, but most either request that reviewers' comments not be signed or leave the choice to the reviewer. When comments are not signed the reviewers' identity must not be revealed to the author or anyone else.

Some journals publish reviewers' comments with the manuscript. No such procedure should be adopted without the consent of the authors and reviewers. However, reviewers' comments may be sent to other reviewers of the same manuscript, and reviewers may be notified of the editor's decision.

MEDICAL JOURNALS AND THE POPULAR MEDIA

The public's interest in news of medical research has led the popular media to compete vigorously to get information about research as soon as possible. Researchers and institutions sometimes encourage the reporting of research in the popular media before full publication in a scientific journal by holding a press conference or giving interviews.

The public is entitled to important medical information without unreasonable delay, and editors have a responsibility to play their part in this process. Doctors, however, need to have reports available in full detail before they can advise their patients about the reports' conclusions. In addition, media reports of scientific research before the work has been peer reviewed and fully published may lead to the dissemination of inaccurate or premature conclusions.

Editors may find the following recommendations useful as they seek to establish policies on these issues.

1. Editors can foster the orderly transmission of medical information from researchers, through peer reviewed journals, to the public. This can be accomplished by an agreement with authors that they will not publicize their work while their manuscript is under consideration or awaiting publication and an agreement with the media that they will not release stories before publication in the journal, in return for which the journal will cooperate with them in preparing accurate stories (see below).
2. Very little medical research has such clear and urgently important clinical implications for the public's health that the news must be released before full publication in a journal. In such exceptional circumstances, however, appropriate authorities responsible for public health should make the decision and should be responsible for the advance dissemination of information to physicians and the media. If the author and the appropriate authorities wish to have a manuscript considered by a particular journal, the editor should be consulted before any public release. If editors accept the need for immediate release, they should waive their policies limiting prepublication publicity.
3. Policies designed to limit prepublication publicity should not apply to accounts in the media of presentations at scientific meetings or to the abstracts from these meetings (see Redundant or Duplicate Publication). Researchers who present their work at a scientific meeting should feel free to discuss their presentations with reporters, but they should be discouraged from offering more

detail about their study than was presented in their talk.

4. When an article is soon to be published, editors may wish to help the media prepare accurate reports by providing news releases, answering questions, supplying advance copies of the journal, or referring reporters to the appropriate experts. This assistance should be contingent on the media's cooperation in timing their release of stories to coincide with the publication of the article.

ADVERTISING

Most medical journals carry advertising, which generates income for their publishers, but advertising must not be allowed to influence editorial decisions. Editors must have full responsibility for advertising policy. Readers should be able to distinguish readily between advertising and editorial material. The juxtaposition of editorial and advertising material on the same products or subjects should be avoided, and advertising should not be sold on the condition that it will appear in the same issue as a particular article.

Journals should not be dominated by advertising, but editors should be careful about publishing advertisements from only one or two advertisers as readers may perceive that the editor has been influenced by these advertisers.

Journals should not carry advertisements for products that have proved to be seriously harmful to health – for example, tobacco. Editors should ensure that existing standards for advertisements are enforced or develop their own standards. Finally, editors should consider all criticisms of advertisements for publication.

SUPPLEMENTS

Supplements are collections of papers that deal with related issues or topics, are published as a separate issue of the journal or as a second part of a regular issue, and are usually funded by sources other than the journal's publisher.

Supplements can serve useful purposes: education, exchange of research information, ease of access to focused content, and improved cooperation between academic and corporate entities. Because of the funding sources, the content of supplements can reflect biases in choice of topics and viewpoints. Editors should therefore consider the following principles.

1. The journal editor must take full responsibility for the policies, practices, and content of supplements. The journal editor must approve the appointment of any editor of the supplement and retain the authority to reject papers.
2. The sources of funding for the research, meeting, and publication should be clearly stated and prominently located in the supplement, preferably on each page. Whenever possible, funding should come from more than one sponsor.
3. Advertising in supplements should follow the same policies as those of the rest of the journal.
4. Editors should enable readers to distinguish readily between ordinary editorial pages and supplement pages.
5. Editing by the funding organization should not be permitted.

Readers should be able to distinguish readily between advertising and editorial material. The juxtaposition of editorial and advertising material on the same products or subjects should be avoided, and advertising should not be sold on the condition that it will appear in the same issue as a particular article.

6. Journal editors and supplement editors should not accept personal favors or excessive compensation from sponsors of supplements.
7. Secondary publication in supplements should be clearly identified by the citation of the original paper. Redundant publication should be avoided.

THE ROLE OF THE CORRESPONDENCE COLUMN

All biomedical journals should have a section carrying comments, questions, or criticisms about articles they have published and where the original authors can respond. Usually, but not necessarily, this may take the form of a correspondence column. The lack of such a section denies readers the possibility of responding to articles in the same journal that published the original work.

COMPETING MANUSCRIPTS BASED ON THE SAME STUDY

Editors may receive manuscripts from different authors offering competing interpretations of the same study. They have to decide whether to review competing manuscripts submitted to them more or less simultaneously by different groups or authors, or they may be asked to consider one such manuscript while a competing manuscript has been or will be submitted to another journal. Setting aside the unresolved question of ownership of data, we discuss here what editors ought to do when confronted

with the submission of competing manuscripts based on the same study.

Two kinds of multiple submissions are considered: submissions by coworkers who disagree on the analysis and interpretation of their study, and submissions by coworkers who disagree on what the facts are and which data should be reported.

The following general observations may help editors and others dealing with this problem.

