Legislative Alert: The Ban on Unauthorized Pelvic Exams

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Introduction

The performance of pelvic examinations on women who are under anesthesia for gynecological surgery has long been a standard educational practice in many teaching hospitals in the United States and other countries. Recently, however, widespread media attention has alerted the U.S. public that many female patients are not aware of these practices and do not always provide specific consent for these intrusive educational exams.[1, 2, 3] And for the first time, patients who learned that they were examined while unconscious for educational purposes have shared their accounts.[3] Consequently, the public outcry demanding justice and transparency with respect to these situations proved formidable and inspired efforts on the part of both advocates and academics. As a result, 22 bills seeking to ban unauthorized pelvic examinations have been put forth in 17 states since January 2019, and four have already become law. Before this present controversy, California, Hawaii, Illinois, Iowa, Oregon, and Virginia had already enacted legislation requiring consent for pelvic exams of women who are unconscious or under anesthesia.[4] Bills in Utah, Maryland, Delaware, and New York have also recently become law, and many more are working their way through the legislative process.[4] Here, we explore what we know about this practice, responses to it locally and abroad, and the ethical violations it involves. We then examine the legislation recently signed into law in New York, highlight aspects emerging as core protections in the laws recently enacted and proposed, and some remaining considerations.

Prevalence

Sparse data exists documenting the frequency or prevalence of the performance of pelvic examinations on women who are unconscious or under anesthesia in the U.S. The most recent empirical data with respect to pelvic examinations conducted on women under anesthesia includes two surveys of medical students from 2003 and 2005. The results of these surveys indicate that this practice was common during medical student education at several medical schools in Philadelphia and at the University of Oklahoma.[5, 6] More recent discussions (from 2007-2016, and 2018) within online forums for medical students suggest this practice is still occurring, although it is not clear where and how frequently.[7, 8, 9] It should be noted that there are varying policies and procedures, and jurisdictional requirements that guide different medical institutions about who precisely is obligated to obtain consent, the scope of the consent, and whether it is obtained verbally or documented in the medical record. In many instances, medical students are not a part of the consent process and remain largely unaware if consent was obtained for a pelvic examination on an unconscious or anesthetized woman,[10] and if consent was obtained, whether general or specific consent for a pelvic exam was provided. It is anticipated that legislation will help to ameliorate this confusion and offer clarity about the roles and responsibilities that physicians and medical institutions have to this vulnerable patient population. Because this practice takes place in teaching hospitals, unauthorized pelvic examinations are likely to occur most frequently on women under anesthesia who are also poor, uninsured, and belong to racial and ethnic minority groups.[10,11]

Professional Response

In 2001, the American Medical Association (AMA) Council on Ethical and Judicial Affairs advised that in situations "where the patient will be temporarily incapacitated (e.g., anesthetized) and where student involvement is anticipated, involvement should be discussed before the procedure is undertaken whenever possible."[12] They also proposed that in instances where a patient may not have the capacity to make decisions, student involvement should be discussed with the surrogate decision-maker involved in the care of the patient when feasible.[12] In 2003, the Association of American Medical Colleges (AAMC) called educational pelvic examinations without consent "unethical and unacceptable" in a press release.[13] In 2011, the American College of Obstetricians and Gynecologists (ACOG) issued a Committee Opinion stating that "pelvic examinations on an anesthetized woman that offer her no personal benefit and are performed solely for teaching purposes should be performed only with her specific informed consent obtained before her surgery."[14] Despite the position of these professional bodies governing medicine, the information above suggests that pelvic exams by medical students are still being performed without specific consent in some teaching hospitals.

