

SUBJECT TO RESOLUTION COMMITTEE REVIEW

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 006
(JUN-21)

Introduced by: Resident and Fellow Section

Subject: Ensuring Consent for Educational Physical Exams on Anesthetized and Unconscious Patients

Referred to: Reference Committee on Amendments to Constitution and Bylaws

1 Whereas, Patient autonomy is one of the basic tenets of medical ethics and includes the
2 patient's right to accept, modify, and refuse treatment^{1,2}; and
3
4 Whereas, A patient desiring treatment must provide informed consent which can only be given
5 after being informed of their diagnosis, if known, the nature and purpose of any recommended
6 interventions, and the anticipated risks, benefits, and consequences of all options³⁻⁵; and
7
8 Whereas, The American College of Obstetricians and Gynecologists (ACOG) defines informed
9 consent as "a process of communication whereby a patient is enabled to make an informed and
10 voluntary decision about accepting or declining medical care"⁶; and
11
12 Whereas, A patient's provider is legally and ethically obligated to inform patients as part of the
13 consent process any party who can be reasonably anticipated to be part in their care team
14 including but not limited to residents, nurses, students, and allied health professionals^{3,7}; and
15
16 Whereas, Teaching hospitals historically used the generalized consent form as permission to
17 perform exams of the genital areas, including for educational purposes, without deliberately
18 informing patients of opportunities to limit how any care teams or their members could be
19 involved in their care experience^{4,8-14}; and
20
21 Whereas, In the 1980s, women vocalized demands to be asked for additional explicit consent
22 prior to undergoing educational pelvic exams in the operating room and indicated that doing so
23 without this consent constituted physical assault¹⁵; and
24
25 Whereas, Surveys conducted in 2003 in Philadelphia and 2005 in Oklahoma found medical
26 students were still conducting educational pelvic and rectal exams on anesthetized or
27 unconscious patients without having obtained prior consent to do so^{12,16,17}; and
28
29 Whereas, Educational pelvic exams were historically performed on patients under anesthesia in
30 operating rooms without explicit patient consent, including by medical students not directly
31 involved or not reasonably anticipating to be involved with the patient's ongoing care and when
32 the patient's surgical indications did not warrant a pelvic exam¹⁸; and
33
34 Whereas, Varying attitudes on educating medical students on invasive exams compounded with
35 pressures on students to achieve high academic and clinical marks may contribute to erosion of
36 consideration for scenarios when additional patient consent is indicated^{16,19-24}; and

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1 Whereas, The Association of American Medical Colleges (AAMC) and ACOG both emphasize
2 that pelvic exams performed under anesthesia for educational purposes should only be done
3 with a patient's informed consent prior to conducting the exam^{4,24}; and
4

5 Whereas, Various states have passed legislation outlawing educational pelvic exams and/or
6 pelvic exams in general, potentially even when indicated as part of a procedure, on a woman
7 who is anesthetized or unconscious without prior consent to specifically do so^{14,25-32}; and
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9 Whereas, The Joint Commission maintains that patients may decline participating in elements of
10 clinical training programs, such as working with medical students^{12,33}; and
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12 Whereas, The AMA Code of Medical Ethics states that patient "participation in medical
13 education is to the mutual benefit of patients and the health care system; nonetheless, patients'
14 (or surrogates') refusal of care by a trainee should be respected in keeping with ethics
15 guidance."³⁴; and
16

17 Whereas, While patients are often open to learner involvement in their care, they may deem
18 scrutiny of more private body parts, particularly when solely for educational purposes, to warrant
19 specific consent beyond the level provided for general care and treatment^{15,35-37}; and
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21 Whereas, Use of professional standardized patients who teach female pelvic, male
22 genitourinary, and rectal exams have already demonstrated significant value in medical
23 education and further highlight the unnecessary nature of educational genital exams performed
24 without explicit patient consent³⁸⁻⁴⁰; therefore be it
25

26 RESOLVED, That our American Medical Association oppose performing physical exams on
27 patients under anesthesia or on unconscious patients that offer the patient no personal benefit
28 and are performed solely for teaching purposes without prior informed consent to do so
29 (Directive to Take Action); and be it further
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31 RESOLVED, That our AMA encourage institutions to align current practices with published
32 guidelines, recommendations, and policies to ensure patients are educated on pelvic,
33 genitourinary, and rectal exams that occur under anesthesia (Directive to Take Action); and be it
34 further
35

