Elements of informed consent: preconditions include patient’s competence, capacity to understand or decide, and voluntary nature of decisions; informational elements include disclosure of material information relevant to patient (eg, risks, benefits, alternative treatments, and recommendation of plan); physician assesses ability of patient to understand and make appropriate decisions; patient decides to authorize treatment or decline recommendations; physician documents process

“Capacity for understanding”: first, analyze patient’s capacity to understand risks, benefits, and alternatives; patient must appreciate impact of clinical situation on plan for treatment; patient must process information, demonstrate ability to make decision, and communicate understanding to clinician; capacity may be problematic (eg, patient in comatose state); assessing degree of dementia often difficult; additional confounding factors include pain, sedative medication, and stress

“Competence”: legal term denoting right to make decisions; includes concept of age of majority; minor may have capacity to understand and make decision but not legally competent; indicates capacity to participate in legal proceedings; mental conditions that can interfere include acute psychosis and profound mental retardation

Case example 1: non-English-speaking patient presents for excision of breast mass; family chose to allow children to translate; family requested monitored anesthesia care, but patient consented to general anesthesia; patient experienced stroke in brainstem and died; family claimed patient would never have consented to general anesthesia because sister died during general anesthesia; errors occurred in communication between family and anesthesiologist during process of translation

Independent translators: required; do not rely on family, hospital personnel, or oneself

Labor: does not typically interfere with providing consent; studies indicate no difference between recall of women in labor and that of other patients; early antenatal education ideal solution; communicating with patient soon after labor begins preferable (ie, before escalation of pain and loss of control)

Children: lack legal competence for making decisions; parents have legal right to make decisions; evaluate child’s capacity for assent

Emancipated minors: teenagers who assume adult responsibility before reaching age of majority and no longer under control of parents; parents may maintain some control; rules vary from state to state

“Voluntariness”: refers to concept that patient has autonomy to determine what happens to his or her own body; patient must make decision voluntarily, without coercion or undue influence from family or physician; treatment alternatives must be offered

Jehovah’s Witnesses: blood transfusions often problematic; some hospitals have checklists; parents cannot invoke freedom of religion to deny treatment to minors; may require court order

Case example 2: case from closed claims database; woman underwent total hip arthroplasty; request for general anesthesia refused by surgeon and anesthesiologist because of surgeon preference; patient received subarachnoid block, after which she experienced inability to move legs in recovery room because of epidural hematoma; only partial recovery of function achieved after surgery; patient paraparetic and unable to ambulate; case illustrates coercion and lack of voluntariness

Material risks: risks that must be discussed with patient to allow for informed choice; common complications — risks associated with general anesthesia include postoperative nausea and vomiting, and damage to teeth; risks associated with regional block include infection, failed block, and pain and discomfort during placement of block; rare but severe complications — may influence patient’s decision; include risk for permanent neurapraxia after interscalene block

Standard of reasonable physician: requirements vary from state to state; some states apply “professional standard” of reasonable physician when determining amount of information that must be disclosed (much left to discretion of physician); many states apply “patient standard” of reasonable physician

Studdert et al (2007): analyzed verdicts in lawsuits involving informed consent; compared professional standard with patient standard; in states with patient standard for informed consent, verdicts for plaintiffs in \( \approx \)30% of lawsuits; in states with professional standard, verdicts for plaintiffs in \( \approx \)18%

Documentation of informed consent: much debated issue; requirements vary among states, local institutions, and insurance companies; speaker’s institution uses signed surgical consent form, with verbal consent for anesthesia documented in medical record; discussion of specific applicable risks documented in record; some institutions use separate signed consent forms for anesthesia; forms should be written in plain English
without jargon; some institutions document time patient spent online reading about risks and benefits of procedures

**Tailored discussion of risk**: use language patient understands instead of technical medical language (adjust language to ≈8th-grade level of education); speaker should assess patient and engage in appropriate discussion of risk beyond elements indicated on consent form; signature of patient on form does not guarantee patient understanding or necessarily protect physician from liability; patient can allege lack of understanding or failure to read form

