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Written Testimony in Support of HB 2371 (Rep. Robbins)
Presented by Mollie Montague, Director of State Legislative Affairs with RAINN

Honorable Co-Chairs and members of the committee, I write to offer our support for HB 2371 (Representative Robbins), which would ensure patients in Minnesota do not wake from anesthesia to find they were subject to an invasive pelvic exam without their knowledge. Requiring informed consent protects physicians, students, and parents and supports best practices. We urge you to advance this bill.

RAINN is the nation's largest anti-sexual assault organization. Founded in 1994, RAINN created and operates the National Sexual Assault Hotline (800.656.HOPE and hotline.rainn.org). RAINN also carries out programs to support victims, educate the public, and improve public policy.

Intimate examinations, which include pelvic, prostate, and rectal examinations, are medically necessary routines that healthcare professionals conduct to assess the health of internal organs. Many medical students perform practice examinations on patients, who are under anesthesia for other procedures and have not provided explicit, informed consent for the pelvic exam.

A study of medical students from U.S. medical schools showed 61% of respondents who had performed a pelvic exam on an anesthetized patient reported doing so without the patient's explicit consent. A study at the University of Oklahoma found that nearly 75% of these women had not consented to the medical student's exam. Furthermore, 72% of women expect to be asked for permission before an exam under anesthesia (EUA), and 62% say they would consent if they were asked. This is uncomfortable and possibly retraumatizing for patients, and also places medical students in difficult situations. As they navigate the power dynamics involved in their education, students should be supported in practicing asking for informed consent rather than feeling such actions may compromise their learning.

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RAINN has heard from survivors regarding unauthorized pelvic exams on patients, despite many medical institutions publicly stating they do not allow the practice. We know that some of these survivors avoid needed medical care out of fear that an undisclosed exam will be practiced on them while they are unconscious. Iowa, Illinois, Ohio, Virginia, and more than 20 other states require informed consent for these exams. American College of Obstetricians and Gynecologists (ACOG) and the American Medical Association (AMA) Code of Medical Ethics support informed consent practices for unconscious educational exams. Additionally, The U.S. Department of Health and Human Services (HHS) issued a memorandum 2024 addressing involuntary pelvic exams and supporting state's requirements of explicit informed consent. We encourage Minnesota to join the growing number of states ensuring transparency and trust in medical environments.

HB 2371 would require explicit informed consent before any possible pelvic examination. Requiring informed consent for invasive pelvic exams will improve the quality of every patient's experience with the medical field and maintain a person's agency over their body during medical interactions. Especially for survivors of sexual assault, ensuring that medical interactions are transparent and safe protects against retraumatization and avoidance of needed healthcare from fear. Transparency cannot occur without both the comfort and consent of patients and medical professionals.

We urge you to move this bill forward and stand with survivors of sexual violence in Minnesota. I stand prepared to answer your questions about this issue and the nationwide effort to protect physicians and patients. Thank you for your consideration and continued leadership.

Protect unconscious patients from unwanted pelvic exams!

"Our oath as medical students and physicians is to do no harm to the patient. Performing unauthorized pelvic exams on anesthetized patients for the sole purpose of medical student education violates this principle and may cause unacceptable psychological harm to patients. No learning opportunity is worth sacrificing a patient's well being." - Proponent testimony from a medical student on Ohio legislation requiring informed consent for educational pelvic exams

- 61% of medical students who performed a pelvic exam on an anesthetized patient reported doing so without the patient's explicit consent. A study at the University of Oklahoma found that nearly 75% of women had not consented to a gyno exam by students.
- 72% of women expect to be asked for permission before such a procedure, and 62% say they would consent if they were asked.
- American College of Obstetricians and Gynecologists (ACOG), the American Medical Association (AMA) Code of Medical Ethics, & the U.S. Department of Health and Human Services (HHS) support informed consent practices for unconscious practice exams.

