Informed Consent:
An Ethical and Legal Imperative

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Speaker Bio

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Kathleen Divers, RN, MAS, CPHQ, CPPS, CJCP has more than 30 years of experience in healthcare. For the 10 years prior to joining MedPro, she served as the associate vice president of quality management at the fourth largest hospital in the United States. She oversaw risk management, patient safety, regulatory compliance, infection control, and performance improvement.

Kathleen has extensive experience in acute care, behavioral health, and post-acute care. Additionally, she oversaw the patient safety and risk management program for a hospital-based physician practice that included 25 specialties and averaged 60,000 visits per year.

Kathleen is a registered nurse and earned a bachelor's degree from St. Joseph's College, New York and a master's degree from Fairleigh Dickinson University. She is certified professional in healthcare quality (CPHQ) and patient safety (CPPS), and she is a certified Joint Commission professional (CJCP). Additionally, Kathleen is a TeamSTEPPS master trainer and received training on lean healthcare at Johns Hopkins' Armstrong Institute for Patient Safety and Quality.

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Today's faculty, as well as CE planners, content developers, reviewers, editors, and Patient Safety & Risk Solutions staff at MedPro Group have reported that they have no relevant financial relationships with any commercial interests.

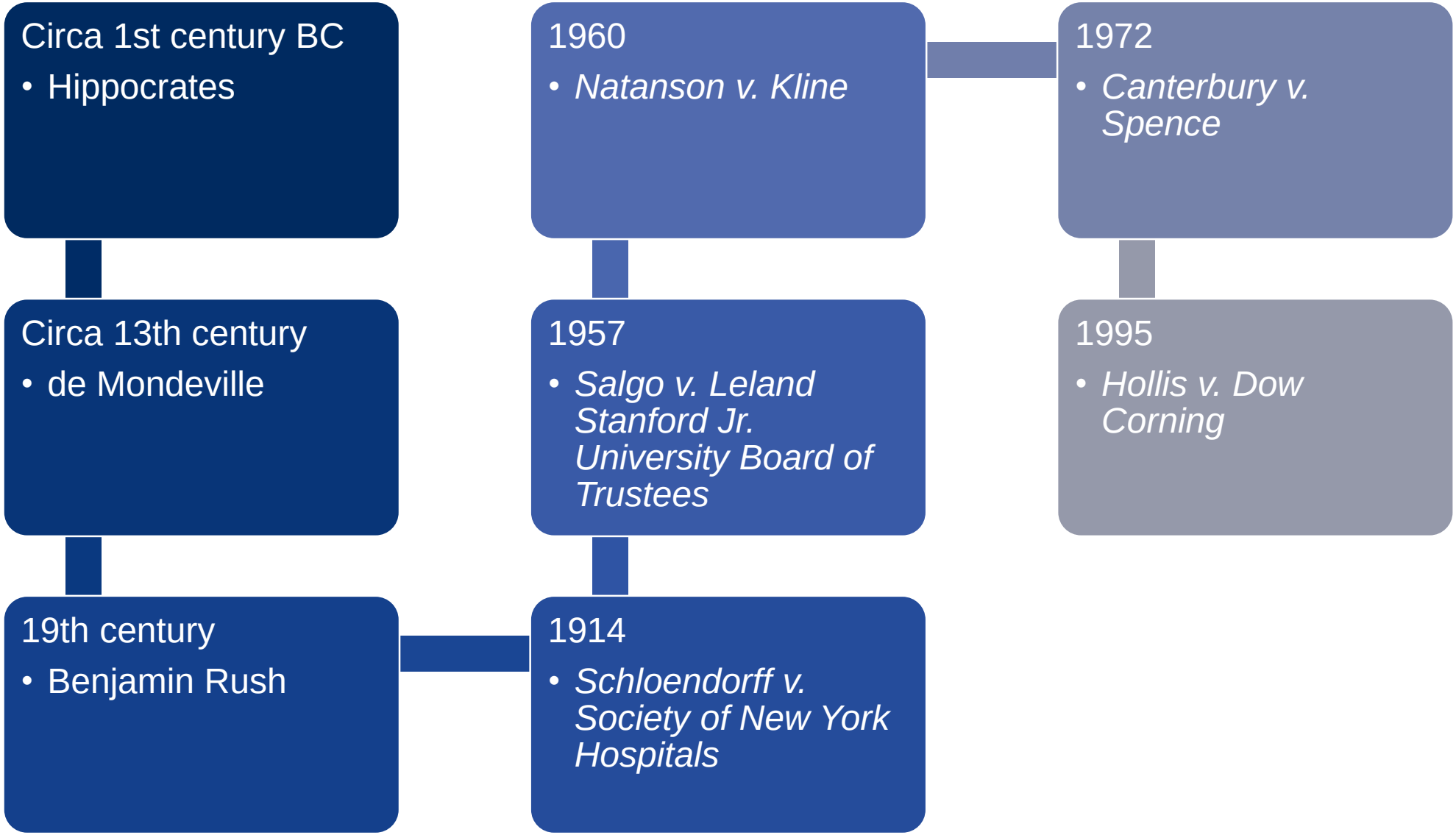
Objectives

At the conclusion of this program, participants should be able to:

- Understand the role of informed consent in malpractice allegations and cases
- Articulate key elements of a thorough informed consent process and criteria to consider incorporating into the process
- Understand informed refusal and strategies to reduce risks associated with refusal
- Identify special populations and considerations that might affect how informed consent is obtained (e.g., minors, individuals who have diminished capacity, emergency situations, therapeutic privilege, etc.)
- Determine strategies to minimize risk exposures relative to the informed consent process

What is informed consent?

Evolution of informed consent



Background

It was case law that introduced the concept of informed consent to medicine in the twentieth century using the language of ‘self-determination.’ Shortly thereafter informed consent was transformed into a social context beyond the law from a malpractice issue to a moral duty incumbent on physicians.

Faden, R. R., Beauchamp, T. L. (1986). *A history and theory of informed consent* (pp. 101). New York, NY: Oxford University Press.

Definition

According to the American Medical Association, ‘Informed consent is a basic policy in both ethics and law that physicians must honor . . .’ The process involves multiple elements, including disclosure, comprehension, voluntary choice, and authorization.