36 RESOLVED, That our AMA strongly oppose issuing blanket bans on student participation in
37 educational physical exams (Directive to Take Action); and be it further
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39 RESOLVED, That our AMA reaffirm policy H-320.951, "AMA Opposition to "Procedure-Specific"
40 Informed Consent." (Reaffirm HOD Policy)

Fiscal Note: Minimal - less than \$1,000

Received: 05/10/21

AUTHOR'S STATEMENT OR PRIORITY

This topic has once again made the news in the last year and is a thorn in the side of our profession. To ensure the continued trust in our profession by our patients and therefore by the public at large, the AMA needs to make a clear statement that unnecessary pelvic exams on sedated patients without their consent is not appropriate. We must not waste the good will and trust we have garnered from the public. This should not be controversial and is already supported by ACOG.

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RELEVANT AMA POLICY

Code of Medical Ethics 2.1.1 Informed Consent

Informed consent to medical treatment is fundamental in both ethics and law. Patients have the right to receive information and ask questions about recommended treatments so that they can make well-considered decisions about care. Successful communication in the patient-physician relationship fosters trust and supports shared decision making.

The process of informed consent occurs when communication between a patient and physician results in the patient's authorization or agreement to undergo a specific medical intervention. In seeking a patient's informed consent (or the consent of the patient's surrogate if the patient lacks decision-making capacity or declines to participate in making decisions), physicians should:

(a) Assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision.

(b) Present relevant information accurately and sensitively, in keeping with the patient's preferences for receiving medical information. The physician should include information about:

- (i) the diagnosis (when known);
- (ii) the nature and purpose of recommended interventions;
- (iii) the burdens, risks, and expected benefits of all options, including forgoing treatment.

(c) Document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. When the patient/surrogate has provided specific written consent, the consent form should be included in the record.

In emergencies, when a decision must be made urgently, the patient is **not** able to participate in decision making, and the patient's surrogate is not available, **physicians** may initiate treatment without prior informed consent. In such situations, the physician **should** inform the patient/surrogate at the earliest opportunity and obtain consent for ongoing treatment in keeping with these guidelines.

2.1.6 Substitution of Surgeon

Patients are entitled to choose their own physicians, **which** includes being permitted to accept or refuse having an intervention performed by a **substitute**. A **surgeon** who allows a substitute to conduct a medical procedure on his or her patient **without** the patient's knowledge or consent risks compromising the trust-based relationship of patient and physician.

When one or more other appropriately **trained** health care **professionals** will participate in performing a surgical intervention, the **surgeon** has an ethical responsibility to:

- (a) Notify the patient (or surrogate if the patient lacks decision-making capacity) that others will participate, including whether they will do **so** under the **physician**'s personal supervision or not.
- (b) Obtain the patient's or surrogate's **informed consent** for the intervention, in keeping with ethical and legal guidelines.

2.3.6 Surgical Co-Management

Surgical co-management refers to the practice of allotting specific responsibilities of patient care to designated clinicians. Such **arrangements** **should** be made only to ensure the highest quality of care.

When **engaging** in this practice, physicians should:

- (a) **Allocate responsibilities** **among** physicians and other clinicians according to each individual's **expertise** and **qualifications**.
- (b) **Work** with the patient and family to designate one physician to be responsible for ensuring that **care** **is** delivered in a coordinated and appropriate manner.
- (c) **Participate** in the provision of care by communicating with the coordinating physician and encouraging **other** **members** of the care team to do the same.
- (d) Obtain patient **consent** for the surgical co-management arrangement of care, including disclosing significant aspects of the arrangement such as qualifications of clinicians, services each clinician will provide, and billing arrangement.
- (e) Obtain informed consent for medical services in keeping with ethics guidance, including provision of all relevant medical facts.
- (f) Employ appropriate safeguards to protect patient confidentiality.
- (g) Ensure that surgical co-management arrangements are in keeping with ethical and legal restrictions.
- (h) Engage another caregiver based on that caregiver's skill and ability to meet the patient's needs, not in the expectation of reciprocal referrals or other self-serving reasons, in keeping with ethics guidance on consultation and referrals.
- (i) Refrain from participating in unethical or illegal financial agreements, such as fee-splitting.