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International Responses

Several other countries have also documented unauthorized pelvic examinations on anesthetized women during clinical encounters[15, 16, 17] and have taken measures to ensure consent is obtained. In the United Kingdom, ethical guidance from the General Medical Council (GMC) specifies that "before you carry out an intimate examination on an anesthetised patient, or supervise a student who intends to carry one out, you must make sure that the patient has given consent in advance, usually in writing."[18] Guidelines released by the Society of Obstetricians and Gynaecologists in Canada specify that if pelvic examinations are to be performed under anesthesia, "physicians and students must be explicit about student participation during the consent process."[19] A consensus statement put forward by several professional and institutional medical bodies in New Zealand reads: "Sensitive examinations under anesthesia require formal written consent obtained in advance and signed by the patient. It is essential that there should be no possibility for the consent to have any element of coercion (e.g., asking in front of a student may make it harder for a patient to refuse). Without such consent, a student cannot undertake such activity."[20]

Discussion

Ethical Violations

It has been argued that failing to specifically consent for educational pelvic examinations constitutes a violation of patients' autonomy and bodily rights and threatens the foundation of trust that the system of health care rests upon.[21] Trust is especially important in sensitive areas of medicine such as gynecology and in relation to practices such as the pelvic exam. A recent meta-analysis reported that during such exams, between 11% to 60% of women report experiencing pain or discomfort, while between 10% to 80% report fear, embarrassment, or anxiety.[22] This is likely to be linked, at least in part, to common experiences of sexual assault in the United States, where the lifetime prevalence of rape among women in the United States is 18.3%.[23] Furthermore, a harmful lesson is conveyed to medical students within this practice, as it suggests that bodies can be used as teaching tools without consent, promulgating paternalistic norms among the next generation of medical doctors.

Implied Consent

Some parties have articulated that consent is implied for pelvic exams because medical student involvement is indicated on the consent forms or because most people know such examinations may take place when they are receiving care in a teaching hospital.[24] However, critics point out that public awareness of medical education or teaching hospital practices is low and little explanation is usually given to patients when they are checked in.[10, 16, 21, 25] In addition, consent forms usually indicate that the involvement of medical students will be confined to patient care and do not specify that educational examinations, which do not lead to patient benefit, may also take place.[25]

Educational Status of Examinations

Some clinicians have taken the position that pelvic examinations are not merely educational but also offer a clinical benefit to the patient and are often necessary for the surgery,[26, 27] although this is arguably only the case if the student is performing the examination in place of the attending surgeon or resident, rather than duplicating an exam that already took place.[10] However, it has been pointed out that, this is rarely the case, as medical students are often legally prohibited from diagnosing and planning care during an intervention such as surgery.[28]

Necessity of Unauthorized Examinations

Some physicians maintain that educational pelvic examinations under anesthesia are integral to medical education and that requiring informed consent will pose a substantial barrier to such education. Pelvic examinations performed on those under anesthesia are especially useful for giving medical students a sense of the scope of unique pathologies that may be present before surgery, and may be felt more easily, since a patient's muscles are relaxed and the patient is not uncomfortable. Additionally, oth when surveyed and probed during clinical encounters, the majority of women stated they would consent to medical students performing pelvic examinations while they are under anesthesia.[29, 30] Importantly however, the vast majority of women also report that they would want to specifically consent before such an exam.[30, 31] Notably, many women said they would feel "physically assaulted" if they did not specifically consent to a pelvic exam performed while they were unconscious.[31] In a legislative memo, the New York Civil Liberties Union took the position that pelvic exams are "uniquely invasive, and without prior consent, these exams inflict a particularly unique and egregious gender-specific harm."[32]

Alternative ways for teaching students how to perform pelvic examinations, including standardized patients and mannequins, also exist.[21] These aids provide unique educational opportunities, in that standardized patients can be both accommodating and helpful in guiding students how to perform examinations in a sensitive manner while mannequins assist medical students in learning anatomy.[33]

Legislative Actions

Legislation in New York State

New York State (NYS) recently enacted legislation prohibiting the performance of unauthorized pelvic exams on anesthetized or unconscious patients. Two bills, NYS Senate Bill S.1092E and NYS Assembly Bill

A.6325C, were introduced in January and March of 2019, respectively. Both bills underwent significant permutations since their introduction. The most recent change to text, which was signed into law, reflects a more thoughtful process about the various clinical situations in which a woman may be unconscious and require a pelvic exam and the type of consent that is warranted. Moreover, the legislation seems to have some bite—that is, if it is not followed, there are implications of professional misconduct implications.

The bullets below provide a snapshot of recent action with regard to the aforementioned bills.