About RAINN

Over the last 30 years, RAINN has served over 3 million survivors through the National Sexual Assault Hotline.

Require permission before invasive educational exams on patients under anesthesia! HF 2371 (Rep. Robbins)

The physician-patient relationship is built on a foundation of trust & this law would ensure that starts during medical training.

- MN law allows medical professionals and residents to perform pelvic & rectal exams on unconscious patients during **unrelated** operations **without the patient's knowledge.**
- This practice violates the patient's trust, puts medical professionals in awkward sitations, & can traumatize survivors of sexual violence, **causing them to avoid future medical care.**
- Requiring explicit informed consent prior to these exams **gives the support of the law to physicians and students** building a culture of communication & consent.
- This bolsters faith in physician training by **requiring informed consent before these practice procedures.**
- At least 25 states have passed laws banning unauthorized pelvic exams to ensure transparency & permission is prioritized for all patients, including: Iowa, Illinois, Ohio, Arkansas, Maryland, Florida, Virginia, Idaho, & Missouri.

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Goldberg, E. (2020, February 17). *She didn't want a pelvic exam. she received one anyway.* The New York Times.
Dr. Tsai, Jennifer. (2021, November 29). *Medical students regularly practice pelvic exams on unconscious patients. should they?* ELLE.
Coleman, E. (2021, April 13). *States move to protect anesthetized women from non-consensual pelvic exams.* Route Fifty.

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Medical Student Perspectives on the Ethics of Pelvic Exams Under Anesthesia: A Multi-Institutional Study☆

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OBJECTIVE: Pelvic examinations under anesthesia (EUAs) are routine components of gynecologic surgery and often used to educate students about female pelvic anatomy. This multi-institutional survey study aims to describe students' experiences with conducting educational pelvic EUAs and their attitudes around the ethics of informed consent for these exams.

DESIGN: An anonymous survey of Likert and open-text response questions about institutions' practices around educational pelvic EUAs was sent to medical students.

SETTING: Medical schools included Vanderbilt University School of Medicine, Indiana University School of Medicine, Emory University School of Medicine, University of New Mexico School of Medicine, Meharry Medical College, and Warren Alpert Medical School of Brown University.

PARTICIPANTS: A total 305 medical students who had completed their obstetrics and gynecology (OB/GYN) clerkship between June 2019 and March 2020 filled out the survey (33% response rate).

RESULTS: Overall, 84% of students performed at least 1 pelvic EUA during their clerkship. Of the 42% (142) of students that observed patient informed consent processes most or every time, 67% reported they never or rarely witnessed an explicit explanation that a medical student may perform a pelvic EUA. Analysis of open-text responses found that students wanted to uphold patient autonomy but felt they did not have the personal autonomy to object to performing pelvic EUAs that they believed were unconsented. They faced significant emotional distress when consent processes were at odds with their personal ethos and professional ethical norms. Students favored more standardized and explicit patient consent processes for educational pelvic EUAs.

CONCLUSIONS: While students regularly perform pelvic EUAs, their involvement is inconsistently disclosed to patients, causing significant distress to students and risking erosion of students' attitudes about upholding patient autonomy and informed consent. Medical institutions must develop consistent, ethical, and patient-centered processes for trainee disclosure around pelvic EUAs. (J Surg Ed 79:1413–1421. © 2022 Association of Program Directors in Surgery. Published by Elsevier Inc. All rights reserved.)

KEY WORDS: Autonomy, Biomedical ethics, Informed consent, Medical education, Professionalism, Trainee disclosure

COMPETENCIES: Patient Care, Professionalism, Interpersonal and Communication Skills

INTRODUCTION

The 2008 Association of American Medical Colleges (AAMC) Recommendations for Clinical Skills Curricula

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include pelvic examinations as a skill that medical students must learn prior to graduation.[1] The process of learning this physical exam maneuver generally involves didactic lectures, simulation on plastic models, and instruction from gynecologic teaching associates. Students then hone this skill by performing pelvic exams on conscious patients in ambulatory clinics or on anesthetized patients undergoing gynecologic surgery.