7.1.2 Informed Consent in Research

Informed consent is an essential safeguard in research. The obligation to obtain informed consent arises out of respect for persons and a desire to respect the autonomy of the individual deciding whether to volunteer to participate in biomedical or health research. For these reasons, no person may be used as a subject in research against his or her will.

Physicians must ensure that the participant (or legally authorized representative) has given voluntary, informed consent before enrolling a prospective participant in a research protocol. With certain exceptions, to be valid, informed consent requires that the individual have the capacity to provide consent and have sufficient understanding of the subject matter involved to form a decision. The individual's consent must also be voluntary.

A valid consent process includes:

- (a) Ascertaining that the individual has decision-making capacity.
- (b) Reviewing the process and any materials to ensure that it is understandable to the study population.
- (c) Disclosing:
 - (i) the nature of the experimental drug(s), device(s), or procedure(s) to be used in the research;
 - (ii) any conflicts of interest relating to the research, in keeping with ethics guidance;
 - (iii) any known risks or foreseeable hazards, including pain or discomfort that the participant might experience;
 - (iv) the likelihood of therapeutic or other direct benefit for the participant;
 - (v) that there are alternative courses of action open to the participant, including choosing standard or no treatment instead of participating in the study;
 - (vi) the nature of the research plan and implications for the participant;
 - (vii) the differences between the physician's responsibilities as a researcher and as the patient's treating physician.
- (d) Answering questions the prospective participant has.
- (e) Refraining from persuading the individual to enroll.
- (f) Avoiding encouraging unrealistic expectations.
- (g) Documenting the individual's voluntary consent to participate.

Participation in research by minors or other individuals who lack decision-making capacity is permissible in limited circumstances when:

- (h) Consent is given by the individual's legally authorized representative, under circumstances in which informed and prudent adults would reasonably be expected to volunteer themselves or their children in research.
- (i) The participant gives his or her assent to participation, where possible. Physicians should respect the refusal of an individual who lacks decision-making capacity.
- (j) There is potential for the individual to benefit from the study.

In certain situations, with special safeguards in keeping with ethics guidance, the obligation to obtain informed consent may be waived in research on emergency interventions.

9.2.1 Medical Student Involvement in Patient Care

Having contact with patients is essential for training medical students, and both patients and the public benefit from the integrated care that is provided by health care teams that include medical students. However, the obligation to develop the next generation of physicians must be balanced against patients' freedom to choose from whom they receive treatment. All physicians share an obligation to ensure that patients are aware that medical students may participate in their care and have the opportunity to decline care from students. Attending physicians may be best suited to fulfill this obligation. Before involving medical students in a patient's care, physicians should: (a) Convey to the patient the benefits of having medical students participate in their care. (b) Inform the patients about the identity and training status of individuals involved

in care. Students, their supervisors, and all health care professionals should avoid confusing terms and properly identify themselves to patients. (c) Inform the patient that trainees will participate before a procedure is undertaken when the patient will be temporarily incapacitated. (d) Discuss student involvement in care with the patient's surrogate when the patient lacks decision-making capacity. (e) Confirm that the patient is willing to permit medical students to participate in care.

9.2.2 Resident & Fellow Physicians' Involvement in Patient Care

Residents and fellows have dual roles as trainees and caregivers. Residents and fellows share responsibility with physicians involved in their training to facilitate educational and patient care goals. Residents and fellows are physicians first and foremost and should always regard the interests of patients as paramount. When they are involved in patient care, residents and fellows should: (a) Interact honestly with patients, including clearly identifying themselves as members of a team that is supervised by the attending physician and clarifying the role they will play in patient care. They should notify the attending physician if a patient refuses care from a resident or fellow. (b) Participate fully in established mechanisms in their training programs and hospital systems for reporting and analyzing errors. They should cooperate with attending physicians in communicating errors to patients. (c) Monitor their own health and level of alertness so that these factors do not compromise their ability to care for patients safely. Residents and fellows should recognize that providing patient care beyond time permitted by their programs (for example, "moonlighting" or other activities that interfere with adequate rest during off hours) might be harmful to themselves and patients. Physicians involved in training residents and fellows should: (d) Take steps to help ensure that training programs are structured to be conducive to the learning process as well as to promote the patient's welfare and dignity. (e) Address patient refusal of care from a resident or fellow. If after discussion, a patient does not want to participate in training, the physician may exclude residents or fellows from the patient's care. If appropriate, the physician may transfer the patient's care to another physician or nonteaching service or another health care facility. (f) Provide residents and fellows with appropriate faculty supervision and availability of faculty consultants, and with graduated responsibility relative to level of training and expertise. (g) Observe pertinent regulations and seek consultation with appropriate institutional resources, such as an ethics committee, to resolve educational or patient care conflicts that arise in the course of training. All parties involved in such conflicts must continue to regard patient welfare as the first priority. Conflict resolution should not be punitive, but should aim at assisting residents and fellows to complete their training successfully.

