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## ETHICS CASE

### Is Proxy Consent for an Invasive Procedure on a Patient with Intellectual Disabilities Ethically Sufficient?

Commentaries by Stephen Corey, MD, and Peter Bulova, MD, and by Sonya Charles, PhD

Dr. Smith, a family medicine physician, is preparing for a full day of patient appointments. She is looking over the chart of Stephanie, a new patient, who is here for an annual physical. Stephanie is 30 years old and has autism. Dr. Smith notices that Stephanie has had regular uneventful periods but has never had a pap smear. Dr. Smith knows that pap smears are recommended for all women starting at the age of 21, so she makes a mental note to ask specifically about any previous pap smears and enters the room to meet Stephanie, who is sitting quietly in the corner, looking intently at one of the pictures hanging on the wall. Dr. Smith first introduces herself by saying, "Hi Stephanie, my name is Dr. Smith, but you can call me Julie. Nice to meet you." Stephanie looks up and nods but does not say anything. Dr. Smith introduces herself to Stephanie's caseworker, Hannah, then turns back to Stephanie and asks, "Tell me how you have been doing over the past year, Stephanie."

Stephanie waves her hand, expressing "so-so," and Hannah explains, "She's nonverbal, but you can ask me any questions you need to know. I have her whole file and know her well." As the conversation progresses, Dr. Smith learns that Stephanie has lived in a group home for about 15 years. She struggles with some behavioral problems at the home and has difficulty communicating her needs to the staff.

Dr. Smith remarks, "I notice that Stephanie has never had a pap smear before, at least according to our records. I wanted to check and make sure that information is accurate, since we would typically recommend this important screening for a patient of her age."

Hannah responds, "Yes, that is correct. It has been discussed in the past, but we have always been concerned that a pap smear would be too distressing for her. Stephanie is very sensitive to sensory stimuli, especially anything painful. She's required to get a flu shot every year to live in the group home, and it's always so awful for her. I am not sure that a pap would be worth her distress, especially because she is not sexually active."

Dr. Smith wonders if this is true. She asks, "Have there ever been any concerns about sexual abuse with Stephanie?"

Hannah answers, "Certainly not since she has been in the group home. She is very well supervised, and we have never had any problems with abuse among our staff. But we have very little information about her life prior to coming to the group home. She does not have any family involved in her care at this time."

Dr. Smith replies, "Screening recommendations are indeed recommendations and not requirements, so I am open to discussion about the pap smear for Stephanie. However, given her unclear history I am inclined to err on the side of doing one. There is a high rate of sexual abuse in patients with intellectual disabilities. Since we do not know much about her previous history, I would rather be safe than sorry."

Hannah sighs and says, "Well, Stephanie has dental work done under sedation every year, so perhaps she could just have her pap smear done at the same time. She wouldn't even have to know it was done. We have done it before with some of the other residents, and it was a great solution."

Dr. Smith considers Hannah's suggestion, but she feels uncomfortable performing such an invasive procedure if it can only be done by deceiving the patient and by using a sedative as a chemical restraint. Dr. Smith feels that doing a vaginal exam and cervical test without Stephanie's knowledge or consent to be more ethically problematic than doing a routine dental exam. She worries that performing the pap without permission of a sedated patient borders morally on rape. Even though Hannah is Stephanie's official decision maker, Dr. Smith wonders whether it is ethical to leave Stephanie out of the decision entirely.

### **Commentary 1** **by Stephen Corey, MD, and Peter Bulova, MD**

Informed consent is a cornerstone of medicine and ethics and is generally regarded as a foundational expression of a clinician's respect for a patient's autonomy. No procedure can legally or ethically be performed without consent. However, consent decisions for patients with intellectual disabilities are typically legally assigned to a surrogate, usually a relative or caregiver. In Stephanie's situation, the case suggests that her autism is so disabling that she does not have decision-making capacity and so cannot give informed consent. It is assumed, therefore, that she also does not have the capacity to give an informed refusal. From a legal perspective, she can neither consent nor refuse. But what about from an ethics perspective?

The case suggests that Stephanie gets dental care under sedation, and that consent for this is given by Hannah. Should it be any different for a pelvic exam and pap test? What are ethically relevant considerations when deliberating about how we ought to regard

consent, assent, or refusals for patients with intellectual disabilities? The rest of this article considers these questions.

### **Justifiability of Restraint**

Even though patients with severe developmental disabilities can require restraining for activities of daily living such as meals, medications, shots, and bedtime, and even when consent has been legally obtained from a surrogate decision maker who endorses these reasons for physical restraint of a patient, we suggest that there are good reasons to question whether physical restraint is appropriate to facilitate a pelvic exam for Stephanie. We argue in what follows that the use of physical restraint is inappropriate in this case. Additionally, we argue that there should be no exceptions to respecting the refusal of a person with intellectual disabilities to undergo an invasive exam if physical restraint is required to carry out the exam, even if the patient's surrogate authorizes the use of physical restraint.