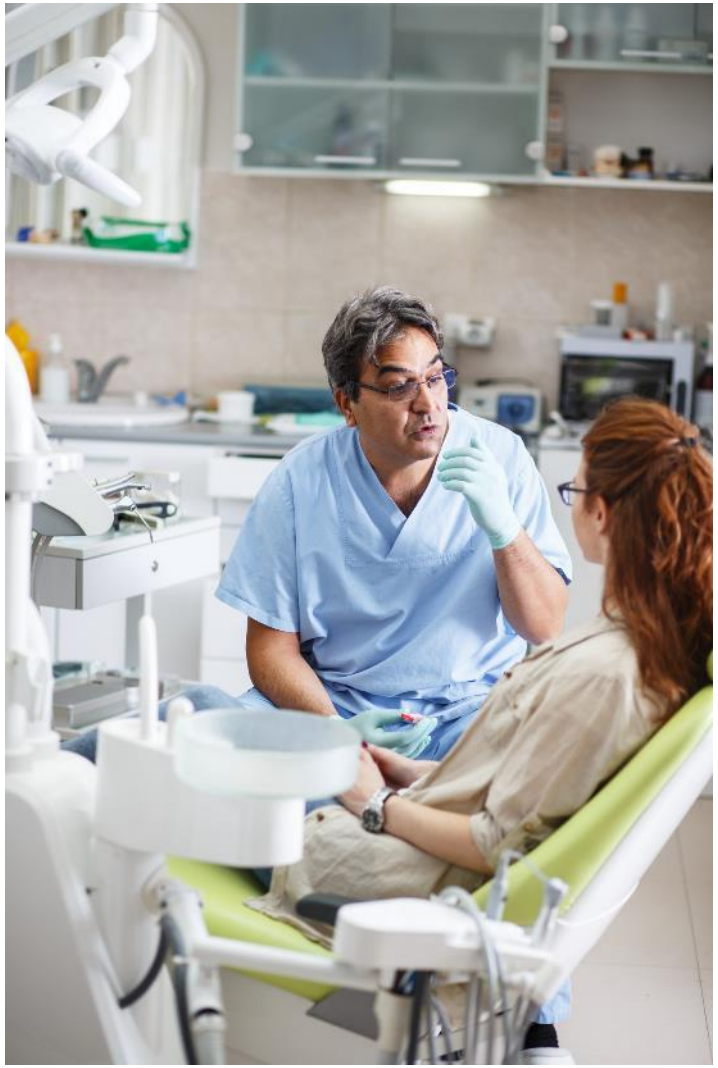
Grady, C. (2015). Enduring and emerging challenges of informed consent. *New England Journal of Medicine, 372,* 855-862.

An informed discussion

Discuss the risks and benefits of the recommended treatment, alternative treatment options, and the risks of not receiving treatment.

Give the patient an opportunity to ask questions and receive answers to his/her satisfaction.

Document all of the above details in the patient's health record.



An authorization form

Primarily for the purpose of the patient's signature agreeing to the proposed treatment

Lists the risks and benefits of the proposed treatment, alternative treatment options, risks of no treatment, and notice of right to withdraw (rescind) consent

Consent is not coercion

“Coercion occurs when an overt threat of harm is intentionally presented by one person to another in order to obtain compliance.”

Informed consent in malpractice cases

Informed consent as a contributing factor in malpractice cases

Process-of-care failures

Contributing factors are multi-layered issues or failures in the process of care that appear to have contributed to the patient outcome and/or to the initiation of the case — or they had a significant impact on case resolution.

Generally, multiple contributing factors are identified in each case.

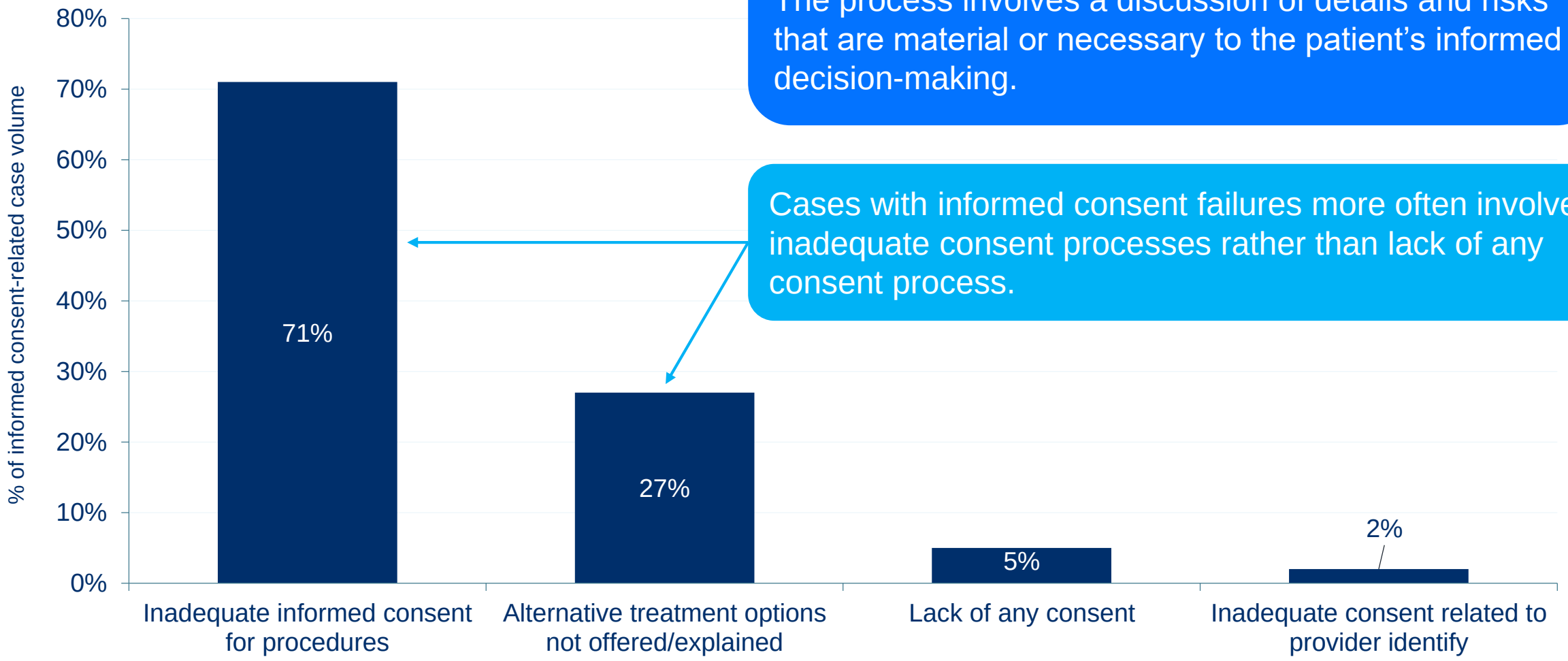
Contributing factors reflect both provider and patient issues, but are not programmatically assigned to specific individuals. They denote breakdowns in technical skill, clinical judgment, communication, behavior, systems, environment, equipment/tools, and teamwork. The majority are relevant across clinical specialties, settings and disciplines; thus, they identify opportunities for broad remediation.

