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The Impact of Obtaining Explicit Informed Consent for Medical Student Participation in the Pelvic Exam Under Anesthesia: A Qualitative Interview Study

Research Article

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Abstract

The pelvic exam under anesthesia (EUA) is an essential step in gynecologic surgery. Attending, fellow, and/or resident physicians utilize exam findings for surgical planning. Afterwards, medical students often perform this exam for their own learning; the student exam provides no direct clinical benefit to patients. Historically, consent for trainee EUAs was embedded within the surgical consent form. At one urban academic medical center, a written consent form specifically for medical student participation in the pelvic EUA was introduced. Our study examines patient, physician, and operating room (OR) staff perceptions of this new, explicit consent process between May 2021 and May 2023. Thirty-one (31) subjects including patients, OR staff, and physicians were interviewed and Northwestern University IRB approval was obtained. Our data suggest patients appreciated being asked to explicitly consent to or refuse the student pelvic EUA and having a dedicated consent form left them with a positive feeling about the hospital and their healthcare providers. OR staff and physicians agreed that the student pelvic EUA is necessary and almost all supported an explicit consent form. Physicians did not find the additional consent form burdensome and noted only a modest decline in learning opportunities. Patients and healthcare providers agreed that requiring explicit written consent for the student pelvic EUA respected patient autonomy, improved healthcare quality, and caused minimal disruption to medical education. Our data support the use of an explicit written consent form for student participation in the pelvic exam under anesthesia as standard practice.

Keywords: Informed Consent, Medical Education, Autonomy, Pelvic Exam, Patient-Centered Care

Abbreviations: EUA: Exam Under Anesthesia; OR: Operating Room; MIGS: Minimally Invasive Gynecologic Surgery; NM: Northwestern Medicine

Introduction

In gynecology, the pre-operative pelvic exam is often considered essential to surgical planning and for detecting the presence of patholo-

gy[1] Surgeons may perform a pelvic exam on a patient who is under anesthesia prior to surgical incision to optimize safety by confirming the route of surgery, selecting proper equipment, and planning incision sites in real-time. Fellows and residents who actively participate in surgery examine the pelvic viscera for the same reasons. In addition to reducing patient anxiety, the benefit to performing a pelvic exam under anesthesia rather than in clinic pre-operatively, for example, is that relaxation of pelvic floor muscles allows for more thorough examination. Medical students may participate in the surgery under supervision in ways that provide patient benefit (e.g., by holding a retractor to allow for better visualization), but the advantage of students performing pelvic EUAs is solely educational. In training environments, there is a long history of medical students - regardless of their intended specialty - repeating this sensitive exam to advance their own understanding of the reproductive system and develop their physical examination skills[2]. Additionally, practicing pelvic exams under anesthesia allows the medical student additional time to better appreciate patient anatomy. However, for decades, this training practice occurred with limited patient knowledge and without explicit informed consent, raising both ethical and quality concerns[3,4].

Scrutiny of the medical student pelvic EUA without explicit patient consent is widespread in medical, [5-7] bioethical, [8-10] and legal literature[11]. Between 2001 and 2019, American medical societies guiding student education and gynecologic practice including the AMA, AAMC, ACOG, and APGO, have opined that patient consent for intimate exams is indispensable, and have condemned unconsented pelvic EUAs by students as ethically unacceptable and clinically irresponsible[9,12-15]. For example, a 2011 ACOG Ethics Committee Opinion (reaffirmed in 2017) states, "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]. Similarly, a widely used bioethics textbook instructs medical students that "senior physicians sometimes ask students to perform pelvic examinations on an anesthetized patient in the operating room without her consent. Consent for surgery, however, does not include consent for examination by students so that explicit consent for student examinations is required"[16].

During conversations about ethics, multiple third-year medical students told one author (KW) about their concerns that the broad surgical consent to include trainee participation was not sufficient consent for them to perform a pelvic EUA, and their resulting moral distress. This prompted two authors (KW and SG) to collaborate in bringing these concerns to the Gynecology Quality Improvement committee where consensus was developed for a new explicit consent form (available upon request) for the student pelvic EUA. Shortly thereafter, during a Town Hall version of Departmental Grand Rounds, authors described the need, reviewed the literature, and proposed a new consent form for introduction during the preoperative visit.

