Using Human Subjects in Dental Licensing Exams:

Is this the Best Way to Ensure the Health and Safety of the Public?

Is it time for a change?
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In keeping with the mission of the Journal of the Academy of Distinguished Educators (JADE) — to feature experts on some of the thorny issues confronting dental education — this issue of JADE addresses a fundamental question for the profession: “Is the use of human subjects during dental licensing exams the best way to ensure the health and safety of the public?”

Our centerpiece article, by Alexander J. Schloss, DDS, MSB (Master’s in Bioethics), provides a comprehensive ethical framework in which to consider this question. Utilizing the ADA’s 2018 Principles of Ethics and Code of Professional Conduct, Dr. Schloss systematically argues that it is not possible to uphold the principles of autonomy, nonmaleficence, beneficence, justice, and veracity enshrined in that code when human subjects are used in dental licensing exams. And he advances the intriguing proposition that dental licensing examinations that use human subjects can be viewed from the perspective of research ethics, with all that entails for the protection of the research subject. He concludes that while dental licensing exams help to ensure the health and safety of the public, clinical examination procedures that use human subjects for such licensing exams give rise to significant ethical considerations, and he proposes some potential alternatives.

Commenting on Dr. Schloss’s article are Anthony Vernillo, DDS, PhD, MBE (Bioethics), and Frank R. Recker, DDS, JD.

In his commentary, Dr. Vernillo supports Dr. Schloss’s argument and goes further. He asserts that given advances in current computer and informational technology, board examinations that adequately assess dental students’ clinical skills without the use of human subjects are doable, ethically justified, and should be mandated.

In a second commentary, Dr. Recker views the question from his perspective as a licensed dentist, former dental board member, licensure examiner, and attorney, and concludes that a dental licensing exam using a human subject is wholly unjustified, and, in fact, primitive. And he offers a provocative reason for their continued use, writing that “Justification for such a patient exam boils down to the dental profession’s blind adherence to the past ... and the millions of dollars received by regional testing agencies.”

Clearly, this is a controversial topic. And because it is, we would like to keep the conversation going by considering additional perspectives. To that end, we invite you, our readers, to weigh in with your thoughts on this question, and we will be print as many of your comments as we can in the next issue of JADE. Please send your comments to dental.academy@nyu.edu.

I want to thank all the authors for sharing their views and expertise in such a thoughtful and thought-provoking manner, and I thank the members of the JADE editorial board for their input and suggestions. We look forward to your comments.
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)*, 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.

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.”

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.”

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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.*

In 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 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 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.

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
The theory of common morality holds that all humans — at least all morally serious humans — have an awareness of certain ethical norms upon which they can all agree and which guide their behavior. In dentistry, that concept is embodied in the ADA Principles of Ethics and Code of Professional Conduct, which is organized around five normative principles: autonomy, nonmaleficence, beneficence, justice, and veracity.

In his centerpiece article for the Journal of the Academy of Distinguished Educators, “Do Dental Licensing Exams Help to Ensure the Health and Safety of the Public?”, Dr. Alexander Schloss applies these ethical principles in his cogent argument against the use of human subjects in dental board exams for licensure. Furthermore, he lists alternative models, which include the Canadian Model for Licensure (dental) and the United States Medical Licensing Examination (USMLE), that effectively assess students’ clinical skills. The Canadian Model uses a station-type examination in which candidate-students review information and answer questions. The USMLE uses actors simulating patients who are interviewed and examined by medical students. No actual clinical procedures are performed on human subjects in either the Canadian or the USMLE Models. However, the Buffalo Model uses human subjects to assess dental students’ clinical skills. Legitimate doubt is thus raised about
whether human subjects are truly needed during dental licensing board exams and if such a testing design actually ensures the health and safety of the public. It is an intelligent analysis that is long overdue.

Predoctoral dental students typically complete a comprehensive curriculum in professional school over several years of both didactic instruction in the basic sciences and clinical training in history taking and the acquisition of necessary mechanical skills to restore or replace a patient’s dentition. With respect to an assessment of students’ clinical skills, experienced and dedicated dental faculty typically supervise students in that critical part of their education. Professional school programs must also meet the accreditation standards of the American Dental Association (ADA) and the Commission on Dental Accreditation (CODA). Upon graduation, a student has thus acquired the necessary didactic education and clinical training to enter practice. How could a clinical board exam for licensure that uses human subjects and lasts only several days at most provide an additional, adequate level of protection to the public? Clearly, it does not. However, such a dental licensing board exam may still be viewed by some as protective for the public against unscrupulous or incompetent practitioners. The clinical licensure exam and its use of human subjects was likely a purposeful and historical stopgap measure because most dental students several decades ago entered directly into private practice upon graduation since postgraduate dental programs were not the norm. Today, however, there are many elective, one- to two-year general practice residency (GPR) programs which allow dental students to acquire additional didactic and clinical skills in a hospital setting, thereby delaying immediate entry into private practice.