CRICO Strategies. (2020). *The power to predict: Leveraging medical malpractice data to reduce patient harm and financial loss.* Retrieved from www.rmf.harvard.edu/Malpractice-Data/Annual-Benchmark-Reports/The-Power-to-Predict

Informed consent details

The informed consent process relies on effective communication between the provider and the patient. The process involves a discussion of details and risks that are material or necessary to the patient's informed decision-making.

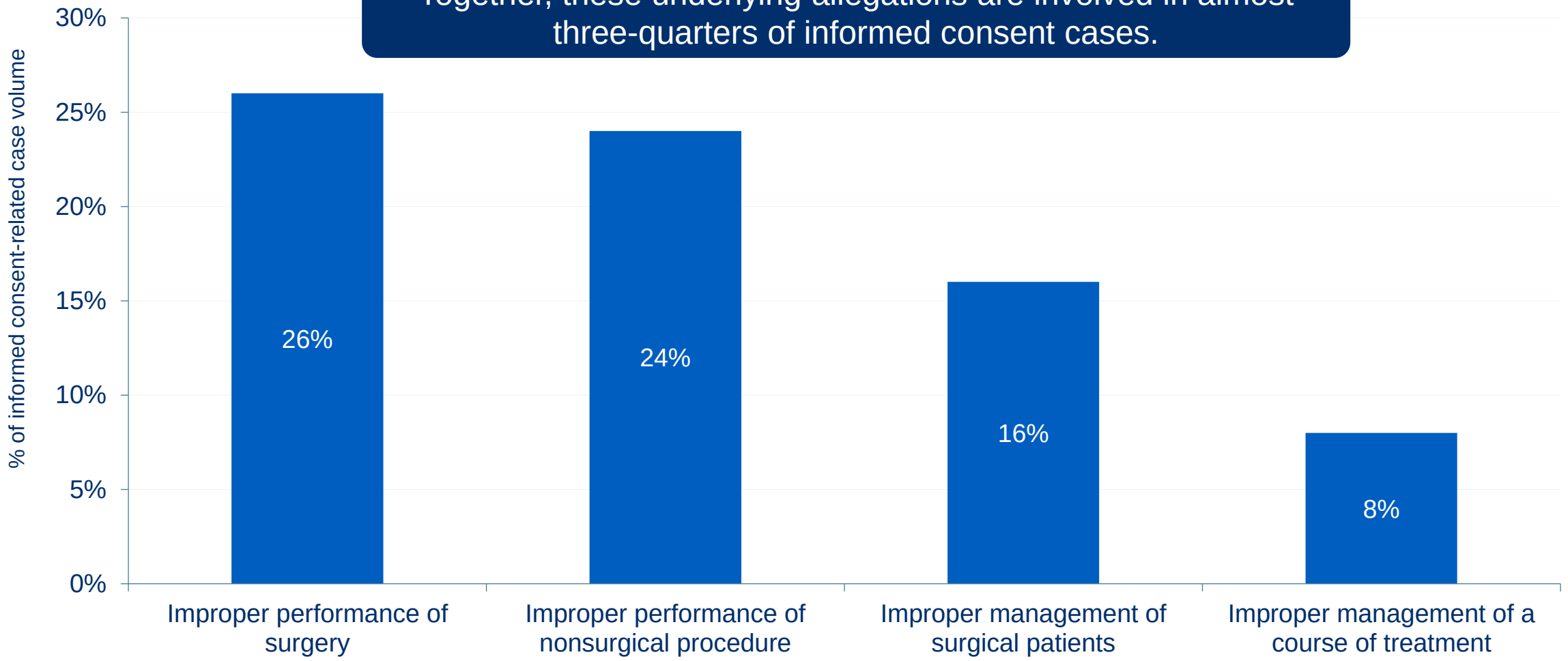
Cases with informed consent failures more often involve inadequate consent processes rather than lack of any consent process.



MedPro Group closed cases, 2010-2019; total exceeds 100% because more than one factor may be associated with each case.

Top allegations associated with informed consent issues

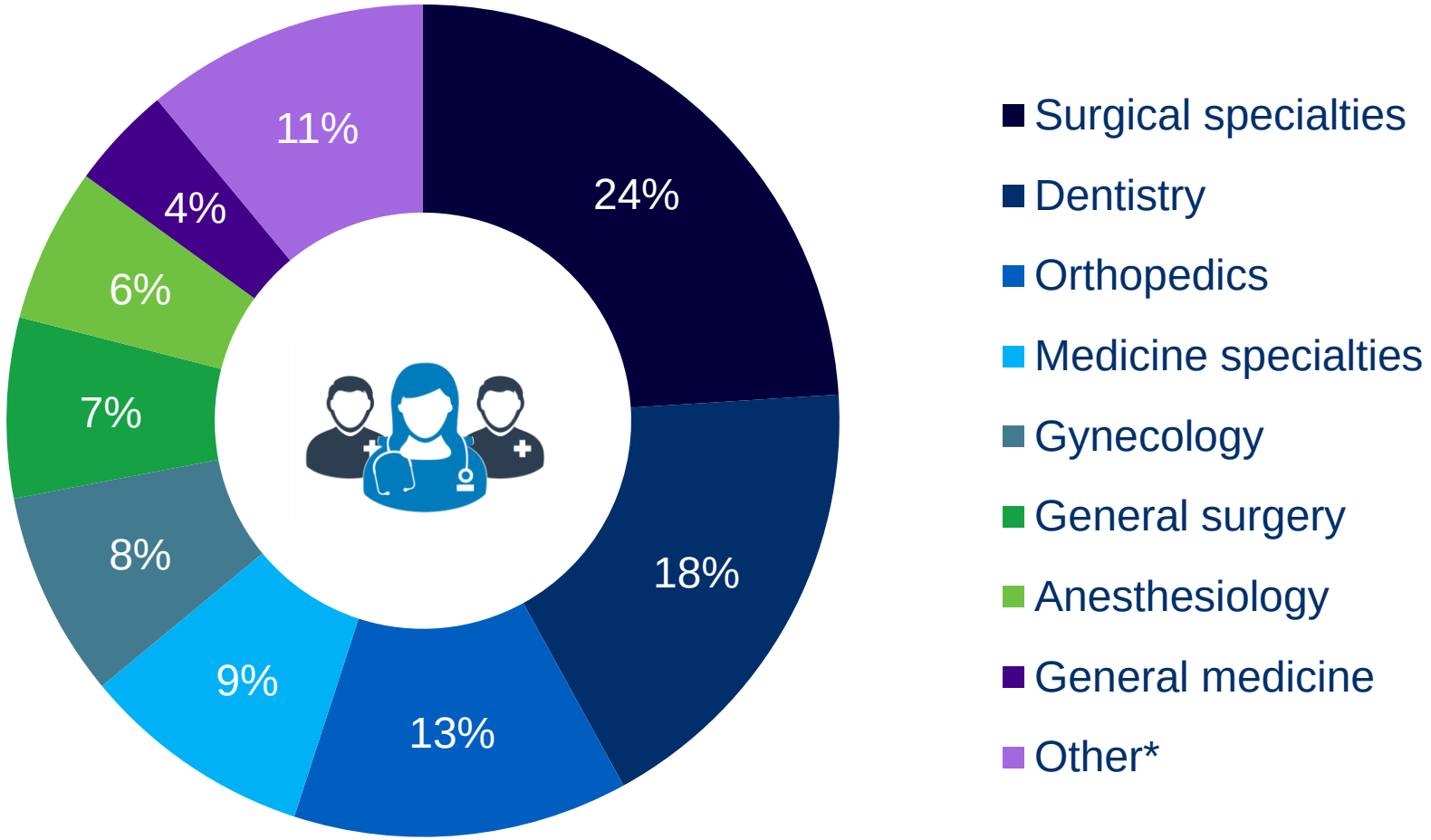
Together, these underlying allegations are involved in almost three-quarters of informed consent cases.