In 2019, the Association of Professors of Gynecology and Obstetrics (APGO) stated that students should only perform pelvic exams under anesthesia (EUAs) when the exam is directly supervised, explicitly consented to, directly related to the procedure, and only performed by a student who is part of the care team.[2] The American College of Obstetricians and Gynecologists Committee on Ethics also stated 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."[3] Interpretation of these guidelines is still variable within and across institutions and reflects the medical field's variable definition of "informed consent."[4]

After several publications in the lay media describing unconsented educational pelvic EUAs incited public outrage, state legislators, professional societies, and bioethicists have called for reform ranging from changing informed consent guidelines to completely banning this educational practice.[5-8] Several states have passed legislation limiting the scope of pelvic EUAs, from requiring the exam to be relevant to the procedure to needing patient informed consent for any medical personnel to perform a pelvic EUA.[8]

Medical students who perform pelvic EUAs are often caught in an ethical dilemma of advancing their skills for the benefit of their future patients while respecting the autonomy of their current patients. Research on medical student perceptions of consent processes for pelvic EUAs is limited and has yet to capture any qualitative analysis of student experiences, including the complex ethical dilemmas students face in trying to achieve informed consent for pelvic EUAs.[9-13] This multi-institutional survey study aims to describe students' experiences with conducting educational pelvic EUAs and their attitudes around the ethics of informed consent for these exams

MATERIAL AND METHODS

Survey Development

Two medical students identified research domains (demographic information, student role, student experiences, consent processes) and developed a survey containing Likert scale and open-text questions. Then an expert committee of Obstetrics and Gynecology (OB/GYN) clinicians and bioethicists reviewed the survey for content validity. Five medical students separate from the sampling group at the primary institution, Vanderbilt University Medical Center (VUMC), piloted the survey. The students were aware of the research domains and study aims. The survey was modified to reflect their feedback and improve face validity of the survey instrument (Supplement A).

VUMC served as the central Institutional Review Board and data coordinating center for this multi-institutional study. Exempt Institutional Review Board approval was obtained as the survey excluded identifying information to ensure student anonymity.

Participant Recruitment and Survey Distribution

We identified 6 medical schools to represent a geographically diverse sample of public and private institutions. A collaboration of OB/GYN clerkship directors and medical students at each institution identified medical students who completed their OB/GYN clerkship between January 2019 and March 2020. For students meeting this inclusion criteria, each school's study coordinator distributed the survey by email between February and September 2020. Two email reminders were sent. No incentives were given or implied, and survey completion had no impact on clerkship evaluations. Survey data was captured using Research Electronic Data Capture, a secure web-based platform, and stored on encrypted VUMC servers.[14]

Statistical Analysis

We performed statistical analyses using SPSS Statistics Version 17.0 for Macintosh (SPSS Inc, Chicago, IL). We used the Kruskal-Wallis test to compare distributions of ordinal variables across groups. We used Chi-square analysis to compare categorical variables and ANOVA for continuous variables. Content analysis was performed on open-text responses using NVivo Software Version 1.3.2 (QSR International, Melbourne, Australia).[15] One researcher developed codes using an iterative process looking for emergent themes aimed at understanding student perspectives. Codes were triangulated between institutions and with the quantitative data to validate the codes generated. Utilizing codes generated from 3 institutions to compare against the other institutions showed that the codes generated reached saturation.

RESULTS

We surveyed 925 students across 6 institutions with an overall response rate of 33% (n = 305). Response rate by institution and characteristics of each school are listed in Supplement B. Of the survey respondents, 57.4% (n = 175) identified their gender as female and 41.3% (n = 126) identified as male. One respondent identified as non-binary, 1 as genderqueer, and 2 did not report their gender identity.