The use of anesthesia, is, however, ethically acceptable in our view. It is acceptable to do a pelvic exam at the same time as Stephanie's dental work. Stephanie might resist having an intravenous needle for anesthesia and consequently may need to be physically restrained by the arm for this procedure, but, in our experience, most caregivers would feel that the surrogate's legal consent to physically restrain a patient for insertion of an intravenous needle for the purpose of anesthesia administration is appropriate, if it is absolutely necessary to facilitate an important procedure or treatment.

### **Distinguishing a Pelvic Exam from Dental Work**

Restraining Stephanie for a pelvic exam is different from restraining her to facilitate the dental work. Dr. Smith has concerns that performing a pap without Stephanie's permission might constitute rape. But, if a clinician has legal consent and either anesthetizes or gains the cooperation of the patient, it certainly would not be rape. The pap test not only detects cancer of the cervix, but can also detect precancerous conditions that are 100 percent curable if treated early. When appropriately performed, a pelvic exam and pap test do not incur physical trauma. With an anesthetized patient there's no reason to expect that a patient would be physically or mentally traumatized. Additionally, there are significant benefits, including screening for sexual abuse that would not be discovered any other way. However, if, as a clinician, you still feel the procedure performed under anesthesia would in any way cause a degree of trauma similar to that caused by rape, then you ought absolutely not to do the procedure.

Dr. Smith considers not even doing a pap test. This brings up the question of what kind of reproductive health care should be given to a woman with an intellectual disability. Some suggest that the answer is *the same care that would be given to a person without a disability*. So, if women with a disability should have the same reproductive health care as women without a disability, this means that, like care for other patients, a decision to do

something should be based on whether the patient needs it and after deliberating collectively on the balance of risks and benefits involved.

There are cases in which one should consider the patient's refusal of an indicated procedure, even though the patient does not have capacity to refuse appropriate care. This again requires evaluating the risks and benefits of the procedure in context [1].

### **Assumptions about the Sexual Lives of People with Intellectual Disabilities**

So does Stephanie need a pap test? Clinicians might assume that patients with disabilities have low rates of sexual activity, and therefore that a pap smear is not indicated [2]. This is a myth; there is a significant rate of sexual activity, as well as sexually transmitted infections, among women with disabilities. Although it does not specify whether sexual contact is consensual, the National Study of Women with Physical Disabilities found that 94 percent of respondents were sexually active, with sexually transmitted infection rates the same as in women with no disabilities [3]. Although women who have never been sexually active are at low risk of cervical cancer and abnormalities on a pap test, to assume a particular woman with a disability is in that category does not take into account the high rate of sexual abuse, which is more commonly experienced by women with disabilities than women in the general population. One literature review found that people with developmental disabilities were 4 to 10 times more likely to be victims of violence and/or sexual assault [4].

Sexual abuse can also be difficult to detect. Women with intellectual disabilities might lack the verbal skills to report abuse [5] and are more likely than women without disabilities to experience abuse at the hands of someone we assume can be trusted, such as attendants, caregivers, and even health care professionals (M.A. Nosek, PhD, unpublished data, 2003). While Stephanie's caregiver does not suspect that Stephanie has ever suffered sexual abuse, it is still a possibility, and therefore it is the responsibility of the physician to consider and screen for it.

And how ought we to determine whether the benefits of the pap smear balance or outweigh the risks? Guidelines recommend pap tests on all women ages 21 to 65 who have a cervix [6]. At age 21, Stephanie would not be due for another pap for three years. Should Stephanie be given anesthesia for an annual pelvic exam when she is not due for a pap? The American College of Obstetricians and Gynecologists (ACOG) recommends annual gynecologic exams whether or not a pap test is due [7]. ACOG does not specifically address this issue in women with disabilities or those without decision-making capacity. The organization does not clarify whether and when these recommendations would change for a patient who is assessed as needing anesthesia to undergo the exam. However, given the additional risks of anesthesia, we would not recommend doing yearly pelvic exams for an asymptomatic woman who needs anesthesia for her exams. Instead, we would recommend only doing a pelvic exam when

the patient is due for a pap test, since the potential benefits might not outweigh the risks in these cases. We recommend reviewing the benefit/risk ratio on a case-by-case basis.

However, it is important to make sure that this recommendation does not lead to underscreening of cervical cancer for women with intellectual disabilities. In the past, physicians have underscreened: overall, women with intellectual disabilities receive poorer-quality general health care and have significantly lower rates of screening for cervical cancer than women without intellectual disabilities [2]. Yet, screening has become more important than ever, and there is a national movement to improve screening practices in this population [8]. People with intellectual and physical disabilities are now living longer lives than they once did [9], and intellectual disability might have only a minor impact on a person's longevity [9, 10].