Differences in Analysis or Interpretation: Journals would not normally wish to publish separate articles by contending members of a research team who have differing analyses and interpretations of the data, and submission of such manuscripts should be discouraged. If coworkers cannot resolve their differences in interpretation before submitting a manuscript, they should consider submitting one manuscript containing multiple interpretations and calling their dispute to the attention of the editor so that reviewers can focus on the problem. One of the important functions of peer review is to evaluate the authors' analysis and interpretation and to suggest appropriate changes to the conclusions before publication. Alternatively, after the disputed version is published, editors may wish to consider a letter to the editor or a second manuscript from the dissenting authors. Multiple submissions present editors with a dilemma. Publication of contending manuscripts to air authors' disputes may waste journal space and confuse readers. On the other hand, if editors knowingly publish a manuscript written by only some of the collaborating team, they could be denying the rest of the team their legitimate coauthorship rights.

Differences in Reported Methods or Results: Workers sometimes differ in their opinions about what was

actually done or observed and which data ought to be reported. Peer review cannot be expected to resolve this problem. Editors should decline further consideration of such multiple submissions until the problem is settled. Furthermore, if there are allegations of dishonesty or fraud, editors should inform the appropriate authorities.

The cases described above should be distinguished from instances in which independent, noncollaborating authors submit separate manuscripts based on different analyses of data that are publicly available. In this circumstance, editorial consideration of multiple submissions may be justified, and there may even be a good reason for publishing more than one manuscript because different analytical approaches may be complementary and equally valid. ■

Members of the International Committee of Medical Journal Editors:

Linda Hawes Clever, *Western Journal of Medicine*

Lois Ann Colaiani, U.S. National Library of Medicine

Frank Davidoff, *Annals of Internal Medicine*

Richard Glass, *Journal of the American Medical Association*

Richard Horton, *The Lancet*

George Lundberg, *Journal of the American Medical Association*

Magne Nylenna, *Tidsskrift for Den Norske Lægeforening*

Richard G. Robinson, *New Zealand Medical Journal*

Richard Smith, *British Medical Journal*

Bruce P. Squires, *Canadian Medical Association Journal*

Robert Utiger, *The New England Journal of Medicine*

Martin VanDer Weyden, *The Medical Journal of Australia*

Patricia Woolf, Princeton University

THE ETHICS OF EXPERIMENTING IN DENTAL PRACTICE

There is a common misconception that scientists conduct research in their labs or clinics and practitioners do not experiment, but only use the best results reported in the literature. This confusion comes about because dentists are not trained in, nor do they normally observe, the formal requirements of research protocol or ethics. It is generally believed that the norms that apply to clinical practice also cover all situations where dentists innovate in their treatment protocols with a view toward discovering more effective ways to treat patients or where they modify a standard protocol in hopes of better serving the needs of an atypical patient.

In this 2002 paper from the *Dental Clinics of North America* (Volume 46, Number 1, pp. 29-44), David W. Chambers challenges the concept that useful general knowledge is created only outside dental practice and then transferred into the office. But if it is the case that practitioners experiment, even to the limited extent of customizing materials and methods to their own needs or the particular circumstances of patients, there are ethical considerations. All modifications are not equally justifiable, the patient should be involved in “partially tested” approaches in a different way from the routine, and there needs to be sound reason to believe the innovation will not fall below the standard of care.

Experimental practice has the characteristics of high probability of success, structured observation, realistic settings, and careful documentation. Heroic measures can only be undertaken when available options have failed and with full consent of the patient. A two-part ethical test is proposed for experimenting in practice: (a) If the dentist believes members of the community (patients, colleagues, or society generally) would be offended or outraged by an action, provided that they became aware of the relevant details – to not do it! (b) If the dentist believes members of the community would be concerned by an action, provided they became aware of the relevant details – discuss it with them.

There is also an ethics of evaluating and adopting the research literature to one’s office. Some of the requirements in this area include maintaining a current and critical familiarity with developments, understanding the difference between the internal validity of studies in the context where they were conducted and the likely adaptations or cautions needed when customizing the literature to individual practices, and knowing the proper weights to give to the literature and one’s own clinical experience.

David W. Chambers, EdM, MBA,
PhD, FACD

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 (Chambers, 2000a). 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.

An ethical situation exists whenever members of the community are compromised in their potentials.

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.

A DISCURSIVE APPROACH TO ETHICS

The discursive approach to ethics builds on the traditional methods presented previously (Chambers, 1996). 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 (Chambers & Abrams, 1986). 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 (Chambers, 2000b). 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:

1. 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!
2. 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 (Chambers & Eng, 1994). 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*, however, Donald Schön (1983) 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 (American College of Dentists, 1998).

An experiment is any planned and purposeful action where the results can be observed and the outcomes contain risk. The table on p. 37 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 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 appropriate 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 in the bicyclist's skill as in 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:

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."

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.

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: (a) it forces the dentist to think through what is being done in a rigorous fashion; (b) it offers some legal

protection; and (c) 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 outcome 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

TAXONOMY of EXPERIMENTS

<i>Type</i>	<i>Characteristics</i>
Scientific investigation	Extreme uncertainty regarding outcomes, rigorous control, nonpractice context, purpose to discover general principles, results in publication
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

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 research (International Association for Dental Research, 1996). 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 (Callahan et al., 1998). 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: (a) internal versus external validity, (b) generalizability, and (c) 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 (Brunette, 1996). 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, 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 that the application is biased. An appropriate analogy is shipping cookies across country: sometimes they arrive only 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

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 that the application is biased.