MedPro Group closed cases, 2010-2019.

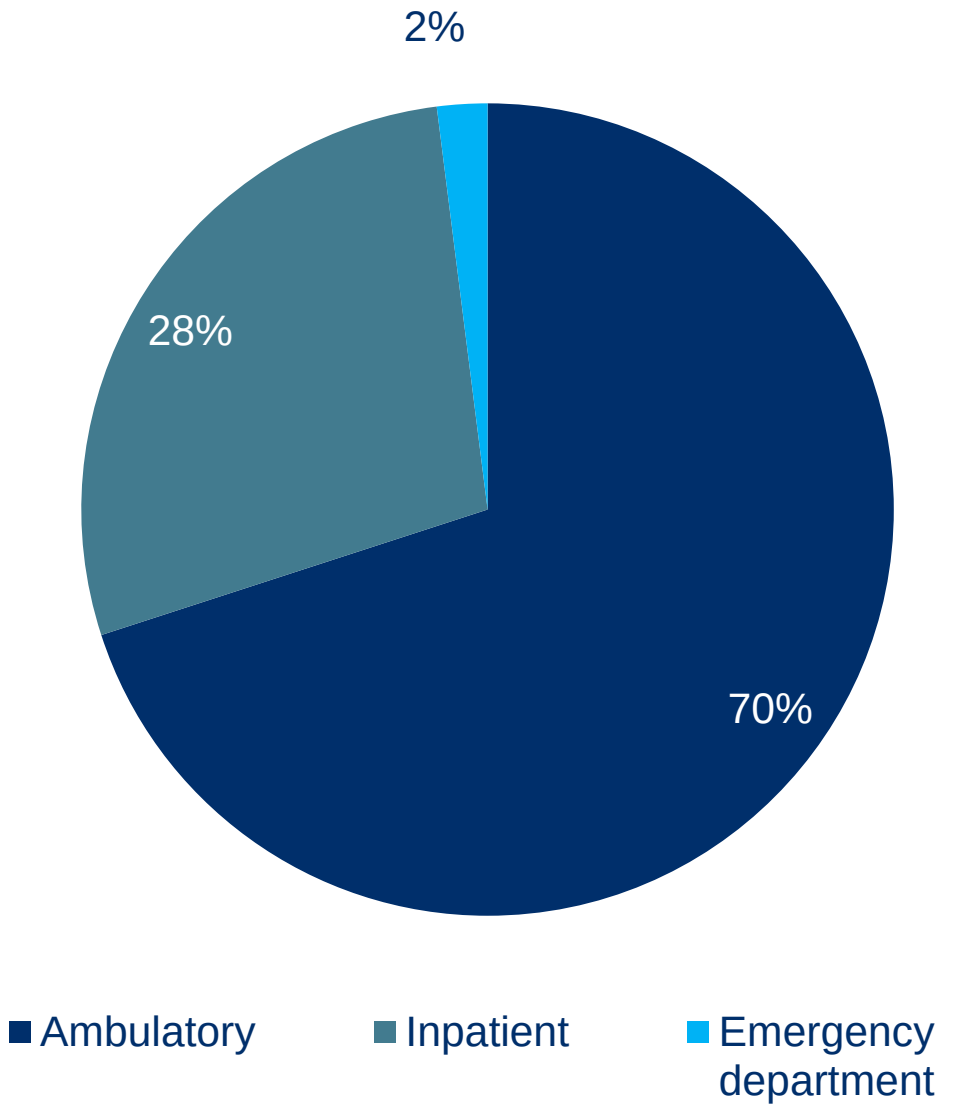
Responsible services associated with informed consent issues

