

DENTAL ETHICS

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➤ Ethics and dental research

➤ Importance of Dental Research:

Dentistry is not an exact science in the way that mathematics and physics are. It is evidence based and has many general principles that are valid most of the time, but every patient is different and what is an effective treatment for 90% of the population may not work for the other 10%. Thus, dentistry is inherently experimental. Even the most widely accepted treatments need to be monitored and evaluated to determine whether they are effective for specific patients and, for that matter, for patients in general. This is one of the functions of dental research.

Another, perhaps better known, function is the development of new dental materials, devices and techniques. Great progress has been made in this area over the past 50 years and today there is more dental research underway than ever before. Nevertheless, there are still many unanswered questions about the causes of oral diseases (both familiar and novel ones) and the best ways to prevent or cure them. Dental research is the only means of answering these questions.

➤ Research in Dental Practice:

All dentists make use of the results of dental research in their clinical practice. To maintain their competence, dentists must keep up with the current research in their area of practice through Continuing Dental Education/Continuing Professional Development programs, dentistry journals and interaction with knowledgeable colleagues. Even if they do not engage in research themselves, dentists must know how to interpret the results of research and apply them to their patients. Thus, a basic familiarity with research methods is essential for competent dental practice. The best way to gain this familiarity is to take part in a research project, either as a dental student or following qualification.

Ideally, all aspects of dental practice should be validated by research. Materials such as dental amalgams and pharmaceutical products such as anaesthetics do require evidence for their safety and efficacy before they are given governmental approval for their distribution and use. However, dental techniques do not require any such approval. Most dentists trust that the techniques they learn in dental school are appropriate but are ready to adopt new ones if these appear to be better. Rather than

relying on their own, necessarily limited, experience, dentists need to have recourse to the results of research for determining which materials, drugs and techniques are best for their patients.

The most common method of research for comparing and evaluating drugs is the clinical trial process, which with certain modifications serves for materials and techniques as well. The process usually begins with laboratory studies followed by testing on animals. If these prove promising, the four steps, or phases, of clinical research, are next:

- Phase one research, usually conducted on a relatively small number of healthy volunteers, who are often paid for their participation, is intended to determine what dosage of a drug is required to produce a response in the human body, how the body processes the drug, and whether the drug produces toxic or harmful effects.
- Phase two research is conducted on a group of patients who have the disease that the drug is intended to treat. Its goals are to determine whether the drug has any beneficial effect on the disease and has any harmful side effects.
- Phase three research is the clinical trial, in which the drug is administered to a large number of patients and compared to another drug, if there is one for the condition in question, and/or to a placebo. Where possible, such trials are 'double-blinded', i.e., neither research subjects nor their dentists know who is receiving which drug or placebo.
- Phase four research takes place after the drug is licensed and marketed. For the first few years, a new drug is monitored for side effects that did not show up in the earlier phases. Additionally, the pharmaceutical company is usually interested in how well the drug is being received by physicians and dentists who prescribe it and patients who take it.

The rapid increase in recent years in the number of ongoing trials has required finding and enrolling ever-larger numbers of patients to meet the statistical requirements of the trials. For dental research, those in charge of the trials, whether academic researchers or industry, now rely on many dentists, often in different countries, to enrol patients as research subjects.

Although such participation in research is valuable experience for dentists, there are potential problems that must be recognised and avoided. In the first place, the dentist's role in the dentist-patient relationship is different from the researcher's role in the researcher-research subject relationship, even if the dentist and the researcher are the same person. The dentist's primary responsibility is the health and well-being of the patient, whereas the researcher's primary responsibility is the generation of knowledge, which may or may not contribute to the research subject's health and

well-being. Thus, there is a potential for conflict between the two roles. When this occurs, the dentist role must take precedence over the researcher.

Another potential problem in combining these two roles is conflict of interest. Dental research is a well-funded enterprise, and dentists are sometimes offered considerable rewards for participating. These can include cash payments for enrolling research subjects, equipment such as computers to transmit the research data, invitations to conferences to discuss the research findings, and co-authorship of publications on the results of the research. The dentist's interest in obtaining these benefits can sometimes conflict with the duty to provide the patient with the best available treatment. It can also conflict with the right of the patient to receive all the necessary information to make a fully informed decision whether or not to participate in a research study.

These potential problems can be overcome. The ethical values of the dentist – compassion, competence, autonomy – apply to the dental researcher as well. As long as dentists understand and follow the basic rules of research ethics, they can successfully integrate research into their clinical practice.