- January 10, 2019: 2019 NY S. B. 1092 is introduced.[34]
- March 5, 2019: 2019 NY A.B. 6325 is introduced.[35]
- June 11, 2019:Assembly Bill A.6325C is reported as the "Same As" Senate Bill S.1092E.[36]
- A bill with the "Same As" designation in the alternate house is a promising sign that a bill could pass both the Senate and Assembly because it signifies that individual lawmakers in each house are supportive of the bill.[36]
- June 14, 2019: NYS Senate repassed bill S.1092E; and Assembly bill A.6325C was reported to be on the floor.[37]
- June 18, 2019: A.6325C was substituted by S.1092E.[38]
- Bill substitution is a mechanism used near the end of a bill's lifecycle which permits both houses to pass a single bill (so that it can be delivered to the Governor) while preserving an official reference to identical bills still pending in the legislature. Bill substitution serves as a strong indication that the bill will pass both houses and will be delivered to the governor for signature or veto.[38]
- Bill S.1092E was put up for a vote in the Assembly and passed.[38]
- Bill S.1092E was returned to Senate.[38]
- Bill S.1092E was signed into law by the Governor on October 7, 2019.[39]

The new law requires that:

NO PERSON SHALL PERFORM A PELVIC EXAMINATION OR SUPERVISE THE PERFORMANCE OF A PELVIC EXAMINATION ON AN ANESTHETIZED OR UNCONSCIOUS PATIENT UNLESS THE PERSON PERFORMING THE PELVIC EXAMINATION IS LEGALLY AUTHORIZED TO DO SO **AND** THE PERSON SUPERVISING THE PERFORMANCE OF THE PELVIC EXAMINATION IS LEGALLY AUTHORIZED TO DO SO

AND:

(A) THE PATIENT OR THE PATIENT'S AUTHORIZED REPRESENTATIVE GIVES PRIOR ORAL OR WRITTEN INFORMED CONSENT SPECIFIC TO THE PELVIC EXAMINATION;

(B) THE PERFORMANCE OF A PELVIC EXAMINATION IS WITHIN THE SCOPE OF CARE FOR THE SURGICAL PROCEDURE OR DIAGNOSTIC EXAMINATION SCHEDULED TO BE PERFORMED ON THE PATIENT AND TO WHICH THE PATIENT HAS ALREADY GIVEN ORAL OR WRITTEN CONSENT;

OR

(C) THE PATIENT IS UNCONSCIOUS AND THE PELVIC EXAMINATION IS MEDICALLY NECESSARY FOR DIAGNOSTIC OR TREATMENT PURPOSES, AND THE PATIENT IS IN IMMEDIATE NEED OF MEDICAL ATTENTION AND AN ATTEMPT TO SECURE CONSENT WOULD RESULT IN A DELAY OF TREATMENT WHICH WOULD INCREASE THE RISK TO THE PATIENT'S LIFE OR HEALTH.[39]

Moreover, nothing in the law diminishes any other requirement to obtain informed consent for a pelvic exam or any other procedure.[39]

It is imperative to note that under the new law, it will be considered professional misconduct if someone performs a pelvic exam or supervises a pelvic exam(s) without informed consent or medical necessity. [39] The newly enacted legislation also adds a new subdivision to the education law which will "expand existing medical malpractice protections to include pelvic examinations or supervising the performance of a pelvic examination without informed consent or medical necessity."[34] The newly enacted legislation will take effect on April 4, 2020.[39]

Enacted and Pending Legislation in Other Jurisdictions

Legislation in other states varies in terms of the scope and requirements surrounding informed consent (see Figure 1). All of the pelvic exam bills but Nebraska's use an informed consent framework. The Nebraska proposal allows regulatory agencies to establish protocols. With the exception of Nebraska, all prohibit performing exams without consent. Like New York, Delaware bans supervising prohibited exams, as would five additional states. The overwhelming majority of the prohibitions in enacted and pending legislation apply to medical students; almost all apply specifically to physicians, a small number expressly name surgeons, nurses, physician assistants, and residents. New York's regulation applies to all persons while two of the newly enacted laws apply to all health care providers, which presumably include all of the specific categories in Figure 1; seven pending bills take a similarly expansive scope. All but Nebraska apply to anesthetized or unconscious patients, though New Jersey's and Texas's laws would apply to any patient. Each new law and every pending bill contemplates exceptional circumstances, the most common being necessary treatments or diagnoses. Some bills also provide an exemption that permits a court to order the exam for evidentiary purposes.