Instead of forgoing screening, clinicians need to find ways to make care more accessible and acceptable for those with disabilities. For example, in this case, one possible alternative, particularly for patients whose disability does not substantially compromise their manual dexterity, is a "self-collected" cervical sample performed by the patient or a trusted caregiver [11]. Given her sensitivity to physical stimuli, it's not clear whether self-collection would be an option for Stephanie, but we offer it as an option that might be suitable for some patients.

We would like to clarify here that anesthesia can describe relieving pain, discomfort, and anxiety, and does not necessitate unconsciousness that might be inferred from the term *sedation*. Regardless of whether Dr. Smith decides to give Stephanie a pap smear under anesthesia or obtain a sample some other way, maintaining a respectful environment for the patient—through strategies such as explaining the procedure beforehand with words or pictures in a manner appropriate to the patient's health literacy level, having the patient tell the clinician when she is ready for him to begin, and honoring her requests to stop or pause—is paramount [12], as is preventing Stephanie's experience from being negative or frightening. Additional strategies for doing so include having a trusted caregiver present and reducing the anxiety-provoking effect of stimuli by introducing equipment and people during a preprocedure visit. Implementing these strategies would require the physician explicitly to clarify that his conduct is therapeutic and neither intentionally sexual nor abusive. Clinical language used by the physician should explain the examination processes thoroughly. Counseling done by people experienced in working with patients with intellectual disabilities might also help Stephanie through an examination.

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## Commentary 2

by Sonya Charles, PhD

At the end of the case scenario, Dr. Smith “worries that performing the pap without permission of a sedated patient borders morally on rape.” Some might find this attitude perplexing, but this commentary will show this is a valid concern. While it might be *legal* to perform a pelvic exam and pap test action with proxy consent, we can still ask whether and when it is *ethical*. Chemical constraint—sedation, in this case—can count as a form of coercion. If chemical restraint is required to subdue a patient or quell her verbal or nonverbal expressions of resistance or opposition to a pelvic exam, then it does begin to look a lot like rape. According to the Department of Justice, the definition of rape is this: “The penetration, no matter how slight, of the vagina or anus with any body part or object, or oral penetration by a sex organ of another person, *without the consent of the victim*” (emphasis added) [1]. As we can see, consent is the crucial element in determining whether and when penetration is defined as rape. Thus, the main issues in this case are information disclosure and the patient’s capacity to respond to that information. I will argue that Dr. Smith and Hannah owe Stephanie a developmentally appropriate conversation at her level of health literacy about their concerns and suggested course of treatment. If possible, they should obtain Stephanie’s assent to continue. To illustrate why this is ethically required, I consider two relevant practices: nondisclosed pelvic exams in teaching hospitals and assent for children unable to legally consent to treatment.

### **Controversy Regarding Nondisclosed Pelvic Exams: The Example of Teaching Hospitals**

To begin, let us consider the similar issue of nondisclosure of [pelvic exams on sedated women](#) at teaching hospitals. If a woman has routine gynecological surgery at a teaching hospital, she (like everyone else) will likely sign a consent form that includes a blanket consent to allow students to examine and do procedures on her. Historically, teaching hospitals have used this as an opportunity for medical students to practice vaginal exams and have not required any explicit consent for them [2]. After some controversy in 2003, many hospitals revised their practices to require explicit consent for pelvic exams [2, 3] and some states instituted legal requirements [4]. However, blanket consent is still perfectly legal in most places, and some hospitals continue to perform pelvic exams on unconscious women without explicit consent [5]. Those who argue against the practice claim that women would be “upset” [3] and some anecdotal evidence suggests that many women would feel “violated” [6] to find out that this could be happening without their explicit consent.

I believe the uneasiness that many medical students and women feel about this practice is because of the parallels to rape [7]—especially since research shows that many women are willing to give consent for a pelvic exam in a teaching context when they are explicitly asked [2]. When fully autonomous women—despite having voluntarily signed

blanket consent forms—are being penetrated (sometimes by multiple people) without their knowledge or explicit consent [5, 6] and are not comforted by the legality of blanket consent [4], it suggests that consent for a particular examination at a particular point in time for a particular purpose (presumably, a clinical or teaching purpose) is important.

Since ethical questions have been raised about vaginal exams on unconscious women who are (presumably) fully competent [2, 4, 5], it is certainly worth taking a closer look at the ethics of a pelvic exam for Stephanie in this case, particularly if her unconsciousness is required to carry it through. Given patients' alarm at penetration without specific disclosure, I argue that, if any physician plans to perform an invasive procedure or examination on an unconscious woman, he or she is ethically required to disclose this information to the patient—in a way appropriate to that patient's health literacy level.