The aim of our study was to identify strengths and weaknesses in the new explicit consent form and reduce unintended harm from student performance of the pelvic EUA. We hypothesized that explicit informed consent for pelvic EUAs by medical students would strengthen patient autonomy, increase clarity around the role of learners, and improve patient-provider relationships, but possibly reduce opportunities for students to develop this skill.

Materials and Methods

Study Design

Following the introduction of a new explicit written consent form for medical student participation in the pelvic EUA, a series of qualitative interviews was conducted with patients, physicians, and gynecology OR staff with the goal of characterizing the impact of obtaining explicit consent on patient care, student education, and perioperative workflow. The number of participants remained flexible, with a goal of achieving saturation of concepts from semi-structured interviews within each of three subgroups[17]. In total, 10 patients, 10 physicians, and 11 OR staff members were interviewed via Zoom. This study was approved by the Northwestern University Institutional Review Board.

Participant Recruitment

Participants were recruited from the Minimally Invasive Gynecologic Surgery (MIGS) division at Northwestern Medicine (NM) in Chicago, Illinois. For the patient subgroup, we recruited patients undergoing gynecologic surgery who completed the explicit pelvic EUA informed consent or refusal form and who represented a range of patient demographics, major and minor surgeries, and indications for surgery. For the physician subgroup, we recruited attendings and fellows affiliated with NM who regularly perform pelvic EUAs alongside medical students. Finally, we recruited nurses and surgical technologists affiliated with gynecologic procedures at NM who regularly witness medical students participate in pelvic EUAs. During recruitment, we carefully monitored for equitable coverage of participant demographics across and within subgroups.

Data Collection and Analysis

Participants were contacted through email by a researcher to provide a copy of the study consent form and arrange the virtual interview. Verbal consent was obtained from each participant prior to their interview. Each interview followed an interview guide and ranged in duration from 5 minutes 9 seconds to 29 minutes 17 seconds (average 14 minutes 45 seconds); the interview guide was revised iteratively based on insight gained from each subsequent interview. Interviews were then de-identified and transcribed by researchers; the transcripts were shared with trained coders (RH and AZ) who analyzed the data systematically using a constant comparative approach. After independently generating a preliminary list of emergent themes for the data, the coders met to discuss initial thoughts, insights, and observations for the development of initial coding categories. Through a systematic analysis process, these analysts continually refined themes by collapsing redundant themes and removing irrelevant ones. Once no new categories emerged, coding dictionaries were developed for the remaining analysis. Coded data were summarized and the most important themes in terms of prevalence and impact were identified.

Results

Data collection occurred between May 2021 and May 2023. All 10 interviewed patients expressed that it was important for physicians to explicitly ask for consent to a medical student pelvic EUA. They explained this significance using concepts of vulnerability, trauma, and the importance of patient autonomy. Half relayed that patients undergoing the pelvic EUA were inherently more vulnerable than during other exams due to the intimate nature of the examination location and to being unconscious. Four discussed prior trauma history that they or others they know had endured through sexual assault. These patients explained they were not against student participation in pelvic examinations; they were willing if formally consented or if they were conscious for the exam. Underlying all patient feedback was the primacy of being able to decide what happens to their body under anesthesia and knowing who is performing which parts of an examination or operation. Four patients said the new explicit consent form increased their trust in their attending and surgical team, and three said it made them feel more "prepared and comfortable." One patient stated that if specific consent had not been solicited, "I would feel that it was assault...and given that it's an intimate exam, I would feel that it is sexual assault." Another patient said, "I would have been mad had I learned after the fact that this happened without asking me first." Finally, patients noted that explicit consent offered an opportunity for increased discussion and education to better understand their operation and the individuals involved in their surgical team.

Five patients volunteered that the explicit consent form positively impacted their impression of NM. Three patients explained that it

increased their respect for and trust in NM, sharing that the request for explicit consent and how the form was introduced made them feel that they were in the "best hands." Three patients used similar language to express that the form made them feel welcomed, empathized with, and cared for. Two patients said it made them feel respected and empowered. These patients felt that the explicit consent form was helpful, providing additional information and explanation they otherwise would not have received, and they appreciated the openness and transparency of the consent process. Five patients reported that the explicit consent form had no effect on their decision to give or not give consent, their relationship with their surgical team, or their surgical experience; one patient explained further, "I recognize[d] the need for [the student pelvic exam under anesthesia]." All 10 patients felt it was important to obtain explicit consent for the student pelvic EUA.