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 (Chambers, 1999). 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. ■

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PATIENTS WHO MAKE TERRIBLE THERAPEUTIC CHOICES

Howard J. Curzer, PhD

ABSTRACT

The traditional approaches to dental ethics include appeals to principles, duties (deontology), and consequences (utilitarianism). These approaches are often inadequate when faced with the case of a patient who refuses reasonable treatment and does not share the same ethical framework the dentist is using. An approach based on virtue ethics may be helpful in this and other cases. Virtue ethics is a tradition going back to Plato and Aristotle. It depends on forming a holistic character supporting general appropriate behavior. By correctly diagnosing the real issues at stake in a patient's inappropriate oral health choices and working to build effective habits, dentists can sometimes respond to ethical challenges that remain intractable given rule-based methods.

Patients who resolutely stick to terrible therapeutic choices present a common problem requiring not only diagnostic, therapeutic, and management skills, but also people skills. A moral theory focused on people rather than impersonal rules would help. Consider the following terrible-choice situation.

Ms. Take's dentist, Dr. Phronesis, recommends a certain treatment. Call it option A. Option A involves some significant discomfort and cost in the short term, but it will almost certainly prevent more pain, higher costs, and significant degeneration later. Ms. Take refuses option A in favor of option B which is much less painful and costly in the short term, but also much less effective. (Option B might be to do nothing; no treatment at all.)

Dr. Phronesis is appalled. Option B is not merely a suboptimal choice; it is an unreasonable choice. When Dr. Phronesis asks Ms. Take why she chooses B, Ms. Take exhibits confusion about what she thinks is the case and the balance of risks, says that her cousin told her that option B is a sure thing, and avers that she can't afford option A. Dr. Phronesis corrects the information about risk factors, counters the cousin's claim, and offers a payment plan. But nothing Dr. Phronesis says makes any difference. Ms. Take resolutely rejects option A, and remains committed to option B.

Why does Ms. Take choose option B rather than option A? What should Dr. Phronesis do about Ms. Take's choice? What should dentists as a group do to prevent such terrible choice situations? I shall show that the traditional answers fail, and then offer an explanation, a short-term strategy, and a long-term policy from the perspective of virtue ethics.

TRADITIONAL EXPLANATIONS, STRATEGIES, AND POLICIES

The traditional view of this terrible choice situation has three components.

- (a) Ms. Take's statements are her real reasons. They are accepted at face value.
- (b) Ms. Take has false beliefs and makes errors in reasoning.
- (c) Ms. Take's false beliefs and bad reasoning cause (or mostly explain) her terrible choice.

The traditional view of this situation holds Ms. Take to be making some sort of mistake. Her problem is fundamentally an intellectual problem.

If Dr. Phronesis embraces a Kantian deontologist view, her first thought will be to respect Ms. Take's choice of option B in order to avoid paternalism. Deontology says that Dr. Phronesis



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To improve yourself, pick role models, and imitate them. The idea is to train the whole person, not merely behavior, so imitate not just the choices and actions, but also the passions, desires, values, and perceptions of your role models.

should continue to provide information and clarify the implications of Ms. Take's treatment options in hopes of persuading her (Smith & Pettegrew, 1986). "If Ms. Take could just see..." "If Ms. Take could just understand..." This imperative is defeasible, but it is the default option. Dr. Phronesis would need a reason to do otherwise. For example, if Ms. Take's expressed choice is not her real choice, or if she is not competent to make a choice, then Dr. Phronesis would be free to try other strategies. But typically patients like Ms. Take are competently expressing their real choices.

If Dr. Phronesis is a consequentialist, after giving persuasion a reasonable chance, her first thought will be to trick or bully Ms. Take into accepting option A for her own good. Consequentialism says that Dr. Phronesis should give up on persuasion, and find some ruse or pressure tactic which would bypass Ms. Take's beliefs and reasoning, enabling Dr. Phronesis to do what is best (Swindell et al, 2010). "This won't hurt a bit..." "Sign the consent form OR ELSE..." This imperative is defeasible, but it is the default option. Dr. Phronesis would need a reason to do otherwise. For example, if harm to Ms. Take from the deception or intimidation would outweigh the benefits, or if harm to society as a whole from adopting such a policy would be great, then Dr. Phronesis would be free to try other strategies. But typically patients like Ms. Take are not harmed much by this sort of deception or intimidation, and society as a whole is safe as long as deception and intimidation are deployed rarely and subtly.

If Dr. Phronesis accepts Beauchamp and Childress's set of principles (or any other theory which strives to accommodate multiple, incommensurable values), this situation will look like a clash between the principles of benevolence and autonomy (Beauchamp & Childress,

2012). Since both principles have some plausibility, the situation presents a moral dilemma. The right choice might be to favor benevolent health outcomes (consequentialism), or respect the patient's autonomy (the deontologist's choice), or some combination. But whatever the right choice turns out to be, it will be an unpalatable choice. Dr. Phronesis will end up doing something with a sizeable downside.

Now sometimes the deontological or consequentialist strategy solves the problem; Ms. Take might eventually, happily switch to option A. But a striking fact is that these strategies often fail. The patients just keep on repeating their bankrupt rationales. Or they simply bounce from one flawed rationale to another. This presents an explanatory puzzle. After all, if the problem is misinformation or fallacious reasoning, then correcting the information through persuasion or deception, or bypassing the intellect through intimidation ought to correct the patient's decisions. Why do these strategies work so rarely? Their low success rate suggests that something is wrong with the traditional view of terrible choice situations.

The failure of these strategies also presents an immediate, practical, problem. What else could Dr. Phronesis do in this situation? Dismissing the patient at this point might be tempting, but it would be an inappropriate abdication of responsibility if a reasonable further effort has a good chance of persuading Ms. Take to make a better choice. Yet if neither information nor disinformation nor intimidation work, what is left?

