

## ***Don't Examine without Me – the Role of the Patient in Learning Pelvic Exams***

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### INTRODUCTION

Consent is indispensable to everyday society, enabling proper stewardship of people and resources whether used in general verbal communications or complex functions and transactions.<sup>1</sup> In healthcare, a patient requesting treatment must provide informed consent, which is defined as “a process of communication whereby a patient is enabled to make an informed and voluntary decision about accepting or declining medical care.”<sup>2</sup> Informed consent can only be given once a patient fully understands all relevant details pertaining to the medical options at hand, recommendations on interventions, and the potential risks, benefits, and consequences.<sup>3</sup> In reality some patients hardly think twice about what informed consent fully entails, what it allows, and what might call for detailed extra consent documents. It could be that they simply trust physicians to provide care and make relevant recommendations.

Patients in hospitals complete forms providing general consent to treatment upon registration and admission. They may also acknowledge on their forms that students from various professions (medical, nursing, physiotherapy, etc) may take part in their treatment. In teaching hospitals specifically, medical students are often entrusted with the responsibility of interviewing and examining patients, synthesizing differential diagnoses, and recommending lab and imaging tests to their clinical preceptors as part of their learning processes.<sup>4</sup> They can learn, through their preceptors' examples, how to empower patients in making informed decisions and how to balance evidence-based recommendations with each individual patient's treatment preferences.<sup>5</sup> By agreeing to work with students, patients not only enable teaching experiences to be incorporated within their own healthcare experiences, they also help guide students in growing into their roles as integral members of a patient's care team.<sup>6</sup>

Patients are protected by guidelines set by the Joint Commission on Accreditation of Healthcare Organizations, and by tenets of biomedical ethics which include as basic principles the four pillars: autonomy, beneficence, non-maleficence, and justice.<sup>7</sup> The principle of autonomy dictates that patients have the right to accept a treatment plan as is, to request changes to the plan, and/or to decline care from any treatment programs, teams, or participating members including students. There may be instances where patients do not want students involved despite agreeing to work with them in other capacities. A particular scenario arises when care involves more intimate areas such as sexual health. Patients may restrict who may do what, especially if the value of the exam or intervention seems unclear.

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## Evolution of Informed Consent

The concept of consent for treatment extends at least as far back to the ancient Greek and Byzantine empires.<sup>8</sup> Hippocrates and Plato both suggested the importance of patient buy-in prior to conducting an intervention, despite the then-status quo of not inviting patient involvement. This was further developed by Alexander the Great who after being wounded on the battlefield expressed his understanding of his situation to his doctors and asked them to treat him.<sup>9</sup> The Middle Ages largely continued previous attitudes about patient participation and consent in decision-making, and they shifted only minimally toward increased patient inclusion during the Enlightenment period.<sup>10</sup> Today's informed consent policy structure derives significantly from English common law surrounding assault which is commonly described as one individual threatening physical harm to another and battery which is one individual physically contacting another without permission.

*Slater v Baker & Stapleton* (1767) marked the first decision pertaining to informed consent in medicine, and further progress slowly continued through the nineteenth century.<sup>11</sup> The twentieth century laid foundations addressing the medical battery component of informed consent through cases including *Mohr v. Williams* (1905), *Pratt v. Davis* (1906), *Rolater v Strain* (1913), and *Scholendorff v Society of New York Hospitals* (1914).<sup>12</sup> In *Scholendorff*, Chief Justice Cardozo notably established the need for consent and reinforced a patient's right to self-determination.

Society's expectations around consent were further stimulated in the post-Nuremberg trial era. The case of *Salgo v. Leland Stanford Jr University Board of Trustees* (1957) formally marked the birth of the term "informed consent".<sup>13</sup> The process of informed consent was further refined through *Natanson v. Kline* (1960) which marked physician liability through negligence, *Cobbs v. Grant* (1972) which shifted the standard of disclosure from physician-based to patient-based, and *Canterbury v. Spence* (1972) which established a duty to disclose risks and the reasonable-person standard.<sup>14</sup> Together, they lend agency to the integral role of the four pillars of biomedical ethics in healthcare and guide the ongoing evolution of medical practice and medical education.

## At the Intersection of Sexual Health and Medical Education

Whether a patient signing a general consent for treatment constitutes permission for students to perform pelvic exams for educational purposes is an ongoing debate. In general, the pelvic exam is a clinical skill and an indispensable component of a physical exam. This is especially important when a patient presents with a relevant chief complaint such as abnormal vaginal bleeding, pelvic pain, or ruptured membranes in pregnancy.<sup>15</sup> Normally, these patients possess decision-making capacity and are able to choose whether they consent to a medical student performing a pelvic exam under proper supervision. The student then uses patient and preceptor feedback to further guide their examination, including terminating an exam at the patient's request. Concern arises though when patients are incapacitated, or unable to provide or withdraw consent, such as when under anesthesia for a surgical procedure.<sup>16</sup>

Patients have the right to voice their approval or disapproval of their care and generally have a say over who is on their care team and what functions they perform.<sup>17</sup> However, medical students historically learned how to conduct pelvic exams by practicing on patients under anesthesia without their prior knowledge or approval.<sup>18</sup> Some of these sessions included students who may not have been part of the patient's care team and patients whose surgical indications may not have warranted a pelvic exam under anesthesia.<sup>19</sup> Normally, physicians perform a pelvic exam under anesthesia prior to proceeding with a gynecologic surgery to understand the patient's anatomy and assess for abnormalities. For generations of medical students, these patients were a crucial means of acquiring experience in performing pelvic exams and progressing toward being ready to help patients upon their graduation. However, the

lack of patient consent to an education-based exam rather than or in addition to a medically-indicated exam violates today's informed consent standards and the principles guiding them.