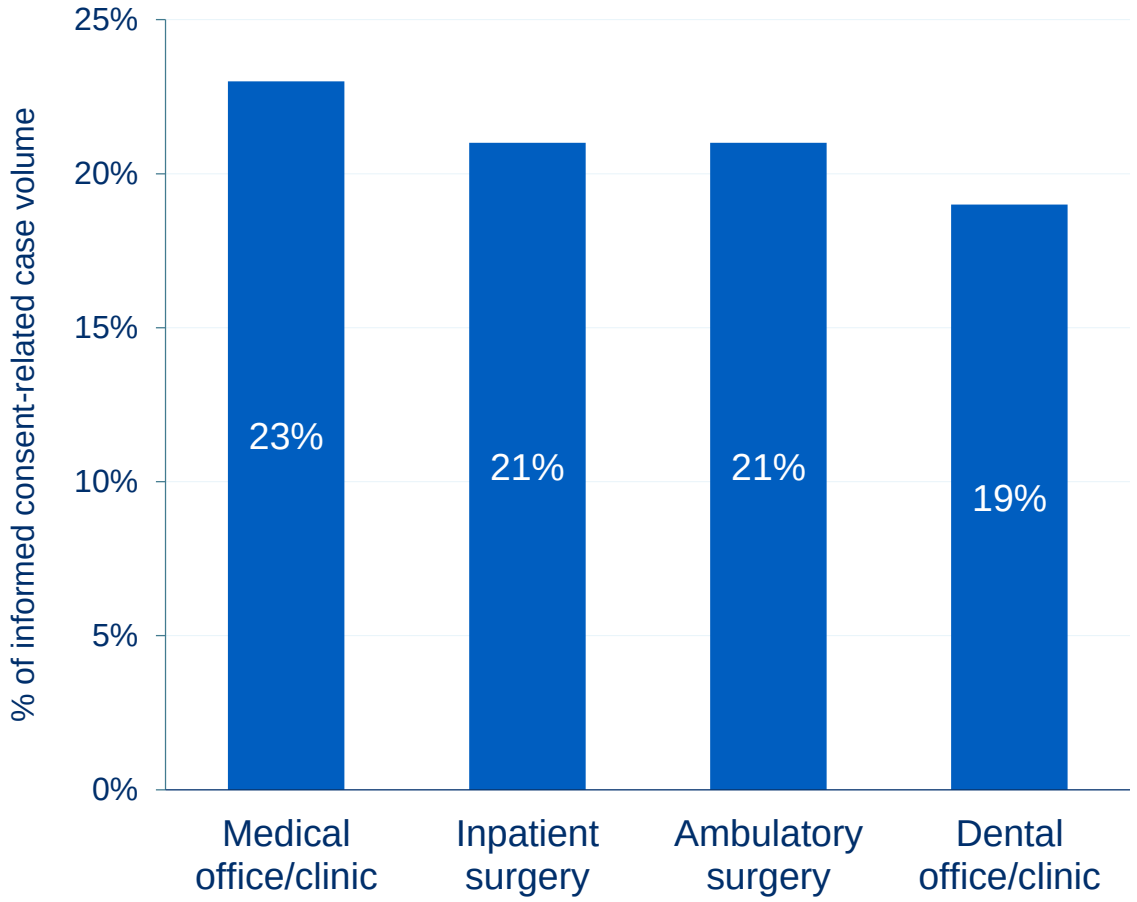
Informed consent process failures are noted across a wide variety of specialties.



MedPro Group closed cases, 2010-2019; *Other = those specialties without significant case volume.

Top locations associated with informed consent issues

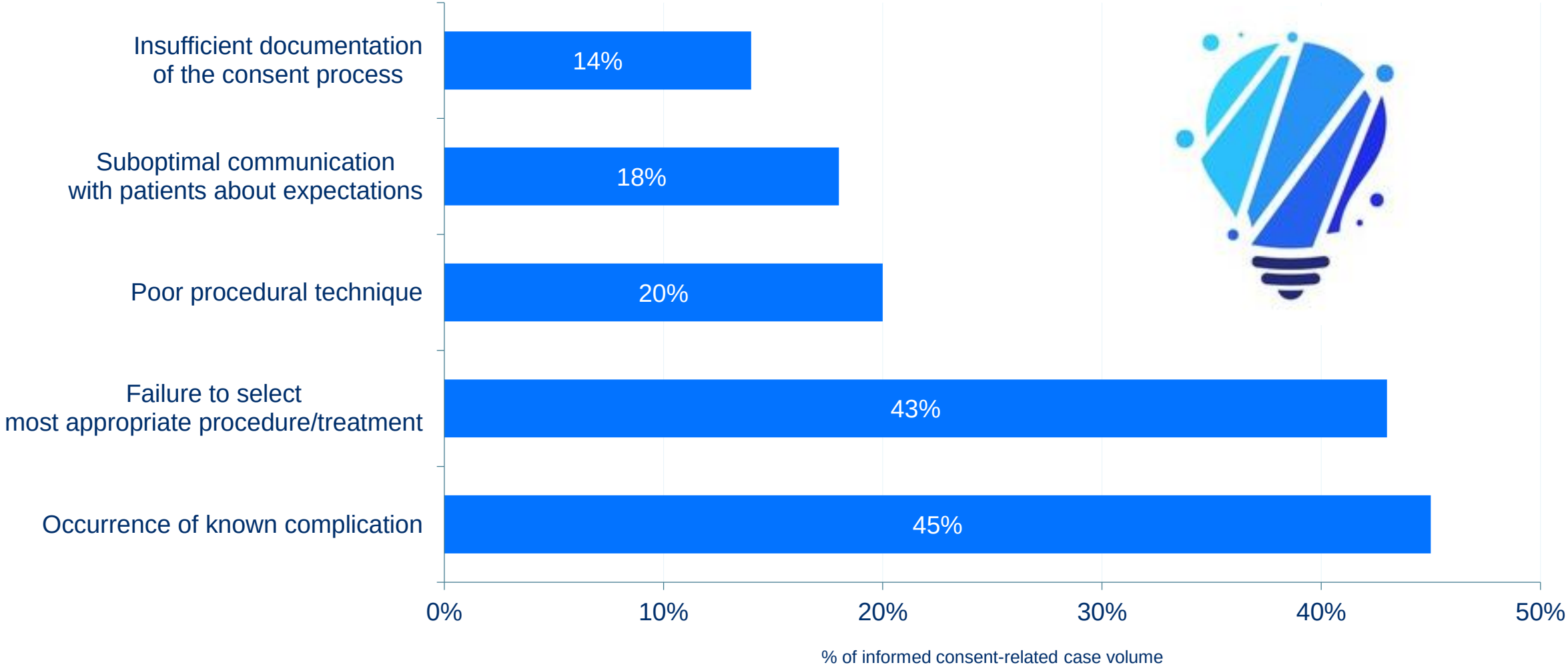




MedPro Group closed cases, 2010-2019.

Other contributing risk factors

These other risk factors are common in informed consent cases.



Informed consent minimum disclosures

Minimum disclosures required during a thorough informed consent process include:

- The patient's diagnosis
- Name of the proposed procedure/treatment (both in medical and layman's terms)
- Explanation of the procedure/treatment and its purpose
- Names of all practitioners who will be involved and their significant tasks
- Important risks and benefits (those that the patient might consider to be important as well as those that might affect the patient's decision to accept or reject the recommendation)
- Alternatives to the proposed procedure/treatment, including no action

Consider just the minimum disclosures required for an adequate informed consent. Then, consider if a procedural complication arises and occurs in combination with an inadequate informed consent. Failure to cover any of these disclosures, or failure of the patient to understand any of these disclosures, may set the stage for a subsequent malpractice action.