### **Disclosure to Patients Not Legally Able to Give Consent: The Example of Children**

Next we more fully consider health literacy and the role of the patient's decision-making capacity—specifically at what level she is able to participate in this decision. In Stephanie's case, some readers may feel that disclosure of an intended pelvic exam might be irrelevant or counterproductive because they assume that Stephanie will not understand it. I argue that it is health professionals' responsibility to disclose in a way the patient can understand.

When it comes to informed consent, autism creates a special challenge. While some individuals on the autism spectrum are highly intelligent and have a good understanding of what people are saying to them, some may have problems with expressive communication. For this reason it seems impractical to make a general response to the question of whether proxy consent is appropriate for all patients with autism or other kinds of intellectual disabilities—even those with court-appointed guardians. I will, therefore, consider this question only for Stephanie as an individual in this particular case. We are told Stephanie is nonverbal, lives in a group home, and has a legal guardian [8]. However, it is also clear from her brief exchange with Dr. Smith that she has some ability to communicate; Stephanie appears to understand Dr. Smith's general question and to appropriately respond. With this in mind, would it be possible for her to participate in some kind of patient education or consent process? We have a clear example of such processes in pediatric ethics.

Most children are not legally allowed to give consent for health care treatment. Yet, the Committee on Bioethics for the American Academy of Pediatrics (AAP) strongly encourages developmentally appropriate disclosure and an attempt to obtain assent [9]. So, there seems to be a relevant consensus in the pediatric community that

Patients should participate in decision-making commensurate with their development; they should provide assent to care whenever reasonable.



Parents and physicians should not exclude children and adolescents from decision-making without persuasive reasons [10].

Let me clarify that, in referring to the AAP statement, I am not trying to infantilize those with disabilities. Rather, I am using this statement to establish precedent for involving patients in the decision-making process even when they are not legally able to give informed consent. Children have legally recognized proxy decision makers—their parents—but the AAP recognizes the inadequacy of proxy consent (especially as children get older) and promotes a policy of transparency and empowerment [9]. To better assess our current case, it is worth reviewing this summary of specific AAP recommendations for obtaining assent, which should include at least the following elements:

1. Helping the patient achieve a developmentally appropriate awareness of the nature of his or her condition.
2. Telling the patient what he or she can expect with tests and treatment(s).
3. Making a clinical assessment of the patient's understanding of the situation and the factors influencing how he or she is responding (including whether there is inappropriate pressure to accept testing or therapy).
4. Soliciting an expression of the patient's willingness to accept the proposed care. Regarding this final point, we note that no one should solicit a patient's views without intending to weigh them seriously. *In situations in which the patient will have to receive medical care despite his or her objection, the patient should be told that fact and should not be deceived* [11] (emphasis added).

If children (even young children) deserve this level of disclosure and consideration, it is very difficult to argue that Stephanie does not.

### **Recommendation**

Dr. Smith and Hannah should explain their concerns and what they plan to do in a way that meets Stephanie's level of understanding. Explaining that they would like to sedate her so that she can avoid the unpleasant sensory experiences that cause her distress can and should be part of this discussion. Stephanie clearly knows that she is sensitive to stimuli and might welcome the sedation. Indeed, sedation as a chemical constraint is not coercive or an unjustifiable use of force *if one has consent or assent* from the patient.

Furthermore, as we see from the AAP recommendations, even if Stephanie does not assent and Dr. Smith and Hannah decide there are good reasons to proceed with this procedure anyway, they still have an ethical responsibility to *disclose* as fully as possible

to Stephanie what they are planning to do. To sedate her and penetrate her without disclosure does indeed put their (technically legal) actions dangerously close to the definition of rape.

Finally, we must consider that current practices set precedents for future practices—which makes disclosure and assent even more necessary for establishing an ethical track record of patient care over time. So, what might this mean for Stephanie? If the pap is performed and there are precancerous or cancerous cells, what then? Presumably, Stephanie would need a series of medical procedures in order to determine the severity of her health issue and to treat it. Would this mean that Dr. Smith is now faced with the need to repeatedly sedate Stephanie and perform invasive treatments? Even if no problems are found during the initial exam, it is likely Dr. Smith and Hannah would consider other preventative exams in the future. Therefore, how Dr. Smith approaches this exam will set a precedent for his future treatment of Stephanie and with other patients.

In sum, I argue that disclosure and assent are crucial in this case. Controversy noted above over practicing pelvic exams on unconscious women without their explicit knowledge and consent suggests that legal consent does not always coincide with ethical practice. Fortunately, the AAP guidelines for obtaining assent from pediatric patients provide an example of how we might meet ethical standards in our current case. Even though Stephanie has a legal guardian, it is clear that she also has some ability to understand and communicate. For this reason, Dr. Smith and Hannah owe Stephanie an explicit discussion about their proposed plan of treatment.

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### **Related in the *AMA Journal of Ethics***

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