The traditional view presents a parallel, long-term, public policy problem. What can be done to reduce the number of patients who make terrible decisions? Long-term versions of the deontological and consequentialist strategies would be public education, public deception, or public intimidation campaigns. But

again we encounter similar failures. Such campaigns are not very effective. Information bounces off of the public; deceptions are soon exposed; pressure is resisted. What is the alternative?

ENTER VIRTUE ETHICS

When it comes to moral theories, virtue ethics is the old new kid on the block. Virtue ethics is a recently updated version of moral theories promulgated long ago by Plato, Aristotle, and their followers in the West, and Confucius, Mencius, and their followers in the East. I shall briefly describe a bit of the theory, and then apply it to Ms. Take's case.

Virtue ethics maintains that what makes acts right is not that they conform to a rule to maximize good consequences, or a different rule to respect duties, or some combination of these, or some third system. Instead, virtue ethics begins with a description of the psychology of good people. Academics quarrel and quibble about the details and borderline cases, but we all know more or less who the good people are, what character traits make them admirable, and how they approach moral problems. They are the people we call courageous, temperate, honest, etc. Virtue ethics specifies which actions are right in terms of these good people. Right actions are those acts typically performed by these good people. The focus and foundation of virtue ethics is character.

However, virtue ethics is not focused solely, or even primarily, on action. It concerns the whole character. Thus, virtue ethics encourages agents to broaden their focus. Do not just ask yourself what your role model would do; instead, ask more generally how your role model would approach the problem you currently face?

The reason for asking this broad question is that virtue ethics takes a

rather holistic picture of moral decision-making. Decisions flow from a person's whole character. Character consists of integrated packages of dispositions. Not just habits of thought, but also habits of choice, action, passion, desire, perception, and beliefs (particularly values). Each item has major effects on the others. For example, when you perceive something that looks like a threat (e.g., footsteps coming closer in a dark alley) you feel fear. Less obviously, when you feel fear, the fear changes what you perceive. Emotions are salience-projectors and transformers; they foreground some things, background other things, and relabel everything. Doorways jump out at you and become "hiding places"; well-lit areas become "refuges of safety"; large sticks become "potential weapons"; and so on. There are long-term interactions as well. One flawed aspect of character will tend to erode others aspects. If you are a generally fearful person, you will tend to adopt false beliefs to rationalize your fear. Conversely, if you believe that various things are more dangerous than they actually are, you will tend to become a generally fearful person (Cushman, Young, & Greene, 2010).

Everyone wants to know how to improve themselves, raise good children, uplift their students, and rehabilitate criminals. In contrast to the moral reasoning approach which generally flows from deontology and the moral conditioning approach which generally flows from consequentialism, virtue ethics recommends guided habituation with buy-in from the subject. To improve yourself, pick role models, and imitate them. The idea is to train the whole person, not merely behavior, so imitate not just the choices and actions, but also the passions, desires, values, and perceptions of your role models. To improve others, explain the strategy and then offer aid and encouragement while they change themselves.

People can clearly change their habits of thought and action, but can they really change their habits of passion and desire? Clearly, people can develop a taste for certain foods, certain music, certain sorts of activities, certain people, etc. Similarly, one can develop a taste for helping others, distributing goods justly, taking worthwhile risks, and so forth. This is neither easy nor quick, but it is possible.

VIRTUE ETHICS EXPLAINS MS. TAKE

Because virtue ethics focuses on character and maintains that decision-making is holistic, virtue ethicists would find it easy to question and then reject the traditional view of terrible choice situations. Virtue ethicists would not assume Ms. Take's statements to be the results of a purely intellectual process. Her statements do not explain the tenacity of her choice, after all. Instead, virtue ethicists would hypothesize that there is something else going on besides a failure of knowledge or reasoning which would explain Ms. Take's refusal to budge from option B. Her intransigence suggests that the "reasons" she gives are just rationalizations. Perhaps a failure of perception is the root of Ms. Take's resistance. Ms. Take is foregrounding the needle and back-grounding Dr. Phronesis's reassurances. And that misperception leads to inappropriate fears, desires, beliefs, and eventually to choices and rationalizations. Or maybe Ms. Take's primary problem is emotional; she is depressed, and thus cannot muster the start-up energy required to try something new. Or maybe her fundamental flaw is foolish beliefs; Ms. Take's subconscious suspicion of health care providers blocks her from trusting dentists.

FEAR-RELATED CHARACTER PROBLEMS

Scope	Degree	Diagnosis	Treatment
Localized	Mild	Normal	Provide teddy bear
Localized	Moderate	Character glitch	Depends
Localized	Severe	Phobia	Refer to therapist, internist, etc.
Widespread	Mild	Normal	Provide teddy bear
Widespread	Moderate	Cowardice	Depends
Widespread	Severe	Anxiety disorder	Refer to therapist, internist, etc.

There are lots of possibilities; how is one to identify the basic problem? As usual, certainty is impossible, but sometimes tipoffs present themselves as soon as one begins to look. Suppose Ms. Take says that she is recovering from PTSD or has expressed fear about riskless therapies on previous visits. Then the virtue ethicists' best guess about this situation might be that Ms. Take has a fear-management problem.

- (d) Ms. Take is disposed to fear the wrong things or the right things to inappropriate degrees.
- (e) Ms. Take's inappropriate fears cause her to reject option A.
- (f) Ms. Take's inappropriate fears also cause her to latch onto false beliefs or bad reasoning in order to use them as rationalizations.

Ms. Take is *not* simply making some sort of factual or reasoning error. The traditional approaches fail because her problem is fundamentally not an intellectual problem. Rather it is at root an emotional problem which has become an overall character problem corrupting her decision-making process. Thus, providing information and clarification address symptoms, but not the fundamental problem.