Overall, 84% (n = 254) of students reported having performed at least 1 pelvic EUA during the OB/GYN clerkship. Of those students, the mean number of exams per student across institutions was 5.7 (SD 4.2). The mean number of exams per student at each institution was statistically significantly different between study sites ($p < 0.001$) (Supplement C). There was no statistically significant difference between the overall number of female-identifying respondents who performed a pelvic EUA compared to those who identified as male ($p = 0.85$). The total number of nonbinary and genderqueer participants was too small to statistically analyze.

Twenty-four percent (n = 73) of students overall strongly agreed with the statement "I consider the bimanual exam to be different from other operating room activities in which medical students participate (suturing, cutting, retracting)", while 15% (n = 47) disagreed with this statement. Answer distribution was not significantly different between study sites. Table 1 summarizes all Likert scale responses. Thirty-six percent of respondents (n = 109) strongly agreed with the statement "I consider the bimanual exam under anesthesia to be a different learning experience than a bimanual exam in the outpatient clinic setting," while only 6% (n = 18) disagreed. Overall, 64% (n = 194) of students strongly or somewhat agreed that pelvic EUAs were important to their learning. We found no significant difference in distribution between male and female gender identity, but did observe variability between institutions (Supplement D). In open-text responses some students discussed how practicing pelvic EUAs helped with the identification of abnormal exam findings, allowed for real-time feedback from attendings, and gave students the time they needed to practice bimanual exams without causing physical discomfort to the patient.

When asked if the medical community should continue educating students through pelvic EUAs, 56% (n = 172) of students overall strongly or somewhat agreed; however, 25% (n = 77) of students disagreed or somewhat disagreed. We found no significant difference in distributions between respondents of female and male gender identity. Analysis of open-text responses illustrated a spectrum of student opinions about the nature, purpose, and setting of educational pelvic EUAs (Fig. 1). Some students felt that pelvic EUAs should not be treated differently than other procedures, while others felt that the sensitive nature of the exam made it innately different. Some students felt that by coming to a teaching hospital, patients inherently agree to learner participation in their care, while others felt that patients have the

TABLE 1. Levels of Agreement With Statements About Performing Pelvic Exams Under Anesthesia From Survey Respondents Across All 6 Institutions (n = 305)

Statement	Disagree n (%)	Somewhat Disagree n (%)	Neither Agree Nor Disagree n (%)	Somewhat Agree n (%)	Strongly Agree n (%)
"It was a clear expectation that students should introduce themselves/be introduced to patients preoperatively when on a surgical gynecology service."	8 (3)	16 (5)	11 (4)	58 (19)	212 (70)
"I consider the bimanual exam to be different from other operating room activities in which medical students participate (suturing, cutting, retracting)."	47 (15)	50 (16)	30 (10)	105 (34)	73 (24)
"In my opinion, conducting a bimanual exam on a patient under anesthesia in the operating room was important to my learning."	30 (10)	29 (10)	52 (17)	109 (38)	85 (28)
"I consider the bimanual exam under anesthesia to be a different learning experience than a bimanual exam in the outpatient clinic setting."	18 (6)	34 (11)	34 (11)	110 (36)	109 (36)
"In my opinion, the medical community should continue educating students on the bimanual exam by having them perform it on patients who are under anesthesia in the OR."	52 (17)	25 (8)	56 (18)	99 (33)	73 (24)