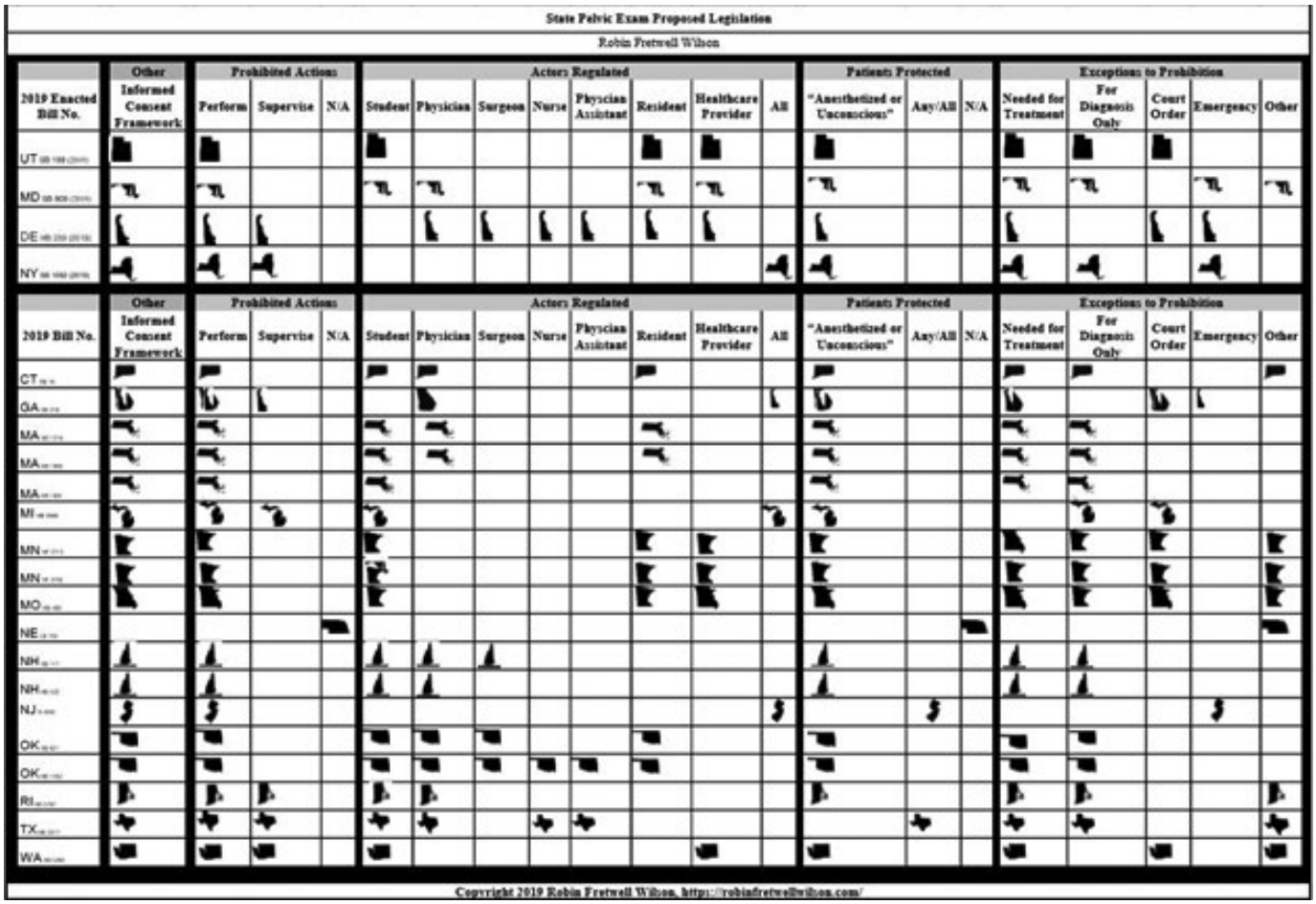

Figure 1. Recently Enacted and Proposed Bills Related to Unauthorized Pelvic Exams