Let me immediately inoculate against a possible misunderstanding. To say that Ms. Take has a character flaw

is *not* to blame Ms. Take or burden her with the sole responsibility for her own character improvement. In order to appropriately assign blame, one would have to know how Ms. Take's flawed character trait was acquired. For example, one might blame her if her character flaw is the result of many years of neglect of New Year's resolutions, allowing a minor imperfection to fester and grow. However, one should not blame her if her character flaw is the result of abuse in childhood. (Blame is a complex issue beyond the scope of this paper. To mention just one line of thought, if women are socialized to be inappropriately fearful, then society should at least share the blame and burden of character rehabilitation.)

VIRTUE ETHICS SUGGESTS SHORT-TERM STRATEGIES

If the virtue ethics explanation is correct, what should Dr. Phronesis do in this situation? That depends. Different sorts of character problems can produce similar terrible decisions by patients, but require different approaches. As all dentists know, common outcome does not imply common cause or common cure. The first step is simple classification.

If Ms. Take's fundamental problem is a psychological disease, Dr. Phronesis should probably refer the patient for professional help. Perhaps Ms. Take needs a therapist (e.g., psychiatrist, psychologist, ministerial counselling). Alternatively, she might just need an internist to

prescribe an anti-anxiety medication before her next visit to Dr. Phronesis.

If the problem does not rise to the level of disease, and thus referral, Dr. Phronesis should take a stab at handling it herself. If Ms. Take remains intransigent after persuasion has been given a thorough trial, Dr. Phronesis must choose between two alternatives.

Alternative #1: If Dr. Phronesis decides that she does not have the talent to handle this problem in a fine-grained way, she should bracket Ms. Take's statements. Forget about all of that; it is just rationalization. Then Dr. Phronesis should go to the literature on helping people with decision making, find out what generally works best, and use that strategy. If studies have shown that balking patients are best convinced by giving them two weeks to think about their options, then Dr. Phronesis would make a return appointment for Ms. Take in two weeks to revisit the decision.

Alternative #2: Dr. Phronesis might consider herself to be capable of subtle insights into patients' characters. If so, she should try to diagnose the problem. Dr. Phronesis should not begin by bracketing Ms. Take's statements, but should not take Ms. Take's statements at face value either. Instead, she would use what Ms. Take says to classify the problem (e.g., fear-management, depression, lack of trust). Next she would determine the degree of the problem (mild, moderate, or severe) and its scope (localized or widespread). Once Dr. Phronesis has pigeon-holed Ms. Take's problem, she should go to the literature on helping people with decision making. But under this alternative, Dr. Phronesis should look for tailored solutions (i.e., for what works best in dealing with Ms. Take's particular sort of problem).

Of course, under both alternatives Dr. Phronesis must obtain Ms. Take's

consent. For example, Dr. Phronesis might say, “This is an important decision that should not be rushed. Can we revisit the decision in two weeks?”

VIRTUE ETHICS SUGGESTS LONG-TERM POLICIES

Since the focus of virtue ethics is character traits, and character traits are integrated collections of habits of choice, action, passion, desire, perception, and belief. Virtue ethics addresses character-related problems by recommending habituation of these aspects of character. In particular, to reduce the number of patients who make terrible decisions, virtue ethics recommends a long-term policy of building better character traits in patients through habit formation.

How can dentists inculcate dispositions such as reliably having appropriate levels of fear for appropriate situations? Dentist play two roles in the character development of their patients: they model reasonable ways of thinking, feeling, perceiving about health matters and they encourage patients to practice these ways of thinking, feeling, perceiving.

Begin by explaining the process and obtaining consent when patients first appear. Say something like, “Over time, I would like to teach you how to think about your dental health, how to observe symptoms and effects of treatment, what to worry about, and so on. This will enable you to be a full partner in your own dental health care. Is that OK with you?” Start with low-stakes matters. As issues arise, talk through them with the patient. I am not suggesting anything esoteric, difficult, or unusual here. For example, one might say, “The small procedure we just finished is very safe; you need not worry about anything unless there is bleeding. So check for bleeding over the next two days. If you see blood or bruising, call my office.” Over time, and as the stakes rise, conversations will tend to become

more complex. The important thing is to help the patient not only to think in reasonable ways, but also to feel, perceive, and so forth in reasonable ways.

Presumably, most dentists already do all of this. Dentists already share the understanding, and employ the strategies and policies suggested by virtue ethics. Like most people, dentists have an intuitive understanding of people and how to help others build character. What virtue ethics offers is not a radical shift in perspective or practice. Instead, virtue ethics systematizes procedures already in use and articulates their theoretical foundations.

SUMMARY

Many moral problems facing dentists arise when trying to choose the right treatment in complex clinical situations, but this paper concerns different sorts of problems: (a) how to respond when the clinical situation is clear, but the patient makes an unreasonable choice of therapy, and (b) how to forestall patients from making such choices.

Consequentialism and deontology are not blocked from proposing analyses, strategies, and policies similar to those proposed above. But because consequentialism and deontology are not focused on character—and because their picture of decision making is intellectualist rather than holistic—these analyses, strategies, and policies can only emerge as epicycles or addenda. By contrast, virtue ethics offers a promising perspective on situations where patients cling doggedly to terrible therapeutic choices. Virtue ethics suggests fruitful ways of explaining and dealing with such situations (and various other issues) because its focus and starting point is character. ■

Dentists play two roles in the character development of their patients: they model reasonable ways of thinking, feeling, perceiving about health matters and they encourage patients to practice these ways of thinking, feeling, perceiving.