Two of the 10 interviewed patients offered informed refusal of medical student involvement in their pelvic EUAs. Both patients described their own complicated medical histories and expressed concern that the medical student pelvic exam may introduce unnecessary risk. One patient stated, "I think for me the concern would...[be]...the possibility of anything going wrong, like any injury to me or any kind of setback...just given all of the medical stuff I've been through...I think if you had any...statistics...something to just underscore that it's very rare that anything goes wrong...that might have helped." One of these patients also described feeling uncomfortable that the student was in the room during the consent form discussion. By contrast, two other patients wished that the student had been in the room during the explicit consent conversation to meet them and learn about their background. When asked how to improve the process of eliciting consent, five patients wished they had access to consent forms before the day of surgery so they could read them more carefully in advance.

The 21 interviewed healthcare providers – including physicians (n=10) and OR staff (n=11) - were asked if the new explicit consent form impacted their ability to work. None of them indicated a negative impact on their workflow or on their relationships with their patients. Nine of the 10 physicians interviewed now obtain explicit consent to the medical student pelvic EUA. Six of these nine physicians use the new written form while two verbally ask for explicit consent, including one who obtains verbal consent but also documents the conversation in the pre-operative note and adds "pelvic EUA" to the general surgical consent form. Most physicians (n=8) were actively involved in the explicit consent process and estimated that the form added two to four minutes to the pre-operative workflow, with a range of five added minutes to "about 20 more seconds." This same group estimated that 5% to 40% of their patients declined the student pelvic EUA, with clusters in the 5-10% and 20-30% ranges. One physician could not comment on the pre-operative time burden of the consent form or the proportion of patients who declined it due to delegating completion of the consent form to clinic staff.

Nine of 10 physicians supported the new explicit consent form and remarked on patient benefit. As one put it, "I think the patients appreciate the honesty, and I think that makes the collegiality between patients and the medical team better." Another said, "I don't want to ever be in that situation where someone was traumatized [by learning of a student pelvic EUA after the fact], and we're just sort of waking up now to some of the more subtle aspects of this." Some recognized student benefit as well. For example, one gynecologic surgeon described it as a "win-win": "[Patients] have a better understanding and knowledge of the procedure that they're having … it's a big win for our education, too, because our students now feel much more confident and comfortable that the exam they're doing has been consented for, and they don't feel like they're doing anything that violates patient autonomy." One fellow conveyed that explicit consent improved care quality by increasing patient trust and stated, "I will continue to do this in my own practice when I leave fellowship."

One of 10 interviewed physicians, a subspecialist, said they do not perform a separate pelvic exam under anesthesia before they start a procedure. Instead, they describe themselves as "examining the organ that I am operating on throughout the entire procedure." Thus, this physician found it unnecessary to use the new consent form for student pelvic EUAs because "student exam of the organ and the disease process is happening during their involvement in the actual surgery." This physician said they believed that explicit consent is only necessary for procedures with risk. In ORs where students do perform pelvic EUAs, this physician was concerned that the new form might impair learning in a detrimental way, since skill with pelvic examination is essential in many medical specialties. From this provider's perspective, we learned that not all gynecologic surgery incorporates student pelvic EUAs, and efforts to preserve patient autonomy in the setting of sensitive examinations should take specific provider practices into account.

Among the interviewed OR staff, a universal consensus emerged that explicit consent helped everyone feel more comfortable with student pelvic EUAs. One said, "I was honestly pretty excitedbefore this was implemented, I kind of was like a little hesitant just because I know if I was personally a patient, I might feel a little uncomfortable knowing that the medical student is performing something without my knowledge. So, I think that this has definitely...made me feel more comfortable and obviously our number one role as a nurse is to be an advocate for the patient." Another added, "I like that you can see it in their folder and just that it was documented explicitly that the patient had okayed it…Not that I didn't trust the surgical team, but, you know, it's nice to see it."