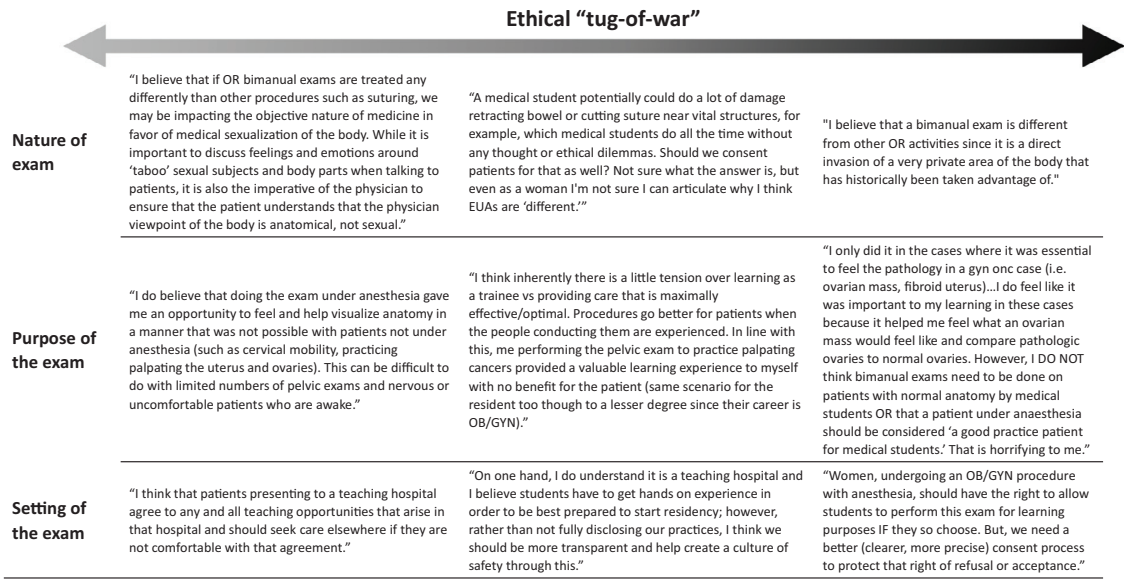

FIGURE 1. Select quotations from open text responses that illustrate the range of medical student opinions on the practice of pelvic exams under anesthesia, representing an ethical "tug-of-war" amongst peers.

right to choose who specifically participates in pelvic EUAs regardless of the setting.

Eighty-nine percent (n = 270) of respondents strongly or somewhat agreed that it was a clear expectation that students should introduce themselves or be introduced to patients preoperatively when on a surgical gynecology service, with similar trends across study sites. When asked how students' roles were most often introduced to the patient, 44% (n = 134) said they were introduced/introduced themselves as "a medical student." Fewer respondents reported being introduced/introducing themselves as "a medical student who will be assisting in the surgery" (n = 87, 29%) or "observing the surgery" (n = 55, 18%). Only 5% (n = 15) of respondents said their introduction included a description of specific procedures they would perform (e.g., suturing, knot tying, physical exam, etc.).

While 42% (n = 142) of students overall reported that they observed the informed consent process during their gynecology rotations every time or most of the time, we saw significant variability in the reported frequency of these observations between institutions (Fig. 2). Of the respondents who observed the informed consent process every or most of the time, 40% (n = 50) reported it was rarely or never explicitly explained to a patient that a pelvic EUA would be conducted by an attending or resident, and 67% (n = 85) rarely or never witnessed explicit explanation that a medical student might perform this exam during the procedure (Fig. 3).

When asked to select any processes they believed were important to achieve informed consent for pelvic EUAs, 55% (n = 168) of students suggested a consent form that listed "pelvic exam under anesthesia" as part of the planned procedure and mentioned "medical students" as members of the clinical team. Forty-nine percent (n = 150) endorsed a consent form explicitly stating that a medical student may perform an educational pelvic EUA, and 47% (n = 143) felt that explicitly asking the patient for verbal consent for a student to perform a pelvic EUA was appropriate. Only 11% (n = 32) of students felt a completely separate consent form for an educational pelvic exam was necessary, and 16% (n = 49) thought using a consent form with no mention of a pelvic exam under anesthesia was sufficient.

Students also felt conflict between their own moral understanding of the consent required for invasive procedures and the perceived approval gained by simply following instructions from senior members of the medical team. This is highlighted in this open-text response, "I felt pressured to perform pelvic exams under anesthesia even though I was uncomfortable with it. I was afraid that the attendings and residents would think I didn't want to learn if I didn't perform the exam. Looking back, that's a pretty cowardly perspective but it's my truth." Students commented on the importance of upholding patient autonomy, but felt they themselves did not have the autonomy to object to performing pelvic EUAs (Fig. 4).