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DENTAL PAIN IN THE ED

COSTS THAT HURT PATIENTS AND EDs

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ABSTRACT

Background and Objectives: The objective of this retrospective study was to determine if the collection rates for dental related visits to the emergency department (ED) are less than collection rates for ED visits for other problems.

Methods: Data were analyzed from one Kentucky hospital's electronic health record system from April 2010 to April 2012. Collection rates for patients who received care in the ED for uncomplicated dental problems were compared to collection rates for all patients who received care in the ED for any reason.

Results: Each month during the study period, an average of 77 patients presented to the ED for dental problems. Compensation rates for physician fees were 9.8% for dental related care and 39% for all patients who received care for any reason. Compensation rates for hospital fees were 16% for dental related care and 20.1% for all patients who received care for any reason. Uninsured patients accounted for 68.8% of physician fees and 62.4% of hospital fees for dental related care.

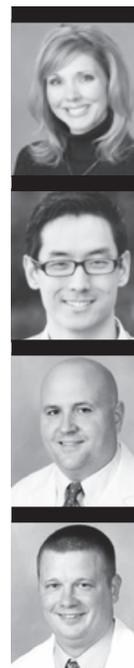
Conclusions: Using the ED as a dental safety net is costly to the patient because the underlying problem is typically not resolved and costly to the hospital because of very low collection rates. In addition, other patients who present to the ED for non-dental, high acuity problems may have delayed care or no care because of the number of patients using the ED for dental pain.

Dental pain is a familiar complaint in emergency departments (EDs). A 2013 research brief from the American Dental Association reported the number of visits to EDs for dental pain had grown from 1.1 million in 2000 to 2.1 million in 2010 (Wall & Kamyar, 2013). Data from the Pew Center on the States (www.pewstates.org/research/reports) provides information about the growth of this problem in individual states. In South Carolina, the number of visits to EDs for tooth or jaw problems increased 59% from 2005-2009. In Hawaii, a 74% increase was seen from 2004-2007. Florida experienced a 40% increase in the number of dental related ED visits among residents enrolled in Medicaid from 2008-2010, while Oregon experienced a 31% increase in the same time period (Pew Center on the States, 2012).

Typical causes for dental pain such as tooth decay are commonly treated in the ED with temporizing measures (McCormick et al, 2013). Pain medications are frequently the primary treatment, and antibiotics may be prescribed if there is evidence of a bacterial infection (Keenan et al, 2005; Okunseri et al, 2012a). Although some dental abscesses can be incised and drained in the ED, most EDs are not equipped to perform definitive treatment such as tooth extraction or root canal treatment. Definitive management for nontraumatic causes of dental pain typically requires referral to a dentist.

However, patients seen in the ED for dental pain may not be able to follow

up with a dentist for definitive care. A national study reports the primary reason that Medicaid recipients do not go to the dentist is that they cannot find a provider who will provide their care (U.S. General Accounting Office, 2000). For patients without public or private dental insurance, the cost of definitive dental treatment may be prohibitive (McCormick et al, 2013). The American Dental Association (2011) reports in a nationwide survey of dental fees the following as median fees charged by United States dentists: Problem focused exam: \$61.35; periapical radiograph: \$25.00; simple extraction: \$147.32. Assuming that an extraction would provide definitive care for most patients that present to the ED with dental pain, the total cost if the patient went to a dentist instead or as a follow-up from the ED, would be approximately \$233.67. This cost may create a barrier to care for



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some patients, particularly those who are uninsured or unemployed.

Previous research indicates that uninsured individuals tend to seek emergency care for dental pain in the ED at disproportionately greater rates (Cohen et al, 2002; Davis et al, 2010; Maiuro, 2009; Okunseri et al, 2012b). A recent national study found that over 40% of patients who visited an ED for a dental problem were uninsured (Allareddy et al, 2014). Those with commercial dental insurance have been found to rarely seek dental care in emergency departments (Davis et al, 2010).

Using the ED for relief of dental pain instead of visiting the dentist for definitive care may be quite costly for the patient in terms of health outcomes. Unaddressed dental pain resulting from acute infection can lead to serious medical conditions. Bacteria from a dental infection may spread into the thorax or brain, causing airway obstruction, brain abscesses or life-threatening cavernous sinus thromboses (Flynn, 2000; Holmstrup et al, 2003; Marioni et al, 2008). From 2008 to 2010, 101 patients in the United States who presented to EDs for dental problems died in the ED (Allareddy et al, 2014).

This study attempted to investigate another “cost” of using the ED to address non-acute dental problems—the financial cost to the hospital because of low collection rates. The goal of this study was to determine if the collection rates for dental related visits to the ED are less than collection rates for ED visits for other problems. This quantification is important because it adds to the body

of literature pointing to the need for new diversion initiatives and may also be a point of reference for hospitals in determining the cost-effectiveness of adding a dentist to their staff. In addition, the Affordable Care Act is placing increasing pressures on hospitals nationwide to decrease costs. Studying the financial cost to hospitals for dental visits to their EDs is timely and necessary.

Methods

This was a retrospective cohort study that used existing data to determine collection rates for patients presenting to a university hospital ED for dental complaints and collection rates for patients presenting to the same ED for any reason from April 2010 through April 2012. Prior to beginning this study, approval was obtained from the Institutional Review Board at the University of Kentucky.

Study Setting and Population

This study was conducted at the University of Kentucky Hospital Emergency Department (UKED). During the study period, UKED volumes ranged between 60,000 and 70,000 patients per year. The U.S. Census Bureau describes the UKED as serving a medium-sized city with a population just over 300,000. Hospital statistics indicate the UKED is also the definitive referral center for a population of approximately 1.4 million people throughout Central and Eastern Kentucky.