Discussion and Conclusion

This is the first qualitative study to examine the perspectives of patients offered explicit consent to or refusal of medical student pelvic EUAs before their gynecologic surgery, and of the surgeons and OR staff actively implementing such a consent process. Overall, patients appreciated being asked for explicit consent to student pelvic EUAs. Most surgeons and all OR staff viewed the pre-operative consent form as a necessary practice and did not find the consent form to significantly interfere with student learning or perioperative workflow. It was clear from our data that a standardized, written, explicit consent form for student pelvic EUAs respected patients' autonomy and created minimal disruption in learning. However, due to conflicting patient perspectives, our data does not provide direction on whether to include face-to-face interaction with students at the time of consent. Future work is needed to find an optimal approach.

Our study reinforces recent publications in the medical, bioethical, and legal literature as well as the media: patients deserve and expect to participate in informed decision-making in all aspects of their care, especially as it pertains to sensitive and vulnerable examinations like the pelvic exam. In addition to protecting patient autonomy, an explicit consent form for medical student pelvic EUAs may positively impact patient-provider relationships as well as those between healthcare professionals. Documentation of consent allows all stakeholders to independently confirm the patient's decision. In our study, both those directly involved in the medical student pelvic EUA (patients) and indirectly involved (surgeons and OR staff) indicated a sense of relief, trust, or reassurance when the consent process was explicit and documented.

For medical students, learning how to successfully perform a pelvic exam under anesthesia and translate physical examination findings into clinical recommendations is a critical skill, highly relevant for those who specialize in obstetrics and gynecology, family medicine, emergency medicine, and more. Use of manikins or models, teaching associates, or standardized patients have been proposed as alternative methods of practicing pelvic exams, though may not accurately reflect true anatomy and/or pathology. This study was, in part, inspired by the question of whether an additional preoperative consent form would lead to a decrease in learning opportunities for medical students, and

thus translate to inexperience with pelvic examinations in residency. Further, there are concerns that medical students, who are invaluable members of the healthcare team, would take on a more passive role in patient care should this learning opportunity be eliminated. Our study results are concordant with previous studies in Germany and Canada which show that patients prefer explicit consent and, if such consent is obtained, will often support student participation in a pelvic EUA during their surgery[18,19]. Our data suggests that, when presented with the choice to include a medical student in their care in this manner, most patients will grant permission.

Medical students have reported feeling coerced into performing pelvic EUA without explicit patient consent, experiencing moral distress as a result, and preferring explicit consent[5,20-22]. In a survey of students from six medical schools conducted in 2019 and 2020, 67% of students who observed patient consent processes on their OB-GYN rotation most or every time reported that they never or rarely witnessed an explicit explanation that a medical student may perform a pelvic EUA.20-22 This report on student experience contrasts with a 2022 survey of institutional policies, in which 79% of responding OB-GYN clerkship directors reported that their program required explicit consent for the medical student pelvic EUA, including 28.4% that required verbal and 71.6% that required written consent[23]. However, as these survey authors note, a disjuncture between policy and student experience might be explained by differences in individual attendings' knowledge and use of the consent policies. It is also possible that the 56% of clerkship directors who did not respond to the survey on the APGO listserv may overrepresent programs that lack policies requiring explicit consent for medical student pelvic EUA[24]. Student knowledge may be lacking too—in a survey of a single school's medical students, only 40% correctly identified that institution's process for obtaining informed consent for educational pelvic EUAs[22]. Our study suggests patients, OR staff, and physicians support medical student participation in pelvic EUAs, which allows for a more robust medical education in preparation for residency, so long as explicit informed consent is first obtained. Future studies may incorporate medical student perspectives and explore whether students should be involved in the conversation to obtain consent.

The rationale behind an explicit consent form for medical student participation in the pelvic EUA aligns with an overall shift in healthcare towards providing patient-centered care; in fact, other surgical specialties, including general surgery, colorectal surgery and urology, are making similar efforts to gather explicit consent when involving students in sensitive exams under anesthesia[24]. Why, then, has it taken so long to implement this practice in gynecologic surgery? One possibility is a lack of awareness among attending surgeons of negative patient and student experiences caused by the absence of explicit consent. Both patient and student perspectives are expressed in the academic literature and lay press[25] but may be silenced in clinical practice by hierarchical norms. Some educators may be concerned that if patients are explicitly asked, they will refuse student participation, which may compromise learning. Time constraints may contribute to clinician resistance since informed consent conversations can be lengthy and potentially burdensome to busy clinics and OR schedules. At most academic medical centers, the general surgical consent form includes broad consent for student participation in care, and some argue this means patients have already consented to pelvic EUA by learners. More pernicious justifications, while hopefully rare, may include paternalistic arguments (such as, "what patients don't know won't hurt them"), a preference for "business as usual" despite knowledge of the associated harms, and implicit biases even in medical encounters that potentially facilitate violence against women. A combination of interrelated factors is likely at play.