➤ **Ethical Requirements:**

The basic principles of research ethics are well established. It was not always so, however. Many prominent medical researchers in the 19th and 20th centuries conducted experiments on patients without their consent and with little if any concern for the patients' well-being. Although there were some statements of research ethics dating from the early 20th century, these did not prevent healthcare professionals in many different countries – and in times of peace and war alike – from performing research on subjects that clearly violated fundamental human rights. Following World War Two, some German physicians were tried and convicted by a special tribunal at Nuremberg, Germany. The basis of the judgment is known as the Nuremberg Code, which has served as one of the foundational documents of modern research ethics. Among the ten principles of this Code is the requirement of voluntary consent if a patient is to serve as a research subject.

The World Medical Association (WMA) was established in 1947, the same year that the Nuremberg Code was set forth. Conscious of the violations of medical ethics before and during World War Two, the founders of the WMA immediately took steps to ensure that physicians would at least be aware of their ethical obligations. In 1954, after several years of study, the WMA adopted a set of Principles for Those in Research and Experimentation. This document was revised over the next ten years and eventually was adopted as the Declaration of Helsinki (DoH) in 1964. It was further revised in 1975, 1983, 1989, 1996 and 2000. The DoH is a concise summary of research ethics. Other, much more detailed, documents have been produced in recent years on research ethics in general (e.g., Council for International organisations of Medical Sciences, International Ethical Guidelines for Biomedical

Research Involving Human Subjects, 1993, revised in 2002) and on specific topics in research ethics (e.g., Nuffield Council on Bioethics [UK], The Ethics of Research Related to Healthcare in Developing Countries, 2002).

Despite the different scope, length and authorship of these documents, they agree to a very large extent on the basic principles of research ethics. These principles have been incorporated in the laws and/or regulations of many countries and international organisations, including those that deal with the approval of drugs and medical devices.

The DoH currently includes 32 principles stating in various ways that: (i) research with humans should be based on laboratory and animal experimentation; (ii) experimental protocols should be reviewed by an independent committee; (iii) informed consent should be required; (iv) subjects who are minors or those with physical or mental incapacity should be protected; (v) research should be conducted by medically/scientifically qualified individuals; (vi) risks and benefits should be balanced; (vii) the privacy of the subjects and confidentiality of the information should be maintained; (viii) research results should be published; (ix) conflicts of interest should be avoided; and (x) placebos should be used under strict guidelines.

Ethics Review Committee Approval

Paragraphs 13 and 14 of the DoH stipulate that every proposal for research on human subjects must be reviewed and approved by an independent ethics committee before it can proceed. In order to obtain approval, researchers must explain the purpose and methodology of the project; demonstrate how research subjects will be recruited, how their consent will be obtained and how their privacy will be protected; specify how the project is being funded; and disclose any potential conflicts of interest on the part of the researchers. The ethics committee may approve the project as presented, require changes before it can start, or refuse approval altogether. Many committees have a further role of monitoring projects that are underway to ensure that the researchers fulfil their obligations and they can if necessary, stop a project because of serious unexpected adverse events.

The reason why ethics committee approval of a project is required is that neither researchers nor research subjects are always knowledgeable and objective enough to determine whether a project is scientifically and ethically appropriate. Researchers need to demonstrate to an impartial expert committee that the project is worthwhile, that they are competent to conduct it, and that potential research subjects will be protected against harm to the greatest extent possible.

One unresolved issue regarding ethics committee review is whether a multi-centre project requires committee approval at each centre or whether approval by one committee is sufficient. If the centres are in different countries, review and approval is generally required in each country.

➤ **Scientific Merit:**

Paragraph 11 of the DoH requires that research involving human subjects must be justifiable on scientific grounds. This requirement is meant to eliminate projects that are unlikely to succeed, for example, because they are methodologically inadequate, or that, even if successful, will likely produce trivial results. If patients are being asked to participate in a research project, even where risk of harm is minimal, there should be an expectation that important scientific knowledge will be the result. To ensure scientific merit, paragraph 11 requires that the project be based on a thorough knowledge of the literature on the topic and on previous laboratory and, where appropriate, animal research that gives good reason to expect that the proposed intervention will be efficacious in human beings. All research on animals must conform to ethical guidelines that minimise the number of animals used and prevent unnecessary pain. Paragraph 15 adds a further requirement – that only scientifically qualified persons should conduct research on human subjects. The ethics review committee needs to be convinced that these conditions are fulfilled before it approves the project.

➤ **Social Value:**

One of the more controversial requirements of a research project is that it contribute to the well-being of society in general. It used to be widely agreed that advances in scientific knowledge were valuable in themselves and needed no further justification. However, as resources available for health research are increasingly inadequate, social value has emerged as an important criterion for judging whether a project should be funded.