Data from two groups were compared. Inclusion criteria for the first group was

However, patients seen in the ED for dental pain may not be able to follow up with a dentist for definitive care. A national study reports the primary reason that Medicaid recipients do not go to the dentist is that they cannot find a provider who will provide their care.

The results of our study suggest that only a fraction of the \$2.7 billion charged was collected by hospitals and that the hospital reimbursement was significantly lower for dental related visits than ED visits for other reasons. Only 14.7% of billed treatment for dental problems treated in the ED was collected.

defined as any patient who was seen in the UKED from April 2010 through April 2012 and who had an International diagnosis including 522.0, 522.5, 522.7, 522.9, 525.9, 525.10, 521.00, 521.81. ICD-9 codes 523 (gingival and periodontal disease), 524 (dentofacial anomalies including malocclusion) and 526 (diseases of jaw) were excluded to avoid complicated infections and extensive trauma. In addition, ED visits paid for by automobile insurance were excluded because these were likely to involve treatment and charges beyond simple dental pain.

Inclusion criteria for the second group were defined as any patient who was seen in the UKED from April 2010 through April 2012 for any reason. No exclusions were made in either group based on age, race, ethnicity, health status, or gender.

STUDY PROTOCOL

The UKED currently uses Sunrise Clinical Manager by Allscripts as an integrated Electronic Health Record (EHR) and Computerized Physician Order Entry (CPOE) system. Using automated search functions, the database was searched for ICD-9 diagnostic codes specific for dental issues for the two-year period of this study.

Each selected case was matched with billed physician service fees as well as hospital charges, and the amount collected towards each was noted. Individual cases were then grouped by payer entity. For example "Patient responsibility" represents all uninsured/self-pay patients. Data regarding amounts billed to each payer entity for physician services and hospital fees was compiled using the previously identified visits to the emergency department with a dental diagnosis (visits that had documentation of the ICD-9 codes included in our search).

Finally, all emergency department physician and hospital fees for all patients visiting the ED from April 2010 through April 2012 were totaled and respective total collection rates were identified for all patients that presented to the emergency department.

RESULTS

In the sample studied here, ED visits for dental problems accounted for approximately 1.5% of all ED visits. Average monthly attendance for dental reasons in the ED by insured patients with insurance was 24, while there was an average of 53 uninsured patients per month who sought care in ED for dental reasons. During the study period, a total of \$252,527 was billed on behalf of ED physician services for treatment of dental complaints found using the ICD-9 codes discussed above, excluding those charged to auto related insurance. Of that amount, \$24,727 was collected for a compensation rate of 9.8%. Hospital fees totaled \$978,050 for the same dental related visits during this time and \$156,628 of that billed amount was collected for a hospital compensation rate of 16% (Table 1).

During the same period, compensation rates of physician fees for all patients that presented to the emergency department in relation to total billed fees was 39%, (Table 2) roughly four times greater than that of the compensation rate for dental visits. The total compensation rate of hospital fees for all patients presenting to the ED was found to be 20.1%, which is greater than that of the 16.0% compensation rate for dental visits (Figure 1).

Of note, \$173,872 of physician charges was made to uninsured patients who presented for dental complaints

found using the ICD-9 codes discussed above. This accounted for 68.8% of physician fees in the ED related to dental complaints. The corresponding hospital fees for these same uninsured patients was \$610,538, representing 62.4% of the hospital fees associated with the selected patients presenting to the ED for a dental complaint using the chosen ICD-9 codes.

In total, only 22.2% of billed treatment was collected. A smaller amount, 14.7% of billed treatment for dental problems was collected. All uninsured patients paid only about one sixth as much of their bills as did insured patients and physicians collected about twice as much of their charges as did hospitals from both insured and uninsured patients. The exception to these overall trends was the fact that physicians collected 39.9% of their billed services in general (compared to 20.1% for hospitals) but only 9.8% of their billed dental services (compared to 16.0% for hospitals).

During the study period, averages of 77 patients with dental complaints were seen per month. Over the same time period an average of 114 patients waiting to be seen for any complaint actually left the ED prior to seeing a physician.

Discussion

Our study showed a much higher proportion of uninsured/self-pay patients than previously reported in the literature (Davis et al, 2010; Hong et al, 2011; Maiuro, 2009). Nationally, 40% of patients who visited an ED for a dental problem have been uninsured (Allareddy et al, 2014) while our study found 68.8% of the physician fees and 62.4% of the hospital charges for dental related visits were attributed to uninsured patients. This may be explained in part by Kentucky’s Medicaid adult dental benefit package that covers preventive,

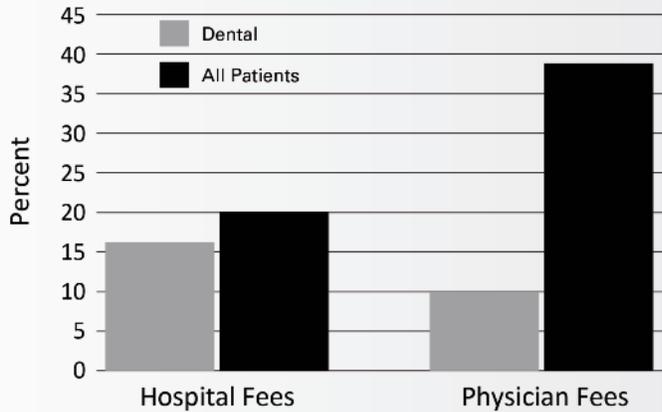
Table 1. DENTAL VISIT COST AND COLLECTION OF FEES BY INSURANCE TYPE FOR THE ED

	<i>Visits/Month</i>	<i>Billed</i>	<i>Collected</i>	<i>Collection Rate</i>
Insured Patients				
Physicians	24	\$ 78,655	\$ 23,339	29.7%
Hospital		367,512	111,445	30.3
Total		446,167	134,784	30.2
Uninsured Patients				
Physicians	53	\$ 173,872	\$ 1,388	0.8%
Hospital		610,538	45,183	7.4
Total		784,410	46,571	5.9
All Patients				
Physicians	77	\$ 252,527	\$ 24,727	9.8%
Hospital		978,050	156,628	16.0
Total		1,230,577	181,355	14.7

