Using Human Subjects in Dental Licensing Exams: Is This the Best Way to Ensure the Health and Safety of the Public?

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In the "Ethical Moment" article in the February 2018 issue of the *Journal of the American Dental Association (JADA),*[1] A.R. Scarbrough addresses a question posed by a recent dental school graduate who had just taken a clinical licensing board examination; namely, *"Does using live patients for dental licensing examinations raise ethical considerations?"*

Scarbrough replies to the new dentist's question by referencing The American Dental Association's 2018 Principles of Ethics and Code of Professional Conduct. He cites the five principles of the ADA Code — patient autonomy, nonmaleficence, beneficence, justice, and veracity — and concludes by asking, "… how could anyone argue that the board examination itself is inherently unethical if he or she is following the dictates of the ADA Code?"

In fact, the answer is far more nuanced than we are led to believe by Scarbrough's reply. Using the same ethical principles of the ADA Code, an argument could be made that would lead to a different conclusion — that there is an inherent tension between the first sentence of the Introduction and the first sentence of the Preamble in the ADA's Code.

The first sentence of the Introduction states that:

The dental profession holds a special position of trust within society. As a consequence, society affords the profession certain privileges that are not available to members of the public-at-large. In return, the profession makes a commitment to society that its members will adhere to high ethical standards of conduct.

The first sentence of the Preamble states that:

The American Dental Association calls upon dentists to follow high ethical standards which have the benefit of the patient as their primary goal.

The ADA, American Dental Education Association (ADEA), and American Student Dental Association (ASDA) have all passed resolutions recommending the "elimination and/or modification of the human subject/patient-based component of the exam due to myriad ethical and logistical issues pertaining to patient involvement."

Thus, one can conclude that the governing body of the dental profession, the American Dental Association, has dual loyalties — one to society and the other to the individual patient. Extrapolating from these two loyalties, the ADA can be shown to have two primary responsibilities — one to ensure that it maintains the trust of society, and the other to ensure that its members provide care that benefits individual patients. These two responsibilities, though usually in harmony, can, however, come into conflict and compete with each other. As we shall see, such is the case in clinical licensing exams like the Commission on Dental Competency Assessments (CDCA) and Western Regional Examining Board (WREB) exams.

Though the profession's responsibility to society is important, its responsibility to the individual patient is paramount. The Hippocratic Oath established several principles of medical ethics that remain relevant today. The object of these principles is the individual patient, not society. A principle that flows from the Hippocratic Oath is widely held to be the principle of highest priority — *primum non nocere,* Latin for "first, do no harm." The supreme importance of this principle in the process of dental licensure was affirmed in a recent article by J. E. Gambacorta et al. titled "The Buffalo Model: Shifting the focus of clinical licensure exams in dentistry to address ethical concerns regarding patient care."[2]

The authors point out that the ADA, American Dental Education Association (ADEA), and American Student Dental Association (ASDA) have all passed resolutions recommending the "elimination and/or modification of the human subject/patient-based component of the exam due to myriad ethical and logistical issues pertaining to patient involvement." This article will expand upon the ethical arguments discussed in the Gambacorta article.

Nonmaleficence

Gambacorta et al. discuss the following concerns that are germane to the ethical principle of Nonmaleficence. They are:

1. Delays in treatment that exceed that which would occur during the execution of a normal treatment plan at the dental school
2. Lack of indicated follow-up care following the treatment rendered during the clinical exam

3. Lack of indicated follow-up care due to inadequate record keeping
4. Lack of indicated follow-up care due to loosely supervised examination in screening the patient for the exam
5. Undue influence on the subject-patients to participate in the exam due to the incentive of financial compensation offered by the students

If any of these concerns arise during the course of the exam process, the patient may experience harm. Such occurrences would be a violation of the principle of nonmaleficence. For example, if, in taking the restorative part of the exam, the student fails the exam and is instructed by the examiner to place a temporary sedative filling in the tooth, then the patient may experience harm of infection and pain. Unless the patient had been informed about how to access and obtain appropriate follow-up care, the principle of nonmaleficence would have been violated.

Patient Autonomy

Such a hypothetical occurrence leads to a discussion of the ethical principle of patient autonomy. Gambacorta et al. write that:

> *The dentist has a duty to respect the patient's rights to self-determination and confidentiality. This principle expresses the concept that professionals have a duty to treat the patient according to the patient's desires, within the bounds of accepted treatment, and to protect the patient's confidentiality. Under this principle, the dentist's primary obligations include involving patients in treatment decisions in a meaningful way, with due consideration being given to the patient's needs, desires and abilities, and safeguarding the patient's privacy.*

Involving the subject-patient in a "meaningful way" entails having the student conduct an informed consent process that is full and complete, and not cursory. A full and complete informed consent document would address all of the concerns raised by Gambacorta et al. In the situation described above, this would require that the informed consent document include information on how the patient could access and obtain immediate emergency care.

Veracity

The omission of a such a full and complete informed consent process would violate the ethical principle of veracity. This principle of "truthfulness" states that:

> *The dentist has a duty to communicate truthfully. This principle expresses the concept that professionals have a duty to be honest and trustworthy in their dealings with people. Under this principle, the dentist's primary obligations include respecting the position of trust inherent in the dentist-patient relationship, communicating truthfully and without deception, and maintaining intellectual integrity.*

In the situation described above, Veracity would entail the subject-patient participating in a full and complete informed consent process that would include all risks of treatment, all possible harms, and also include all future financial obligations that the subject-patient might incur from her/his participation in the licensure exam.