9.2.5 Medical Students Practicing Clinical Skills on Fellow Students

Medical students often learn basic clinical skills by practicing on classmates, patients, or trained instructors. Unlike patients in the clinical setting, students who volunteer to act as "patients" are not seeking to benefit medically from the procedures being performed on them. Their goal is to benefit from educational instruction, yet their right to make decisions about their own bodies remains.

To protect medical students' privacy, autonomy, and sense of propriety in the context of practicing clinical skills on fellow students, instructors should:

- (a) Explain to students how the clinical skills will be performed, making certain that students are not placed in situations that violate their privacy or sense of propriety.
- (b) Discuss the confidentiality, consequences, and appropriate management of a diagnostic finding.
- (c) Ask students to specifically consent to clinical skills being performed by fellow students. The stringency of standards for ensuring explicit, noncoerced informed consent increases as the invasiveness and intimacy of the procedure increase.

- (d) Allow students the choice of whether to participate prior to entering the classroom.
- (e) Never require that students provide a reason for their unwillingness to participate.
- (f) Never penalize students for refusing to participate. Instructors must refrain from evaluating students' overall performance based on their willingness to volunteer as "patients."

Citation: Issued 2016

AMA Opposition to "Procedure-Specific" Informed Consent H-320.951

Our AMA opposes legislative measures that would impose procedure-specific requirements for informed consent or a waiting period for any legal medical procedure.

Citation: Res. 226, A-99; Reaffirmed: Res. 703, A-00; Reaffirmed: BOT Rep. 6, A-10

Informed Consent and Decision-Making in Health Care H-140.989

- (1) Health care professionals should inform patients or their surrogates of their clinical impression or diagnosis; alternative treatments and consequences of treatments, including the consequence of no treatment; and recommendations for treatment. Full disclosure is appropriate in all cases, except in rare situations in which such information would, in the opinion of the health care professional, cause serious harm to the patient.
- (2) Individuals should, at their own option, provide instructions regarding their wishes in the event of their incapacity. Individuals may also wish to designate a surrogate decision-maker. When a patient is incapable of making health care decisions, such decisions should be made by a surrogate acting pursuant to the previously expressed wishes of the patient, and when such wishes are not known or ascertainable, the surrogate should act in the best interests of the patient.
- (3) A patient's health record should include sufficient information for another health care professional to assess previous treatment, to ensure continuity of care, and to avoid unnecessary or inappropriate tests or therapy.
- (4) Conflicts between a patient's right to privacy and a third party's need to know should be resolved in favor of patient privacy, except where that would result in serious health hazard or harm to the patient or others.
- (5) Holders of health record information should be held responsible for reasonable security measures through their respective licensing laws. Third parties that are granted access to patient health care information should be held responsible for reasonable security measures and should be subject to sanctions when confidentiality is breached.
- (6) A patient should have access to the information in his or her health record, except for that information which, in the opinion of the health care professional, would cause harm to the patient or to other people.
- (7) Disclosures of health information about a patient to a third party may only be made upon consent by the patient or the patient's lawfully authorized nominee, except in those cases in which the third party has a legal or predetermined right to gain access to such information.

Citation: BOT Rep. NN, A-87; Reaffirmed: Sunset Report, I-97; Reaffirmed: Res. 408, A-02; Reaffirmed: BOT Rep. 19, I-06; Reaffirmation A-07; Reaffirmation A-09; Reaffirmed: BOT Rep. 05, I-16