Institutional barriers also contribute. Statements from medical associations may be firm and unambiguous, but they may lack enforcement mechanisms. Similarly, state legal requirements are increasingly common, but they rarely include implementation strategies or accountability measures[7]. For example, in a letter to the nation's teaching hospitals and medical schools released on April 1, 2024, the United States Department of Health and Human Services (via Centers for Medicare & Medicaid Services (CMS)), stated, "...as part of medical students' courses of study and training, patients have been subjected to sensitive and intimate examinations – including pelvic, breast, prostate, or rectal examinations – while under anesthesia without proper informed consent being obtained prior to the examination. It is critically important that hospitals set clear guidelines to ensure providers and trainees performing these examinations first obtain and document informed consent from patients before performing sensitive examinations in all circumstances. Informed consent includes the right to refuse consent for sensitive examinations conducted for teaching purposes and the right to refuse to consent to any previously unagreed examinations to treatment while under anesthesia"[26]. (On the same date CMS also issued a memo addressed to State Survey Agency Directors on the same topic titled "Revisions and clarifications to Hospital Interpretive Guidelines for Informed Consent," CMS Memo # QSO-24-10-Hospitals). Health systems may lack incentive to enact and enforce the structural changes needed to upend long-standing behavioral patterns. Furthermore, there is no data on how healthcare systems may go about changing this practice pattern. Only one study, now over 20 years old, surveyed medical school deans and students on the topic of consent for the pelvic EUA and narrated follow-up actions taken by the institution[5]. The authors briefly described updating guidelines, presenting the topic at educational meetings and "grand rounds", and including it in introductory medical student sessions on professionalism. However, there was no follow-up on the changes, and no other studies exist on the implementation of an explicit consent form or an associated policy change. While these explanations do not justify failure to obtain explicit informed consent for the student pelvic EUA, they do highlight practical barriers to institutional change.

One limitation of this study is not including interviews with medical students. However, there was concern for response bias secondary to the evaluation of medical students by attending and fellow physicians for their clerkship scores; additionally, medical students may be considered a vulnerable population. Further, since medical student perspectives are well-represented in the literature,[21,22,27] we focused instead on the gatekeepers to clinical policy implementation (physicians and OR staff) and the patients who are impacted by these policies. The author who previously heard a significant number of medical students express their concerns about doing pelvic EUA without explicit consent before the new form was created can report anecdotally that, since form creation, only one student has raised a concern about implementation of the form, and others have expressed gratitude for it.

As with most qualitative studies, we recognize that selection bias can occur at various stages of the research process. We tried to mitigate convenience sampling by reaching out to a variety of gynecologic surgeons (e.g., obstetrics and gynecology specialists and subspecialists) and by providing a variety of times and locations for the research interviews based on interviewee preferences and availability. Since this topic affects surgeons who work with trainees and individuals who may have strong opinions on student pelvic EUA, as well as patients who may have personal experience with sexual assault or sexual violence, self-selection bias may be present. Future studies could mitigate this effect by incorporating an expanded sample size.

Areas for future study include determining the proper timing of the discussion of the pelvic EUA performed by a student in the operating room, determining which individuals can and should request informed consent (attending surgeon, fellow, resident physician or student), standardizing documentation of the informed decision-making

discussion (to replace inconsistent documentation of verbal consent conversations that is noted in the chart), and determining how best to ensure that patients truly feel free to give or withhold consent.

In conclusion, asking patients for explicit consent for the medical student pelvic EUA should be considered integral to high-quality patient care. It should not cause trepidation because, in this study, it was welcomed by both patients and staff and did not significantly impede medical student learning opportunities.

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Conflicts of Interest

None

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