**Brull et al (2007)**: investigated risks routinely disclosed to patients before nerve blocks; 79 individuals from 12 regional fellowship programs responded to questionnaire; *risks associated with neuraxial block* — those disclosed to patients most commonly include headache, local pain and discomfort, and infection; severe complications disclosed less commonly; *risks associated with peripheral nerve block* — those disclosed most commonly include transient neuropathy, local pain and discomfort, and infection; *regional block* — serious complications disclosed by only ≤20% of physicians, some of whom provided incorrect statistics; speaker suggests providing patient with written information in accessible language

**Factors contributing to inadequate informed consent**: systemic factors — lack of privacy, time pressure, and lack of preanesthesia clinics; controllable factors — poor understanding of state requirements, use of medical jargon, lack of institutional policies, concerns about inducing fear or anxiety in patient, and time pressure; patient-related factors — cultural or social elements, involvement of family, level of education, language barriers, and capacity and competence of patient

**Waisel (2011)**: wrote editorial suggesting informed consent for anesthesia different from other situations involving consent; patient rarely chooses whether to receive anesthesia; choice usually limited to technique; anesthesiologists have no prior relationship with patient and usually given little time to establish rapport; needs of patient and family best met by highlighting relevant elements; author suggested allowing patient and family to determine amount of information disclosed; speaker points out that states may require disclosure of more information than patients desire

**Patient recollection of perioperative risk**: Gillies et al (2013) investigated patients undergoing general anesthesia who received written and verbal information in preanesthesia clinic; major and minor risks detailed; 26% of patients unable to recall any risks of anesthesia, almost 40% unable to recall any major risks, and 84% unable to recall any minor risks

**Patient understanding**: most patients understand plan for anesthesia; ≈80% do not understand risks of anesthesia; most patients have poor understanding of side effects of treatments for pain

**Informed consent in malpractice claims**: speaker found that ≈10% of closed claims (from database) included issue with informed consent as element of lawsuit; speaker reviewed malpractice claims filed since 2000 in relation to general surgery and found ≈20% involved informed consent; issues of consent relatively uncommon in cases of death of patient; consent more often factor in nonfatal injuries (particularly temporary, non disabling injuries) but also in cases of permanent disability; ischemic optic neuropathy after spine surgery in prone position now considered primarily issue of consent, as opposed to standard of care; nonfatal injuries account for 70% of claims and two-thirds of defense costs

**Case example 3**: woman experienced injury to femoral nerve as result of ultrasound-guided block during which no paresthesia reported; patient developed long-term weakness of quadriceps with hematoma and adhesions in femoral nerve; discussion with patient about possibility of permanent neuropathy not documented

**Burkle et al (2013)**: majority of patients desire discussion of common complications and rare but severe complications; *results of patient interviews* — ≈20% believed anxiety generated by discussion of risks outweighed benefit; only 6% supported restriction of discussion of risk based on patient ability to understand care; most preferred verbal interaction, alone or in combination with written information; about half preferred discussion on day of surgery; about half preferred discussion 1 wk prior; *results of parent interviews* — preferred verbal, or combination of verbal and written, information; few (0.4%) preferred not being informed of risks

**Informed medical decision making**: intended to empower patient; clinician’s role — understand patient’s values and preferences, and place patient at center of care; provide information to facilitate informed choice, including evidence related to uncertainties; provide recommendations for medical recourse; verify understanding of patient and mutual agreement

**Shared decision making**: in contrast with conventional approach, confers higher legal standard for informed consent; requires clinician to provide information about the nature of treatment, alternatives, advantages and disadvantages, and related uncertainties; patient must be given opportunity to consider recommendations within context of own life and obtain input from others; clinician must assess patient’s understanding through check-back and consider patient’s preferences

**Patient preferences for informed consent**: researchers performed mock trial about screening for prostate-specific antigen; “jurors” shown informed consent alone or in combination with decision aid (DVD and video); almost 90% considered care substandard if consent not documented; almost 30% considered care substandard if consent documented; most considered informed consent adequate when decision aid used

**Modules for patient education**: American Society of Anesthesiologists (ASA) developed modules and decision aids for educating patients about various types of anesthesia; products soon available through ASA; speaker’s experience — test performed in preanesthesia clinic at speaker’s institution; some patients received decision aids; conversations recorded; regional anesthesia mentioned more frequently; patients asked more questions; alternatives for pain control discussed often; participants liked written information in patient-friendly form; scores on tests of knowledge improved with use of decision aids but remained <60%