### **Social Change Driving Changes in Society's Culture**

In response to how engrained educational pelvic exams under anesthesia were in medical education, women in the 1980s demanded additional consent requirements prior to undergoing educational pelvic exams in the operating room.<sup>20</sup> They asserted that performing them without additional consent constituted physical assault. Yet, the practice persisted even after the turn of the millennium: in the early 2000s medical students were still conducting educational pelvic and rectal exams without prior additional consent on anesthetized or unconscious patients.<sup>21</sup> This fueled new efforts to address concerns through the legislative process. As a result, various states passed legislation with requirements for additional consent for pelvic exams performed under anesthesia.<sup>22</sup> The Association of American Medical Colleges (AAMC) and the American College of Obstetricians and Gynecologists (ACOG) similarly emphasized that pelvic exams performed under anesthesia solely for educational purposes should only be done with a patient's informed consent obtained beforehand.<sup>23</sup>

Medical education programs responded to calls for change as well. Additional simulation components were incorporated into undergraduate medical education curricula, and students now work with standardized patients who specialize in the instruction of sexual health exams in clinical simulation encounters to develop their confidence and competence.<sup>24</sup> Therefore, without any non-consensual patient interaction, students acquire necessary experience and a faculty-appraised skill set to perform examinations on their clinical rotations. Yet, concern persists that educational pelvic exams done under anesthesia, regardless of consent, yield more educational value for the learner than diagnostic or therapeutic value for the patient. In response to this and other relevant concerns, society is witnessing an increasing number of blanket bans on student-conducted pelvic exams on anesthetized patients, regardless of patient consent. Rather than support or participate in the development of these bans, healthcare and medical education should continue encouraging design of meaningful processes for obtaining informed consent that both respect the rights of the patient and continue opportunities for student involvement.

### **Balancing Service versus Education**

Patients may perceive working with students as taking on more risk or burden without changes in their primary outcomes, *i.e.*, their health status, despite enabling desirable secondary outcomes, *i.e.*, further refining student skills to better serve future patients. Another way of framing this is that exams performed by students provide little to no direct benefit to the patient in the course of their own recovery, and continuing to do them has ongoing potential for unnecessary physical and psychological harm. While emotional appeals can be made to patients that today's doctors learned from yesterday's patients and that teaching today's students will benefit tomorrow's patients, healthcare does not mandate them to do so to receive care. As a result, students may continue to be excluded from various components of their patients' care in recognition of their preferences. This deference is supported by the American Medical Association (AMA) Code of Medical Ethics which opines that patient participation "in medical education is to the mutual benefit of patients and the health care system; nonetheless, patients' (or surrogates') refusal of care by a trainee should be respected in keeping with ethics guidance."<sup>25</sup>

Medical student opportunities for performing these exams are further limited by pelvic exam-related legislation as well. In some states, legislation even mandates not only medical students but surgeons as well to obtain specific informed consent prior to performing pelvic exams under anesthesia even when routinely indicated as part of a

surgical procedure.<sup>26</sup> On one hand, this is a reflection of the law being purposed to err on the side of patients' rights. On the other hand, the mandating of procedure-specific consent risks impeding delivery of quality and expedient patient care.<sup>27</sup>

For instance, if an alert and stable female patient in the emergency department is diagnosed with an unruptured ectopic pregnancy and elects for surgical management, normally, the physician performing the surgery will obtain consent from the patient to perform the recommended surgery. Unless instructed otherwise, medical students on their team are expected to ask permission to be part of her surgery as well. They could reasonably request, with minimal additional difficulty, additional consent to perform an educational pelvic exam under anesthesia under the supervision of the operating physician.

If the same patient presented altered and hemodynamically unstable, the physician would likely intervene through surgery under the premise of implied consent. A pelvic exam under anesthesia would similarly be performed prior to initiation of surgery for reasons as previously described. However, whether implied consent applies to medical students on the team to perform an educational pelvic exam under anesthesia is not clear. At least until medical and bioethical guidelines in this area are better defined, students should avoid participation in these circumstances.

### **The Road Moving Forward**

If medical students are expected to obtain additional consent from patients to perform pelvic exams for educational purposes, it is unclear whether they themselves would be expected to complete appropriate documentation with patients independently or under direct physician supervision. There may be novel legal risks that could impact cost of a medical school's student liability insurance and, in effect, exacerbate the fiscal burden of an already costly medical school education. Furthermore, if additional physician time is needed to supervise student acquisition of additional consent, there does not yet seem to be a clear solution to adapting existing workflows to promote both medical education and patient care without overburdening physician preceptor workloads.