Case studies

How informed consent impacts the defensibility of a malpractice or negligence claim

Case study: surgery

Patient	32-year-old male law enforcement officer in auto accident while on the job; accident resulted in a back injury.
Summary	The patient had complaints of lower back pain and was treated conservatively over several months, including receiving three epidurals, which provided some pain relief. The patient returned to work, but ultimately presented to the emergency department with complaints of leg numbness, loss of leg control, and pain while driving. The patient was admitted. An MRI revealed disc bulging at L2-3, L3-4, and L5-S1. The orthopedic surgeon recommended disc removal and fusion surgery at L2-3 for later that afternoon. The patient consented to single-level fusion; however, once in the operating room, the orthopedic surgeon determined the patient needed three disc fusions and proceeded.
Outcome	Malpositioned pedicle screw, lack of disc fusion, movement of intraoperative cage, need for additional surgery, permanent debilitating back pain, loss of job and income.
Allegations	(1) Lack of consent, battery (patient consented to single-level fusion, but 3-level fusion was done), and (2) negligent performance of procedure.

Case study: pain management

Patient	Female in her mid-thirties with reflex sympathetic dystrophy (RSD) referred by orthopedist to anesthesiologist.
Summary	The anesthesiologist treated the patient conservatively with opioids and anticonvulsants without relief. Then the anesthesiologist treated the patient with three to four stellar ganglion blocks over 6 months, which gave only temporary relief. A spinal cord stimulation was done, but the patient complained of anxiety resulting from the hardware in her back. Although she was pain-free during this time, the device was removed 1 week later. Her pain persisted. The anesthesiologist performed several phenol injections in an acute care setting with good results. The anesthesiologist left the hospital, so the patient was sent to an ambulatory setting for her next phenol injection, where she became cyanotic during the procedure. She was transferred to the hospital, intubated, vented, and needed a tracheotomy and gastrostomy.
Outcome	CT showed intrathecal air in spinal cord. Suspected dural tear allowing phenol to infiltrate cerebrospinal fluid resulting in partial paralysis.
Allegations	(1) Inadequate consent discussions and poor documentation; (2) consent forms incomplete; and (3) improper performance of anesthesia procedure.

Case study: medication management

Patient	48-year-old female who had a left femoral artery embolectomy; seen regularly by primary care physician (PCP) for monitoring of warfarin.
Summary	The patient's PCP was not available for one office visit, so the PCP's associate saw the patient. The patient complained of stomach upset from warfarin prescribed by a vascular surgeon; she wanted to discontinue it and begin an aspirin regimen instead. The associate okayed it, without discussing the risks and benefits regarding warfarin discontinuation or alternative options, such as clopidogrel bisulfate. The associate never saw the patient again.
Outcome	4 months after the office visit, the patient had a colonoscopy and developed cardiac symptoms. The cardiology consult led to a cardiac catheterization that revealed significant coronary artery disease. After the catheterization, the patient had a stroke and died.
Allegations	(1) Lack of consent related to risks of discontinuing warfarin; (2) inadequate consent related to other treatment options; and (3) failure to communicate with other providers about approval for patient to discontinue warfarin and replace with an aspirin regimen in lieu of alternative blood thinners.

Informed consent in detail

Informed consent accountability

Provider	Generally, the consent discussion is a nondelegable duty.
	The individual performing the procedure has the obligation to conduct the consent discussion.
Staff	Staff may reinforce the information shared by the provider.
	Staff may provide supplemental educational information, resources, etc.

What medical situations should involve consent?

- Surgery
- Anesthesia
- Medications
- Noninvasive treatments
- Treatment of chronic conditions
- Human subjects research
- Vaccines

Consent for noninvasive treatment

Behavioral health	• Counseling • Group • ECT
Therapy	• Physical • Occupational • Speech
Other treatments	• Nutrition • Hypnotherapy • Massage • Acupuncture
Diagnostic tests	• Stress tests • EMG
Radiology	• Films • Scans • MRI
Chiropractic	• Manipulations • Acupuncture • MUA • Treatment equipment

ECT: electroconvulsive therapy; EMG: electromyogram; MRI: magnetic resonance imaging; MUA: manipulation under anesthesia

Elements of consent

Informed consent

- Discuss proposed treatment/procedure
- Review risks, benefits, and alternatives
- Allow time for questions and answers

Informed choice

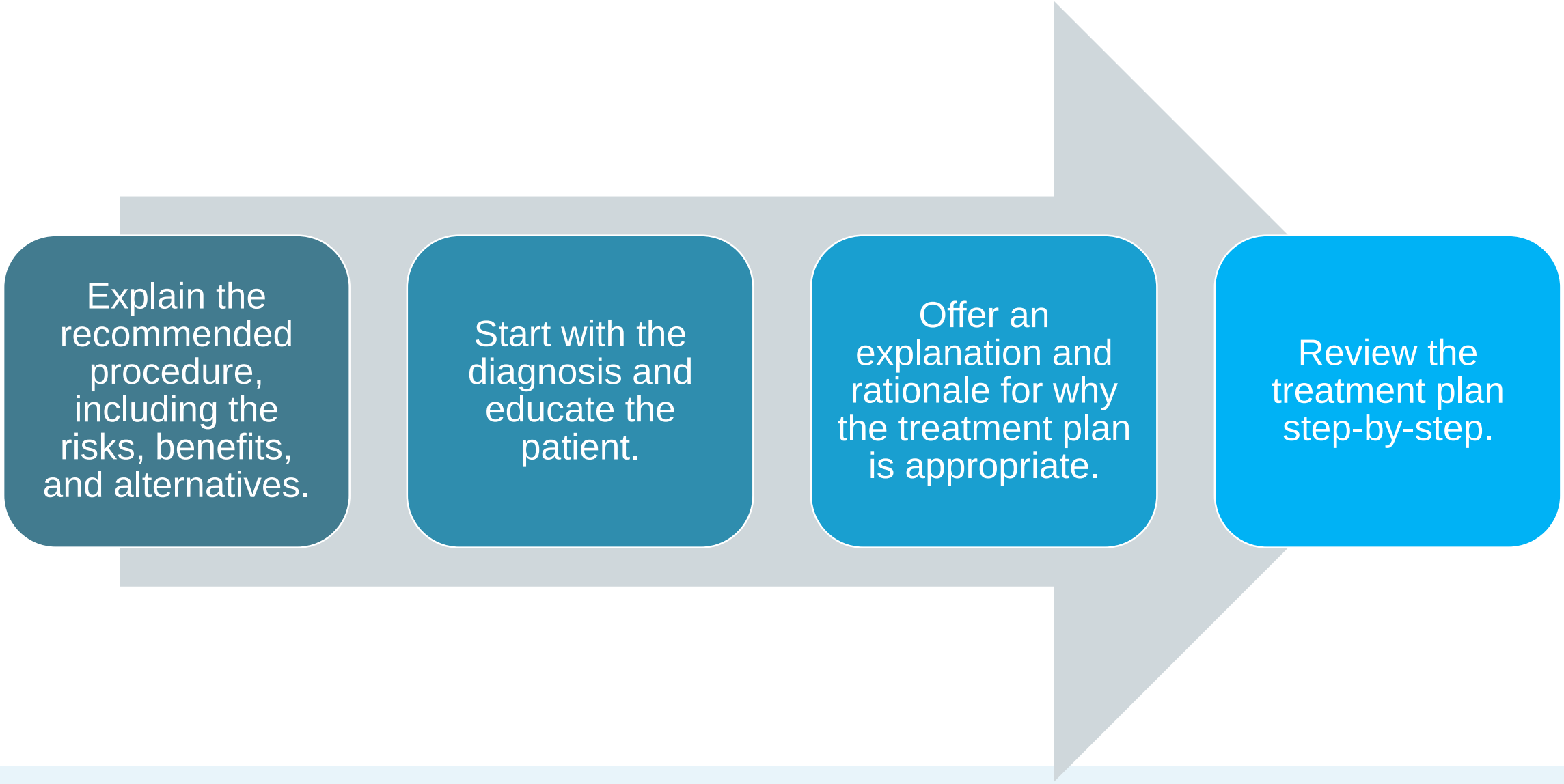
- *Informed consent plus:*
  - Assess the patient's understanding of the consent information
  - Discuss the risks and benefits of each alternative
  - Allow the patient to make his/her choice