Table 2. All visits COST AND COLLECTION OF FEES BY INSURANCE TYPE FOR THE ED

	<i>Visits/Month</i>	<i>Billed</i>	<i>Collected</i>	<i>Collection Rate</i>
Insured Patients				
Physicians	3,926	\$ 21,213,465	\$ 9,572,390	45.1%
Hospital		246,158,838	68,219,895	27.7
Total		267,372,303	77,792,285	29.1
Uninsured Patients				
Physicians	1,465	\$ 7,324,714	\$ 1,549,298	21.2%
Hospital		99,579,547	3,645,599	3.7
Total		106,904,261	5,194,897	4.9
All Patients				
Physicians	5,391	\$ 28,538,179	\$ 11,121,688	39.0%
Hospital		345,738,385	71,865,494	20.1
Total		374,276,564	82,987,182	22.2

FIGURE 1. PERCENT COMPENSATION FOR ED VISITS



restorative, and oral surgical procedures. Lack of adult Medicaid dental benefits in some states may result in higher numbers of Medicaid adult patients presenting to EDs for dental problems compared to uninsured patients.

Controlling unnecessary costs in health care is a primary goal of the Affordable Care Act. A recent study reported total charges for dental related ED visits from 2008-2010 were \$2.7 billion across the United States (Allareddy et al, 2014). The results of our study suggest that only a fraction of the \$2.7 billion charged was collected by hospitals and that the hospital reimbursement was significantly lower for dental related visits than ED visits for other reasons. Only 14.7% of billed treatment for dental problems treated in the ED was collected in our study. Others studies are needed to determine if this very low collection rate is representative of EDs nationally. Given our findings, if even a few patients are treated in EDs for dental problems each month, it could create financial problems for hospitals.

The average charge for a patient presenting to an ED for dental problems is \$760 (Allareddy et al, 2014) and the

patient usually received only palliative measures (McCormick et al, 2013). The cost for actually resolving the patient's problem and providing definitive care at a dental office would be approximately three times less as mentioned previously (\$234 for exam, radiograph, and extraction). Clearly it is in the best interests of hospitals and patients to advocate for dental management systems that shift the burden away from EDs to less costly settings.

It may be cost-efficient for hospitals to employ case managers to navigate patients who have received care for dental issues in the ED, into a dental setting in which they can receive definitive dental care to prevent repeat visits to the ED for dental problems. If lack of ability to pay for a visit to a traditional dental office is a problem for patients, the case manager could refer the patients to a Federally Qualified Health Center with a sliding fee scale, a free clinic, a dental school or dentists in the area who have agreed to serve as referral sites who will accept payments.

A program in Calhoun County Michigan has developed an innovative solution to reduce dental visits to the ED (Higbea et al, 2013). Dentists in this community donate dental treatment for uninsured patients who have completed community service hours. The program's outcomes are encouraging,

with a 70% reduction in ED visits for dental pain from 2006-2012. Replication of this program in other communities may provide some relief for EDs regarding inappropriate use of the ED for uncomplicated dental pain.

Although not the focus of our study, an interesting secondary finding was that an average of 77 patients was seen in the ED each month for dental related problems while an average of 114 patients who came to the ED for any reason and waited, left prior to being seen by a physician each month during the same time period. Providing palliative care for dental pain in the ED takes time away from other patients who present to the ED, sometimes with more acute and potentially life-threatening problems. EDs across the country are often overcrowded and any measures that would allow emergency physicians to focus on the patients who can be given more definitive treatment would likely benefit the community served by an ED and lead to more positive health care outcomes.

The current study has several limitations. Despite our efforts to limit our study to uncomplicated dental pain by selection of dental codes, it is possible that a few of the more complicated dental patients were included in the study numbers. For example, two patients had initially been included in the study had automobile-related insurance providing payment, indicating likely automobile accident as a source of dental pain and the possibility of other concomitant diagnosis. These two patients and their data were removed from our final results; however there is a chance further complicated patients were included artificially inflating the physician and hospital fees. This is more likely to have significantly affected the hospital fees than the emergency physician fee totals. However, it is also

possible that some instances of dental related problems were underreported because of the inadvertent use of incorrect diagnostic codes.

Finally, our results represent findings from one hospital and specific details regarding repayment rates are often influenced by patient demographics and local politics. The results may not be simply generalized to represent the reality in different regions.

CONCLUSIONS

Collection rates for both hospital fees and physician services were significantly less for patients seen in the ED for dental problems compared with the collection rates of patients seen in the ED for all reasons. Further study is needed to determine more cost-effective means of providing definitive care to patients presenting to the ED with uncomplicated dental pain. ■

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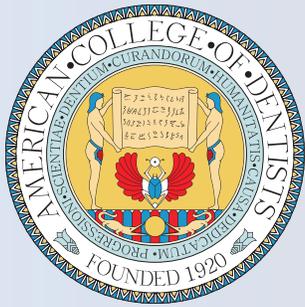
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