Ethical Reply to the New I-STOP Law

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On Aug. 27, 2013, an amendment to the Public Health Law known as I-STOP (Internet System for Tracking Over-Prescribing) went into effect. The I-STOP law requires all dentists (and other prescribers, except veterinarians) to consult the Prescription Monitoring Program (PMP) Registry prior to prescribing or dispensing a controlled substance listed on Schedule II, III or IV. The PMP provides prescribers with a six-month history of controlled substances dispensed to their patients to help them determine whether there is abuse of non-medical use.[1]

In passing this law, legislators had the best interests of society in mind as they sought to reduce the non-medical use of controlled substances. Specifically, their intention was to lessen "...the misuse, diversion and overdose of prescription controlled substances..."[2] and, thus, reduce the concomitant increase in violence that has occurred due to the non-medical use of controlled substances. In order to achieve this noble goal, the law obligated doctors to function in a new role—that of gatekeeper. But, as currently written, the I-STOP law raises questions where it intersects with four of the dental profession's principles of ethics: non-maleficence; beneficence; autonomy; and veracity.[3]

Non-maleficence and beneficence are Hippocratic principles. Non-maleficence obligates a doctor to keep his or her patients from harm. Beneficence obligates a doctor to provide care that benefits the patient.

Autonomy is a non-Hippocratic principle that holds that rules and laws are morally right insofar as they involve respecting the self-determined choices of individuals. It is derived from Western political philosophy, which prioritizes the liberty and freedom of an individual, that is, a person has rights. A person has the right to be left alone and be free from the interference of others.

The principle of informed consent is derived from the principle of autonomy. A series of legal cases from 1969-1972 shifted the emphasis from the paternalistic (the doctor is the sole decision maker) Hippocratic basis for consent to consent based on respect for a person's autonomy and right to make his or her own medical decisions. One case in particular, Canterbury v. Spence,[4] introduced the standard by which doctors practice today. This standard is called the Reasonable Person Standard. It requires a doctor to disclose to a patient what a reasonable patient would want to be told regarding any medical procedure. For example, a person needing extraction of a mandibular third molar would want to be told that there is a risk of paresthesia resulting from such a procedure.

In evaluating the ethical correctness of the I-STOP law, it is first necessary to examine the intent of the law. The intent of the law is to keep people from using controlled substances in a non-medical way, consistent with the principle of non-maleficence—to keep people from harm. However, in the "Frequently Asked Questions" section of the online PMP Registry, the first question is, "What is the purpose of the PMP Registry?" The answer that is given is that the doctor, by viewing the patient's recent controlled substance prescription history, can "... better evaluate patient's treatment as it pertains

to controlled substance prescribing and dispensing." Thus, the law implies that it is now the doctor's obligation to withhold a controlled substance from a patient with a prescription history of controlled substance. Therefore, the law is asking doctors to render a paternalistic value judgment.

In prescribing a controlled substance, like a palliative narcotic, the doctor is seeking to benefit his or her patient by mitigating potential discomfort from pain. However, the doctor must now make a determination if prescribing that controlled substance is creating the potential for abuse of the drug by the patient (maleficence). The doctor becomes a gatekeeper in determining if the benefit of prescribing the controlled substance outweighs the potential risk of causing harm by creating a potential for abuse of the medication by the patient. The I-STOP law provides no guidance to the doctor in making such a determination.

Responding to Pain

There is also the ethical problem of the dentist who withholds a controlled substance from a patient who is, or has the potential to be, suffering from severe pain. In a recent article published in JADA,[5] Moore and Hersh concluded that if severe pain is anticipated, it is recommended that "400 to 600 g of ibuprofen plus an opioid-APAP combination equivalent of either 5 mg of hydrocodone with 325 mg of APAP or 10 mg of hydrocodone with 650 mg of APAP administered every six hours...." The value of nonnarcotic and narcotic analgesic drugs in dentistry is fully appreciated only when a comprehensive description of the symptoms and related pathology of the patient's pain has been recognized. Management of the patient's complaint with adequate and profound pain relief is just as important as an accurate diagnosis of the case and provides momentous and rewarding achievement by the dentist.

In dentistry, the decision to prescribe a narcotic versus a nonnarcotic analgesic depends on the quality and intensity of acute pain experienced by the patient. Generally it is accepted to prescribe or recommend NSAIDs alone (e.g., ibuprofen, naproxen, naproxen sodium) or in combination with acetaminophen for mild-to-moderate pain (e.g., nonsurgical extraction, surgical endodontics, periodontal surgery). If NSAIDs are contraindicated in patients with peptic ulcers or sensitivity to NSAIDs (with asthma and nasal polyps), then acetaminophen can be substituted. Caution should be used in patients with severe liver disease, and, in general, it is recommended that patients not take more than 3 g/day of acetaminophen.

Narcotic analgesics are prescribed in severe dental pain (e.g., surgical extractions, advanced periodontal or implant surgery); however, upon acute administration, many significant adverse effects can occur, especially in opioid naïve patients.

Failure to Inform

Significantly, the I-STOP law skirts the issue of privacy. The law ignores the principle of autonomy. Neither the law, nor the nine pages of frequently asked questions, addresses the principle of autonomy. The new law does not require the doctor to ask for the patient's permission to search his or her controlled substance history. This is a breakdown in autonomy, as a reasonable person would want to know that his or her controlled substance history is being searched. On page 5 of the "Frequently Asked Questions" of the PMP Registry, the following question appears: "Can I share the report of my patient's controlled substance history with my patient?" The answer is, "Yes. Release of the information is allowed to your patients but should be based on your professional medical judgment. All state and confidentiality rules must be adhered to."

As confidentiality rules are based on the Reasonable Person Standard, the failure to share this information with the patient would violate this standard. Thus, the law should say that the release of the information is "required" as opposed to "allowed." Such a situation has the potential for triggering a conflict between the doctor and the patient. How could the doctor release information about the patient without having first obtained the patient's permission to search for such information? Accordingly, the new law places doctors in a conundrum: It may be OK to release information about a patient's controlled substance history, but searching for that information occurred without the informed consent of the patient.

Finally, in skirting the issue of privacy, the I-STOP law also skirts the ethical principle of veracity. Though the Department of Health is supposed to be ensuring that all professionals not violate the privacy of patients when complying with the I-STOP law, the department has yet to issue regulations that specify how professionals avoid violating that privacy. At present, in order to comply with the law, doctors are required to secure information without being required to obtain the consent of the patient when accessing the registry. Such an action is a breakdown in the sacred doctor-patient relationship. This de facto contract between doctor and patient is based on trust. By not being upfront with the patient in securing permission to search his or her controlled substance history, the patient's trust in the doctor has been violated. The principle of veracity has been compromised.

Though the new I-STOP law was passed with the noblest of intentions, it presents ethical quandaries for the profession with regard to beneficence, nonmaleficence, autonomy and veracity.

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