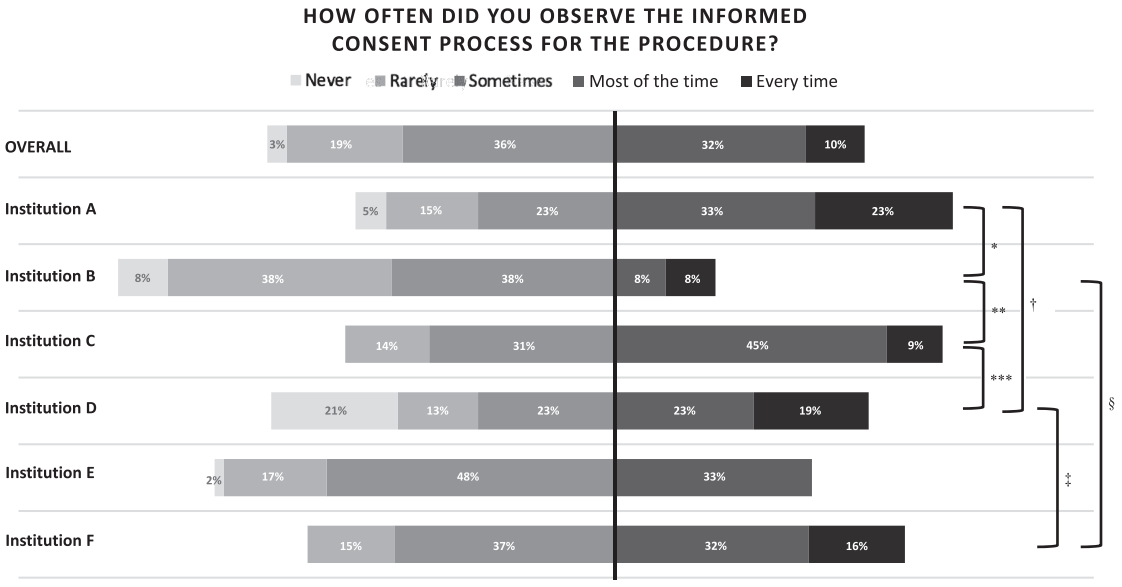

FIGURE 2. Reported frequency of students observing the informed consent process during the gynecology rotation. Institutions have been de-identified. *p = 0.013, **p = 0.009, ***p = 0.012, †p = 0.026, ‡p = 0.023, §p = 0.015.

DISCUSSION

In this multi-institutional survey study of medical students, we found that a large majority performed pelvic EUAs during their OB/GYN clerkship, but student involvement was inconsistently disclosed to patients during consent processes. A 2003 study of 5 Philadelphia medical schools found that a majority of students performed a pelvic EUA, though it was unclear how many of those exams were consented.[11] Our study confirmed the results by Zuchelkowski et al. at a single medical school, which found that students believed EUAs were important to their education and also favored more explicit informed consent processes for pelvic EUAs.[13] Additionally, our study provides qualitative descriptions