Paragraphs 18 and 19 of the DoH clearly favour the consideration of social value in the evaluation of research projects. The importance of the project's objective, understood as both scientific and social importance, should outweigh the risks and burdens to research subjects. Furthermore, the populations in which the research is carried out should benefit from the results of the research. This is especially important in countries where there is potential for unfair treatment of research subjects who undergo the risks and discomfort of research while the drugs developed as a result of the research only benefit patients elsewhere.

The social worth of a research project is more difficult to determine than its scientific merit but that is not a good reason for ignoring it. Researchers, and ethics review committees, must ensure that patients are not subjected to tests that are unlikely to serve any useful social purpose. To do otherwise would waste valuable health resources and weaken the reputation of research as a major contributing factor to human health and well-being.

➤ **Risks and Benefits:**

Once the scientific merit and social worth of the project have been established, it is necessary for the researcher to demonstrate that the risks to the research subjects are not unreasonable or disproportionate to the expected benefits of the research, which may not even go to the research subjects. A risk is the potential for an adverse outcome (harm) to occur. It has two components: (1) the likelihood of the occurrence of harm (from highly unlikely to very likely), and (2) the severity of the harm (from trivial to permanent severe disability or death). A highly unlikely risk of a trivial harm would not be problematic for a good research project. At the other end of the spectrum, a likely risk of a serious harm would be unacceptable unless the project provided the only hope of treatment for terminally ill research subjects. In between these two extremes, paragraph 17 of the DoH requires researchers to adequately assess the risks and be sure that they can be managed. If the risk is entirely unknown, then the researcher should not proceed with the project until some reliable data are available, for example, from laboratory studies or experiments on animals.

➤ **Informed Consent:**

The first principle of the Nuremberg Code reads as follows: "The voluntary consent of the human subject is absolutely essential." The explanatory paragraph attached to this principle requires, among other things, that the research subject "should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision."

The DoH goes into some detail about informed consent. Paragraph 22 specifies what the research subject needs to know in order to make an informed decision about participation. Paragraph 23 warns against pressuring individuals to participate in research, since in such circumstances the consent may not be entirely voluntary. Paragraphs 24 to 26 deal with research subjects who are unable to give consent (minor children, severely mentally handicapped individuals, unconscious patients). They can still serve as research subjects but only under restricted conditions.

The DoH, like other research ethics documents, recommends that informed consent be demonstrated by having the research subject sign a 'consent form' (paragraph 22). Many ethics review committees require the researcher to provide them with the consent form they intend to use for their project. In some countries these forms have become so long and detailed that they no longer serve the purpose of informing the research subject about the project. In any case, the process of obtaining informed consent does not begin and end with the form being signed but must involve a careful oral explanation of the project and all that participation in it will mean to the research subject. Moreover, research subjects should be informed that they are free to withdraw their consent to participate at any time, even after the project has begun, without any sort of reprisal from the researchers or other dentists and without any compromise of their health care.

➤ **Confidentiality:**

As with patients in clinical care, research subjects have a right to privacy with regard to their personal health information. Unlike clinical care, however, research requires the disclosure of personal health information to others, including the wider scientific community and sometimes the general public. In order to protect privacy, researchers must ensure that they obtain the informed consent of research subjects to use their personal health information for research purposes, which requires that the subjects are told in advance about the uses to which their information is going to be put. As a general rule, the information should be de-identified and should be stored and transmitted securely.

➤ **Conflict of Roles:**

It was noted earlier that the dentist's role in the dentist-patient relationship is different from the researcher's role in the researcher-research subject relationship, even if the dentist and the researcher are the same person. Paragraph 28 of the DoH requires that in such cases, the dentist role must take precedence. This means, among other things, that the dentist must be prepared to recommend that the patient not take part in a research project if the patient seems to be doing well with the current treatment and the project requires that patients be randomised to different treatments and/or to a placebo. Only if the dentist, on solid scientific grounds, is truly uncertain whether the patient's current treatment is as suitable as a proposed new treatment, or even a placebo, should the dentist ask the patient to take part in the research project.

➤ **Honest Reporting of Results:**

It should not be necessary to require that research results be reported accurately, but unfortunately there have been numerous recent accounts of dishonest practices in the publication of research results. Problems include plagiarism, data fabrication, duplicate publication, and 'gift' authorship. Such practices may benefit the researcher, at least until they are discovered, but they can cause great harm to patients, who may be given incorrect treatments based on inaccurate or false research reports, and to other researchers, who may waste much time and resources trying to follow up the studies.