Dr. Schloss does not propose eliminating the dental licensing exam altogether. Rather, he persuasively argues that it is unethical to use human subjects in a board exam for licensure to ensure the health and safety of the public. Human subjects paradoxically accrue relatively little, if any, benefit, and may even suffer harm from a procedure. Other participants in the board exam may be subjected to undue influence from the incentive of financial compensation offered by the student.

Yet another major ethical concern is the integrity of the informed consent process. A standard consent form may not be adequate because it may not accommodate the conditions unique to the licensure exam. Is an additional consent form therefore necessary? Does the informed consent document include adequate information on how the patient can access and obtain emergency care if pain results from a procedure performed during that board exam? Informed consent must be a person-to-person agreement between the healthcare provider and the patient with due consideration given to the patient’s needs, desires, financial abilities, and the anticipated procedure. Is that likely obtained given the constraints of time and other logistical issues related to patient involvement during a board exam? If a board participant merely signs the consent form...
but does not fully understand all the conditions related to a procedure, then the consent process is not valid. Dr. Schloss rightly argues that the healthcare professional has a moral duty to treat the patient according to his or her needs and desires. Hence, respect for autonomy means that voluntary informed consent cannot be cursory. Confidentiality must also be preserved whereby the patient decides what private information should or should not be disclosed to others. Autonomy governs informed consent and confidentiality and is central to the conduct of ethical clinical practice.

**A Thought Experiment**

A thought experiment (a favorite tool of philosophers) may further illustrate the absurdity and impracticality of using human subjects during a board exam for licensure. Thought experiments are devices of the imagination used to investigate the nature of things. Hence, one can step outside of the situation, e.g., the use of patients in a dental board exam, and obtain another more rational perspective. Let us say that a medical student who has graduated from professional school now wishes to become a transplant surgeon. After many years of postgraduate training, that young physician now faces his or her clinical board exam in surgery. Imagine now the use of a live patient who needs a kidney. In this fanciful scenario, what should happen to the participating patient if the transplanted kidney should fail? Must that physician on the verge of frustration and despair now frantically scurry about for another kidney? Where, when, and how is the physician to find it?

**Where I Stand**

I feel strongly that the absurdity of using human subjects in a clinical dental board exam cannot be overstated. It is logically fallacious. The ratio of risk to benefit may likely be very unfavorable and is thus ethically impermissible. Obtaining fully informed voluntary consent may not be possible. The use of patients in the design and administration of the clinical dental board exam for licensure is also antiquated. Given advances in our current computer and informational technology, board exams that adequately assess the dental students’ clinical skills without the use of patients are doable, ethically justified, and should be mandated.
I am initially prompted to modify the question that I have been invited to address, and instead ask, what is there about licensing exams that could even potentially protect the public? I will limit my comments to non-ethical issues as they have been thoroughly analyzed by Dr. Schloss. My comments are based upon my personal experiences and observations as a licensed dentist, former dental board member, licensure examiner, and attorney. Let's fast forward.

We have a dental student who has, or will soon, graduate from at least four years of education in a CODA accredited dental school. During that process, the student was closely monitored as he/she performed hundreds of clinical procedures over a number of years. Each step was evaluated and observed by dental faculty familiar with the student's general propensities, academic performance, demeanor, general intelligence and interactions with scores of patients. Each clinical task performed during hundreds of patient encounters was scrutinized, evaluated, critiqued, and documented. Importantly, “one on one” interactional teaching was an inherent part of this process.

Then to the clinical licensing exam. We have a candidate, already assured of graduation from the accredited dental school by its collective faculty, confronted with perhaps the biggest exam of his/her life, overloaded with stress, debt, peer pressure, family expectations, and outside factors having nothing to do with clinical competency. But these extra-
neous factors are of great potential import on the actual demonstration of clinical competency. Of course the student-candidate has performed these clinical examination procedures many, many times in the past and has already been deemed competent by a collective multitude of dental school faculty. But now it’s a one-time “high stakes” performance with so much at risk it verges on psychological cruelty. Not to mention the paperwork, specific procedures to follow, patient arrangements, and all the other related non-clinical “risk” factors.