**Assisted suicide**: legal in Washington state; plan must be discussed with patient and family, and patient’s choices must be honored; physician may recuse self from case; patients with terminal conditions can decline resuscitation; lawsuits have been filed on behalf of patients resuscitated against their will

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**Questions and Answers**

**Obtaining informed consent without inducing anxiety**: informed consent observed to induce anxiety among patients and decrease scores on Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS); situation more challenging in states with patient standard; speaker’s recommendations — present information in nonfrightening manner; ask whether patient wants to hear about rare but serious complications; place risks in perspective; develop preanesthesia clinic and provide patient-friendly information

**Need for independent translator “100% of the time”**: translator required primarily for elective procedures; alternatives (eg, court order, health care personnel) may be used during emergencies; use of independent translator preferable whenever possible
Informed consent for postoperative pain control for sedated patient: document that patient sedated but appears to understand; consult with next of kin; ensure documentation adequate

**Presenting statistics about complications to patients:** speaker suggests using word “rare”; numbers often incorrect; incidence of neuropathy depends on type of block placed

**Value of good informed consent in legal defense:** first issue appropriateness of care; documentation helpful for defense

**Resources for identifying risks of specific procedures:** speaker recommends decision aids; risk calculators available

**Guidelines for continuous pulse oximetry and capnography to prevent postoperative respiratory depression:** ASA guidelines based on randomized controlled trials and meta-analyses; speaker’s institution does not use pulse oximetry and capnography on every patient on floor (some high-risk patients observed in special units); families educated about use of patient-controlled analgesia; nurses trained to evaluate level of sedation; institution can implement protocols for authorization to write orders for pain medication and sedatives

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**Suggested Readings**

INFORMED CONSENT FOR ANESTHESIOLOGISTS

To test online, go to www.audiodigest.org and sign in to online services.
To submit a test form by mail or fax, complete Pretest section before listening and Posttest section after listening.

1. Which of the following elements of informed consent is most accurately defined as the ability of a patient to process information and make a decision?
   (A) Capacity for understanding ** (C) Voluntariness
   (B) Competence (D) Disclosure of material information

2. Which of the following elements of informed consent is a legal term denoting the right to make decisions?
   (A) Capacity for understanding (C) Voluntariness
   (B) Competence ** (D) Disclosure of material information

3. The standard physicians are required to follow when obtaining informed consent:
   (A) Is the standard of the reasonable patient (C) Varies from state to state
   (B) Is the standard of the reasonable physician ** (D) Is determined by institutional policy

4. Materials for patient education should generally be written for which of the following levels of education?
   (A) 3rd grade (C) 8th grade **
   (B) 5th grade (D) High school

5. In a study by Brull et al (2007) investigating the disclosure of risks before regional block, which of the following was LEAST often disclosed to patients?
   (A) Transient neuropathy (C) Infection
   (B) Pain and discomfort ** (D) Serious complications

6. In a study by Gillies et al (2013) investigating patient recollections of perioperative risk, _______ of patients were unable to recall any risks of anesthesia.
   (A) 11% (B) 26% ** (C) 40% (D) 84%

7. According to data from the closed claims database, a malpractice claim related to which of the following is LEAST likely to involve a dispute over informed consent?
   (A) Death of the patient ** (B) Temporary nondisabling injuries
   (C) Permanent disability

8. According to Burkle et al (2013), which of the following accurately describes patient preferences for informed consent?
   (A) Most patients preferred written information over verbal communication
   (B) The majority of parents prefer not to know the risks related to their child’s surgery
   (C) About half of patients surveyed believed the benefit of a discussion of risks was outweighed by the anxiety generated
   (D) About half of patients prefer to discuss risks on the day of surgery as opposed to 1 wk earlier **

9. Compared with conventional informed consent, shared decision making carries a _______ legal standard.
   (A) Lower ** (B) Similar (C) Higher

10. Based on information obtained from mock trials, what percentage of potential jurors would consider care to be substandard if consent is not documented?
    (A) 10% (B) 30% (C) 60% (D) 90% **

Answers to Audio Digest Anesthesiology Volume 59, Issue 05: 1-A, 2-C, 3-A, 4-D, 5-C, 6-D, 7-B, 8-A, 9-A, 10-D