Shared decision-making

- *Informed consent plus informed choice:*
  - Patient needs, values, and goals are considered
  - Provider experience is discussed
  - Costs to patient are evaluated
  - Conversation with the patient and support team occurs

Krishna Prasad G. V. (2020). Shared decision making in peri-operative medicine: Miles to go in Indian scenario. *Journal of Anaesthesiology, Clinical Pharmacology, 36*(3), 316–324. https://doi.org/10.4103/joacp.JOACP_250_19

Elements of the informed consent discussion



Criteria for informed consent

- Competence to understand and to decide
- Voluntary decision-making
- Disclosure of material information
- Recommendation of a plan
- Patient comprehension of disclosure of material information
- Patient comprehension of recommendation of a plan
- Decision in favor of a plan
- Authorization of the plan

Thomas, J., & Moore, G. (2013). Medical-legal issues in the agitated patient: Cases and caveats. *Western Journal of Emergency Medicine, 14*(5). Retrieved from http://westjem.com/articles/medical-legal-issues-in-the-agitated-patient-cases-and-caveats.html

Considerations in consent

Adequate information

- Rationale
- Risks and benefits
- Implications for future choices

Voluntary decision

- Understand right to choose
- Influences on ability to choose (e.g., illness)
- Emotional or mental issues
- Religious or cultural influences
- Situational influences

Capacity to decide

- Ability to communicate clearly
- Ability to understand the information given
- Ability to reason using the information
- Ability to appreciate implications of the decision

Customized (personalized) consent

Study	A percutaneous coronary intervention (PCI) study using the patient risk information services manager (PRISM) — a electronic clinical risk modeling and informed consent tool.
Population	590 PCI patients given standard informed consent form with general information (control group).
	527 PCI patients given informed consent form created specifically for them by PRISM.
Findings	50% of the PRISM group reported 100% understanding of information vs. 30% of the control group.
	50% of PRISM group stated the consent form was easy to read vs. 25% of control group.
	Patients in the PRISM group were more likely to recall specific risks of the PCI procedure.

Spertus, J. A., et al. (2015). Improving the process of informed consent for percutaneous coronary intervention: Patient outcomes from the Patient Risk Information Services Manager (ePRISM) study. *American Heart Journal, 169*(2), 234-241.

Customized (personalized) consent

There is an important ethical mandate, beyond the legal mandate, of informing patients about their risk and to engage them in choosing therapy aligned with their own personal goals and values.

Patients cannot make an informed decision about their own risks or benefits with any given therapy based solely on population-wide data. They need estimates based on their own unique characteristics.

Consequences of lack of, or inadequate, informed consent

Potential allegation of battery (criminal offense)

Unanticipated outcome — patient unprepared for results

Civil liability

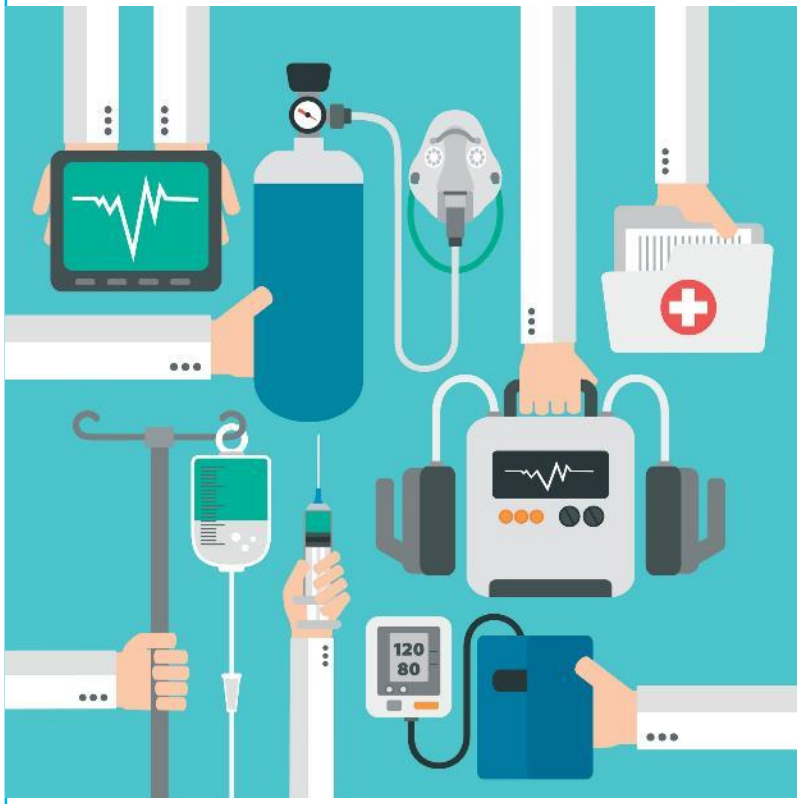
May be in violation of:

- State statutes/regulations
- Organizational policies and procedures
- Governing professional bodies' ethics (American Medical Association, American Dental Association, etc.)

Is consent always necessary?

Consent is not required in medical emergencies.