For the candidate, there are never-ending concerns: Will my patient show up? Will the patient’s dentition/condition be approved for the required procedures? Can these unknown examiners consider the potential negative effects from my patient’s inability to open wide, or tendency to move around in the chair, or extreme fear of pain? Of course any patient-related behavior that results in clinical imperfections are the candidate’s responsibility, because the candidates are inherently expected to procure patients who are unmoving, unemotional, able to indefinitely engage in mouth opening for long periods, and be without any fear of dentistry. In other words, the candidate should strive to obtain virtual human “typodonts.” Indeed, wide variations in patient selection are a reality that every candidate must deal with.

In this environment that is obviously fraught with physical and emotional stress and anxiety, the aspiring licensee will perform very regimented and routine dental procedures that he/she has successfully performed many times in the past, while in an accredited dental school. But none of those successes are relevant now. They were simply required to allow the candidate to graduate, only to then risk it all during this one time roll of the dice.

So how does this scenario potentially “protect the public,” or “insure the health and safety of the public?” In my opinion, there is absolutely no correlation. More than likely, the patient volunteer receives dental treatment in a licensing exam which is within the standard of care, but which takes hours, is performed by a profusely nervous and highly stressed dental graduate/candidate, and only after opening their mouths an incessant number of times of unknown duration. From the patient’s perspective, the entire experience is anything but enjoyable. Let’s face it. The patient is only the necessary “guinea pig.” And at best, after hours of sitting patiently in the dental chair, the patient leaves intact. At worst, a slip of the hand, a sudden movement by the patient, or a margin deemed “open,” will require the patient to obtain follow up treatment from a licensed practitioner at unknown cost.

A dental licensing exam on a human subject is, in my view, wholly unjustified and primitive. We are no longer barbers. It degrades the value of a 4 year dental education in a CODA accredited dental school, dismisses or at best minimizes the collective wisdom and judgment of dental school faculty, and places the entire outcome on a one time review by dental examiners. The dental licensure examiners are not themselves evaluated.
as to their own clinical competency, past malpractice suits, or past licensure issues. So how do these “pieces” of the licensure exam process fit together to “protect the public?” In my judgment, they do not.

Justification for such a patient exam boils down to the dental profession’s blind adherence to the past, resistance to change, “we all had to do it,” and the millions of dollars received by the regional testing agencies. On what basis can we believe that a clinical licensure exam on a human subject benefits anyone? Statistically, virtually 100% of the candidates will eventually pass the exam. If not the first time, it will just require more money, complicated logistical and procedural hurdles, and a replay of all the stress factors. And the eventual passage occurs in the absence of any clinical remediation. But they will pass, if only they continue to retake the exam. And, if by chance a candidate never passes, what have we established? And is that worth the millions of dollars paid to regional testing agencies and the potential harm to a patient volunteer?

Dentistry is the only healthcare profession that requires its professional school graduates to run the clinical, patient-based, licensure exam gauntlet. I am unaware of any empirical study that in any way connects such an exam with protecting the public. Clearly, the ADA’s OSCE exam is far more likely to measure competency and clinical ability, but without subjecting patients to duress and the potential risk of injury emanating from an environment replete with stress, duress, uncertainty, strict protocols, and financial pressures. And OSCE would provide licensure candidates a purely objective exam and a level playing field for comparative evaluation purposes.

After 40 years of involvement, I still can’t comprehend any justification for a clinical licensure exam involving human subjects. I believe it has more to do with the millions of dollars received by (competitive) regional licensing entities with sparse accountability to any person or entity, and the profession’s inherent resistance to change. It really has little or nothing to do with protecting the public from “incompetent” graduates of a CODA accredited 4-year dental school.

Perhaps a candidate fails the clinical exam because of a 1–2 mm overextended preparation, or imperfectly tapered walls, or an arguably “open” margin, or because he/she allowed calculus to remain on a tooth that was difficult to access. Never mind that every dentist who has practiced for any length of time has cemented a crown that was later determined to have an “open” margin, or prepared a less than ideal class II, or encountered an inappropriate “undercut.” This is the nature of dentistry. It happens to the best of practitioners and is simply a reality in the clinical practice of dentistry. It just isn’t “allowed” to happen on the clinical licensure exam.

Hopefully, my opinion will encourage more candor and a more objective and unbiased discussion about the ADA/OSCE exam. Our profession and its future licensees deserve our doing so.