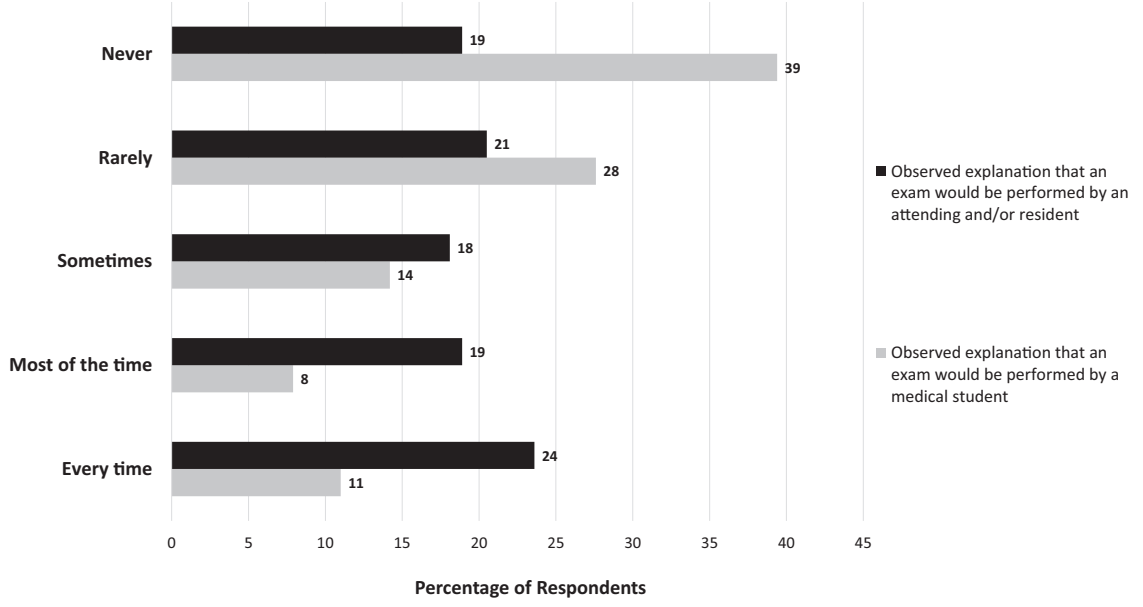

FIGURE 3. Percentage of medical students observing explicit explanation to the patient during the informed consent process that a pelvic exam under anesthesia would be conducted by an attending/resident or a medical student. Responses were from students who had reported observing the informed consent process every time or most of the time (n = 128).

FIGURE 4. Examples of open-text responses that reveal students' aspirations to promote patient autonomy but how disempowerment of their personal autonomy undermined these efforts.

of the ethical conflicts students face in performing these exams.

In our study, a majority of respondents said it was a clear expectation that students should be formally introduced to a patient prior to participating in their gynecologic surgery, and a majority reported abiding by these expectations. During these introductions, the level of transparency about the students' involvement in the operating room was variable, with a tendency towards not explicitly disclosing the pelvic EUA. Though decades old, this is reflective of the results from a 1988 study about student candidness about their status as a student when introducing themselves to patients. They found students were less forthright about their status when given the opportunity to perform invasive procedures.[16] Even so, studies have shown that many patients are willing to allow medical students to perform pelvic EUAs, but patients want to be asked for permission first.[9,17] This sentiment is shared by the students in our study, who generally favored more explicit consent processes, either verbal or written, informing patients that a pelvic EUA would be part of the procedure and potentially performed by a student.

A large proportion of students who regularly observed the patient consent process on their gynecology rotations reported it was not a regular practice for residents and attendings to explicitly discuss the possibility of a pelvic EUA being performed in the operating room by them or by a medical student. Although every study site had information in their consent forms about pelvic EUAs and general language about medical student involvement in patient care, it is questionable whether the lack of direct discussion with patients aligns with the APGO guidelines, which state that students should only perform pelvic exams under anesthesia (EUAs) when the exam is explicitly consented to.[2] It is also important to consider how the inconsistencies in disclosure about pelvic EUAs can affect students' attitudes about informed consent. A 1999 study found students placed less importance on patients being informed of students' roles in surgery compared to patients, and this difference was greater in clinical students compared to preclinical. Authors posited that as students advance in their medical training, they "suffer an erosion in their attitudes about telling patients they are students."[18] Similarly, a 2003 survey study found that students who had completed the OB/GYN clerkship thought that consent was significantly less important than students who had not completed their clerkship, pointing towards a change in attitudes toward seeking consent for pelvic EUAs.[11]

The 2003 study highlights that medical school is a formative time for future physicians to develop their professional ethics and practices around informed consent. In our study, student's open-text reflections demonstrated a sophisticated understanding of the concept of informed consent and how it should be practiced. However, we also found that inconsistencies between what was taught in the classroom and what was observed in actual practice caused significant distress for students.