Patient consent is essential to quality patient care. As suggested by Hippocrates, Plato, and Alexander the Great, a patient-physician relationship functions best when physicians pro-actively involve patients in the decision-making process.<sup>28</sup> It is also well-established that patient buy-in positively impacts patient care and health outcomes. Given the lessons learned through the evolution of tenets of biomedical ethics including the four pillars, it is incumbent upon students to consult patients beforehand for permission to perform educational physical exams under anesthesia. Furthermore, the healthcare system should positively incentivize the implementation of protocols for obtaining patient consent for performing educational physical exams under anesthesia. This should be done even if legislation mandating this informed consent did not exist. Doing so promotes both respect for the dignity and values of today's patient and the quality and integrity of tomorrow's physician.

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<sup>18</sup> Walker, *The Origins of the History and Physical Examination*. In: Walker HK, Hall WD, Hurst JW, Editors. *Clinical Methods: The History, Physical, and Laboratory Examinations*. 3rd Edition. Boston: Butterworths; 1990. Chapter 1.

<sup>19</sup> Friesen, "Educational Pelvic Exams on Anesthetized Women: Why Consent Matters."

<sup>20</sup> Bibby et al., "Consent for Vaginal Examination by Students on Anaesthetised Patients."

<sup>21</sup> Goldstein, "Practice vs. Privacy on Pelvic Exams"; Ubel, Jepson, and Silver-Isenstadt, "Don't Ask, Don't Tell: A Change in Medical Student Attitudes after Obstetrics/Gynecology Clerkships toward Seeking Consent for Pelvic Examinations on an Anesthetized Patient"; Schniederjan and Donovan, "Ethics versus Education: Pelvic Exams on Anesthetized Women."

<sup>22</sup> Dube, "Non-Consensual Pelvic Exams"; Oregon State Legislature, ORS 676.360 Pelvic Examinations; California State Legislature, AB-663 Pelvic Examinations; Hawaii State Legislature, 453-18 Pelvic Examinations on Anesthetized or Unconscious Female Patients; Virginia State Legislature, 54.1-2959. Supervised training programs; students enrolled in schools of medicine or chiropractic schools allowed to engage in certain activities; prohibition of unauthorized pelvic exams; Iowa State Legislature, 147.114 - Prior informed consent relative to pelvic examinations — patient under anesthesia or unconscious — penalties; McDay and Coleman, S.B. 188 CONSENT FOR MEDICAL PROCEDURE AMENDMENTS; Feldman, S.B. 0909 Health Care Practitioners - Medical Examinations on Anesthetized or Unconscious Patients.

<sup>23</sup> ACOG Committee on Ethics, "Professional Responsibilities in Obstetric–Gynecologic Medical Education and Training"; Weiner, "What 'Informed Consent' Really Means."

<sup>24</sup> Wolfberg, "The Patient as Ally--Learning the Pelvic Examination."; Pradhan et al., "Evaluating Pelvic Examination Training : Does Faculty Involvement Make a Difference ? A Randomized Controlled Trial Evaluating Pelvic Examination Training : Does Faculty Involvement Make a Difference ? A Randomized Controlled Trial"; Nitsche et al., "Effectiveness of Labor Cervical Examination Simulation in Medical Student Education."; Dumont et al., "Does an Advanced Pelvic Simulation Curriculum Improve Resident Performance on a Pediatric and Adolescent Gynecology Focused Objective Structured Clinical Examination? A Cohort Study."

<sup>25</sup> AMA Council on Ethical and Judicial Affairs, "AMA Code of Medical Ethics: Chapter 1- Opinions on Patient-Physician Relationships."

<sup>26</sup> Dube, "Non-Consensual Pelvic Exams"; Oregon State Legislature, ORS 676.360 Pelvic Examinations; California State Legislature, AB-663 Pelvic Examinations; Hawaii State Legislature, 453-18 Pelvic Examinations on Anesthetized or Unconscious Female Patients; Virginia State Legislature, 54.1-2959. Supervised training programs; students enrolled in schools of medicine or chiropractic schools allowed to engage in certain activities; prohibition of unauthorized pelvic exams; Iowa State Legislature, 147.114 - Prior informed consent relative to pelvic examinations — patient under anesthesia or unconscious — penalties; McDay and Coleman, S.B. 188 CONSENT FOR MEDICAL PROCEDURE AMENDMENTS; Feldman, S.B. 0909 Health Care Practitioners - Medical Examinations on Anesthetized or Unconscious Patients.

<sup>27</sup> American Medical Association, "H-320.951 AMA Opposition to 'Procedure-Specific' Informed Consent."

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<sup>28</sup> Bibby et al., "Consent for Vaginal Examination by Students on Anaesthetised Patients."; Silver-Isenstadt and Ubel, "Erosion in Medical Students' Attitudes about Telling Patients They Are Students."; Ubel and Silver-Isenstadt, "Are Patients Willing to Participate in Medical Education?"; Wainberg et al., "Teaching Pelvic Examinations Under Anaesthesia: What Do Women Think?"