Dental Licensing Exams Viewed from the Perspective of Research Ethics

An entirely different perspective on the ethics of the clinical licensure exam would place the clinical licensure exam within the realm

of research and the subject-patients could be considered to be research subjects. One could substantiate this supposition by referring to the definitions of research and research-subject in the Code of Federal Regulations Title 45 Part 46 Protection of Human Subjects.

This code defines ***research*** as:

> *A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities which meet this definition constitute research for purposes of this policy, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities.*

This code also defines a ***human subject*** as a living individual about whom an investigator (whether professional or student) conducting research obtains:

1. Data through intervention or interaction with the individual, or
2. Identifiable private information.

First, the clinical exams (CDCA, WREB) fall under the heading of research in that systematic investigations, such as compiling and publishing students' performance data, are performed by the testing bodies and the dental schools which contribute to generalizable knowledge. Second, the patients fall within the category of *"human subjects"* in that the testing bodies and the dental schools obtain data about the results of the intervention and interaction of the students being tested with the patients, and that agents of the testing bodies and the dental schools obtain identifiable private health information.

This code goes on to define *intervention, interaction,* and *private information* as follows:

> ***Intervention*** *includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.*
>
> ***Interaction*** *includes communication or interpersonal contact between investigator and subject.*
>
> ***Private information*** *includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public, e.g., a medical record. Private information must be individually identifiable, i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information in order to obtain the information to constitute research involving human subjects.*

Clearly, the clinical exams involve interventions in which physical procedures are performed by the students upon the human subjects and interactions of communication occur between the students being tested and the human subjects. Moreover, private health information can be individually identified by agents of the testing bodies and by the dental schools.

Finally, the interventions performed by the students being tested on the human subjects involve greater than minimal risk.

This code defines minimal risk as:

… the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

The interventions on the human subjects performed by the dental students being tested entail procedures that are invasive and require the administration of a local anesthetic. The probability of harm and harm occurring with these invasive procedures is greater than that which the human subjects encounter during daily life ...

The interventions on the human subjects performed by the dental students being tested entail procedures that are invasive and require the administration of a local anesthetic. The probability of harm and harm occurring with these invasive procedures is greater than that which the human subjects encounter during daily life or during the performance of routine physical or psychological examinations.

Accordingly, clinical dental examinations on human subjects constitute research and should be approved by IRBs of all of the dental schools jointly participating in these examina-tions as per 45CFR46.114: *Cooperative Research:*

Cooperative research projects are those projects covered by this policy which involve more than one institution. In the conduct of cooperative research projects, each institution is responsible for safeguarding the rights and welfare of human subjects and for complying with this policy. With the approval of the department or agency head, an institution participating in a cooperative project may enter into a joint review arrangement, rely upon the review of another qualified IRB, or make similar arrangements for avoiding duplication of effort.

Also according to this code, these examinations are projects involving the cooperation of the dental schools with a vested interest in the outcome of the examinations. And each dental school is "…responsible for safeguarding the rights and welfare of the (live) human subjects."

Those who object to this line of reasoning about the examinations being research, and the human subjects being *research subjects,* might argue that the examinations are educational and not research. 45 CFR 46.101(b) does provide for such exemptions:

Unless otherwise required by department or agency heads, research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from this policy.

As per subparagraph 2, that refers to 'Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior . . .

However, subparagraph 2 does go on to say that such research is exempt ***unless:***

(i) information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of the human subjects' responses outside the research

could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation

Since the clinical exams (CDCA, WREB) are educational achievement tests, they would be exempt from being considered as research, except for the fact that the tests obtain information that is recorded in such a manner that the human subjects can be identified and the test procedure interventions can result in the human subjects providing health information outside that of the test intervention that could be damaging to the subjects' financial standing or employability. For example, in the situation described above, the need for emergency care subsequent to and resulting from the test intervention may cause damage to the subjects' financial standing or employability.

If the CDCA and WREB clinical examinations continue to be used to test the clinical skills of graduating and graduated dental students, then the examination procedures should be reviewed by the IRBs of all of the dental schools allowing the use of their physical facilities, as per 45 CFR 46.403 (IRB duties), 45 CFR 46.405 (Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects), and 45 CFR 46.114 (Cooperative Research.)

Final Thoughts

While dental licensing exams help to ensure the health and safety of the public, clinical examination procedures that use human subjects for dental licensing examinations do raise ethical considerations.

Alternatives include:

1. The Buffalo Model described by Gambacorta et al., in which calibrated dental school faculty evaluate students providing treatment to patients of record within a sequenced treatment plan and timely and appropriate treatment is provided to all patients.
2. The Canadian Model which uses a station-type examination in which candidate students have five minutes to review information supplied at each station, e.g., case history, dental charts, photographs, radiographic images, casts, models, videos, and answer questions at each station.[3]
3. The United States Medical Licensing Examination (USMLE) Step 2 Clinical Skills Model that uses actors simulating patients who are interviewed and examined by medical students.[4]
4. A hybrid of these three models.

The second and third alternatives would not entail research being conducted on human subjects and would thus not be subject to IRB approval. The Buffalo model, however, entails the use of human subjects and would require IRB approval.

This is admittedly a challenging issue for the dental profession. I am hopeful that my analysis will lead to further discussion and a clearer understanding of what type of dental licensing exams might be created to better ensure the health and safety of the public. ■

References
1. A. R. Scarbrough, *JADA* 149 (2): 163-164.
2. Gambacorta JE, Glick M, Anker AE, Shampaine GS. The Buffalo Model: Shifting the focus of clinical licensure exams in dentistry to address ethical concerns regarding patient care." *J Dent Educ* 2016; 80(6):641-647
3. https://ndeb-bned.ca/en/accredited/osce-examination
4. http://www.usmle.org/step-2-ck/.