We highlight the emotional strain students faced when consent processes and clinical practices are at odds with their personal ethos or the ethical norms they are taught in class. We found that students wanted to preserve patient's autonomy but often felt they didn't have the personal autonomy to do so due to expectations by their medical teams. Medical education has the duty to both teach students about the concept of informed consent and then consistently demonstrate how it is achieved in practice. By not performing the latter, we risk erosion of students' attitudes about informed consent.

Strengths and Limitations

Building on prior research on this topic, our study looked to better understand the current state of consent practices for pelvic EUAs, as well as students' experiences and ethical perceptions around performing these exams. By capturing student attitudes through both Likert scale-style questions and open-text responses, we were able to illustrate the variability in perspectives and experiences within and across medical institutions. By drawing on multiple geographically and demographically diverse institutions, we have increased the generalizability of our results and captured a wide range of medical student opinions.

We acknowledge the risk of non-response bias in our study. Respondents to our survey were 57% female-identified; on average, the demographics of possible survey respondents across different medical schools were 53% female-identified (see supplement B). Our data thus reflects a slight over-representation of female-identified students. To protect student identities, we limited the demographic information we collected to just students' gender identities, thus making it difficult to characterize our responders and non-responders. We therefore did not assess whether the race of the student, provider, or patient affected informed consent processes. This would be important to study in the future. We also acknowledge the risk of recall bias when asking students to reflect on past experiences, especially for those furthest removed from their OB/GYN clerkship. To protect student identities, we did not ask when students completed their clerkship during the 15-month study period. This prevented us from controlling for the time between the clerkship and survey completion. However, by limiting our respondent selection to those that had completed their clerkship during this 15-month period, we limited variation in year-to-year practice. We also only collected data from students who completed clerkships prior to COVID-19 related curricular interruptions. Additionally, as dictated by institutional policies, survey solicitation emails came from students at some institutions and the clerkship director at others. At sites where the clerkship director sent the survey email, response rates were lower than at sites where a student coordinator sent the email. Despite these limitations, our study did describe the current status of informed consent processes for medical students performing pelvic EUAs across multiple medical institutions and students' opinions on the educational utility of and consent processes needed for performing pelvic EUAs.

Future Directions

Further investigations of patient preferences around the practice of pelvic EUAs, and the timing and content of informed consent for these exams are warranted. Future directions would also include gathering self-identified race/ethnicity of students, providers, and patients as there are dynamics to be explored between structural racism and informed consent. Furthermore, study of patient and student experiences with other intimate exam maneuvers that occur in other surgical subspecialties under anesthesia, such as rectal examinations and male genitalia exams, is merited.

CONCLUSIONS

Our study highlights variability in consent processes for pelvic EUAs, as well as significant student distress when they felt they were forced to examine patients without appropriate consent. This warrants the development of consistent trainee disclosure processes within standard consent procedures, with the goal of reducing variability across medical centers and relieving student and patient distress. This is important for both patient and student safety and well-being.[4] These guidelines should be created in conjunction with all relevant stakeholders—patients, physicians, residents, and medical students—and revised regularly to represent current societal norms and regulations around informed consent. We specifically recommend the incorporation of explicit discussions with patients about pelvic EUAs during consent processes for gynecologic procedures, including potential student involvement. These conversations should occur between attending, fellow, or resident physicians and the patients, and not between students and patients, although students should observe these conversations, when possible, for their own education. We believe this better aligns with current APGO and American College of Obstetricians and Gynecologists guidelines.[2,3] These changes would be a starting point for medical institutions to generate ethical, patient-centered policies around pelvic EUAs that promote both patient and student autonomy.

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SUPPLEMENTARY INFORMATION

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.jsurg.2022.05.015.