Further Considerations

Scope of Legislation

The legislation recently passed in New York, along with many other states, concentrates on pelvic examinations specifically; however, a question remains as to whether this focus is too narrow. While there is no empirical data, and very little discussion surrounding unauthorized rectal (or other sensitive) examinations (on men or women) under anesthesia, there is some suggestion that such exams are occurring as well.[40, 41] This suggests that the scope of existing legislation, which largely focuses in on pelvic examinations rather than broadening out to include other intimate or sensitive examinations, may be too narrow.

Appropriateness of the Law as a Mechanism of Oversight

Of late, several concerned parties from the Yale University School of Medicine issued a statement in response to the proposed legislation requiring consent for pelvic exams under anesthesia in Connecticut. The statement opined that "the legislative process is imperfect and can have unintended effects" and advised that instead of seeking to legislate this process, we should "rely upon the relevant medical societies to set clear standards."[42] While this statement was written in response to a previous version of the bill, which was scarce in detail and has now been revised, this statement raises the question of whether legal paradigms are the most appropriate mechanism of oversight for responding to issues surrounding unauthorized pelvic exams.

It is clear that existing standards and recommendations have not been adequate to change the practice, so for the present time, the legal requirements that dictate the scope and limit of informed consent for pelvic exams appear to be the most impactful. Whether unforeseen negative consequences (e.g., missed educational opportunities) will occur remains unclear. To date the authors are unaware of any documentation of such consequences from institutions, states, or countries where specific consent is currently required. An alternative to or expansion of these legislative measures could be tying consent requirements to processes of accreditation, which require facilities to document compliance with guidelines or laws surrounding specific consent for pelvic exams, so that teaching hospitals will be motivated to ensure that consent is obtained in the proper manner. Note, however, that oral consent provides both flexibility and risk since it would need to be established in any litigation or misconduct proceeding. It would be important for providers to contemporaneously document

such oral consent, for example, in the patient's chart. Further, this flexibility in the law may make it difficult for accrediting bodies to effectively monitor whether specific consent is in fact being secured.

Penalty of Professional Misconduct

Now that New York Senate Bill S.1092E has passed, medical institutions and medical offices will need to have their operating procedures and consent forms revised. Moreover, medical providers will need to be educated about the new informed consent obligations because professional misconduct allegations and proceedings have serious implications. In New York State, penalties for professional misconduct may include any of the following: 1) censure and reprimand; 2) suspension of license (to varying degrees); 3) limitation of the license to a specified area or type of practice; 4) revocation of license; 5) annulment of license or registration; 6) limitation on registration or issuance of any further license; 7) a fine not to exceed $10,000 upon each specification of charges of which the respondent is determined to be guilty; 8) a requirement that a licensee pursue a course of education or training; and 9) a requirement that a licensee perform up to 500 hours of public service.[43] A question remains, however, as to whether some of the aforementioned possible penalties may be too harsh. For example, for a physician to have his or her license revoked because he or she was unaware of the law and proceeded with conducting an "unauthorized exam" may be considered severe. However, if a medical professional knowingly deviated from the law on multiple occasions despite repeated warnings and trainings, it may very well be justified. Essentially, it remains to be seen precisely how and to what extent this law will affect patient populations, medical facilities, and medical professionals.

Conclusion

More research is warranted in an effort to understand the frequency and prevalence of unauthorized pelvic exams on women who are unconscious and under anesthesia. Further legal action is also required in order to ensure that women are no longer being subjected to educational pelvic examinations without their consent while unconscious or under anesthesia. It is clear that most women do not expect such exams to take place and do not wish for them to take place without their specific consent. In order to respect their autonomy and bodily rights, and to retain trust in the system of health care, specific consent should be obtained. Requiring such consent will not jeopardize medical education. The solution is simple: obtain specific consent unless an emergency, or other compelling circumstances dictate otherwise. As a matter of public policy, the authors urge other states that remain silent on this issue to investigate the matter and implement legislation that will protect patient autonomy and dignity.

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