- Criteria for a medical emergency:
  - Patient is incapacitated and “unable to reach an informed choice.”
  - Incapacitation may be due to:
    - Injury or sudden illness.
    - Alcohol or drug intoxication.
    - Shock or trauma.
    - Underlying mental or physical disease or handicap barring a reasoned choice.
  - Patient must have a life-threatening disease or injury requiring immediate treatment.



Rosovsky, F. A. (2019). *Consent to treatment: A practical guide* (5th ed.). Gaithersburg, MD: Aspen Publishers.

Therapeutic privilege

Therapeutic privilege refers to the withholding of information by the clinician during the consent process in the belief that disclosure of this information would lead to the harm or suffering of the patient.

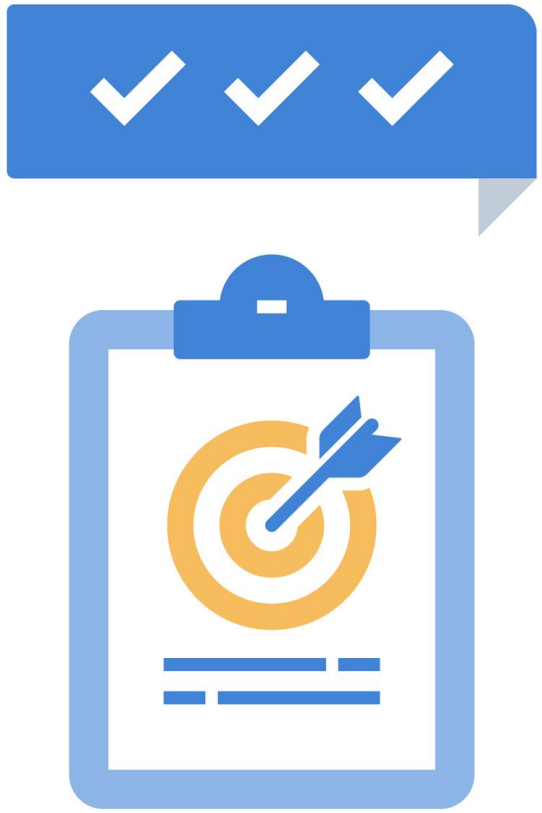
Etchells, E., Sharpe, G., Burgess, M. M., & Singer, P. A. (1996). Bioethics for clinicians: 2. Disclosure. *Canadian Medical Association Journal, 155*(4), 387–391.

Special informed consent considerations

Consent for minors

Minors

- Guardianship: Who has legal authority to give consent?
  - Family/friend/clergy/other?
  - Group home staffer?
  - By what authority can you ask to see paperwork?
- Issues related to divorce:
  - Who has custody?
  - Is it a sole custody or joint custody arrangement?
  - Who is paying for minor's treatment?

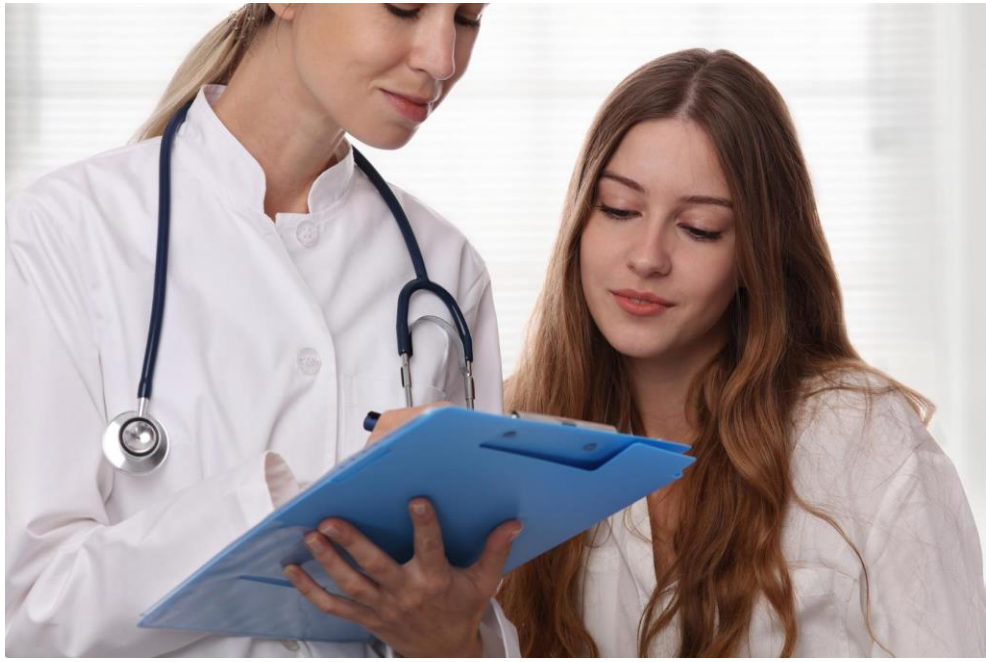


Be sure to comply with your state's regulations.

Consent for minors

In many states, minors can consent to:

- Contraceptive services
- Services for sexually transmitted infections
- Prenatal care
- Adoption
- Medical care for a child
- Confidentiality of health records for these services



Consent for adults who have diminished capacity

Adults who lack capacity or competence to make informed choices should participate in decision-making to the best of their abilities.

Develop policies, best practices, and standards for:			
Identifying patients who may lack capacity	Evaluating capacity	Determining competence	Using appropriate alternative consent procedures

Resource

The Vanderbilt Kennedy Center offers a toolkit for primary care providers titled Health Care for Adults With Intellectual and Developmental Disabilities. The kit includes detailed information about determining capacity, obtaining and documenting consent, and identifying a surrogate decision-maker.

Hahn-Chaet D. (2017) AMA code of medical ethics' opinions on patient decision-making capacity and competency and surrogate decision making. *AMA Journal of Ethics.19* (7) 675-677.

Informed refusal

Informed refusal

Informed refusal:

- A patient’s right to refuse treatment

Decision may be attributed to:

- Religious convictions
- Cultural or ethnic values
- Financial constraints
- Lack of familial/community support
- Fear of discomfort
- Fear of outcome

Informed refusal

Record the patient's refusal

Document in the health record:

- Patient reservations or concerns
- Other obstacles
- Discussion of consequences without proposed treatment

Patient attestation:

- Akin to a consent form
- List proposed benefits
- List potential risks in deciding against treatment
- Note patient's opportunity to ask questions/receive answers

Revocation/withdrawal

- Revocation/withdrawal of prior consent is the patient's right.
- Provider must comply, unless treatment or procedure has begun, and to stop would put the patient at further risk.

Risk strategies

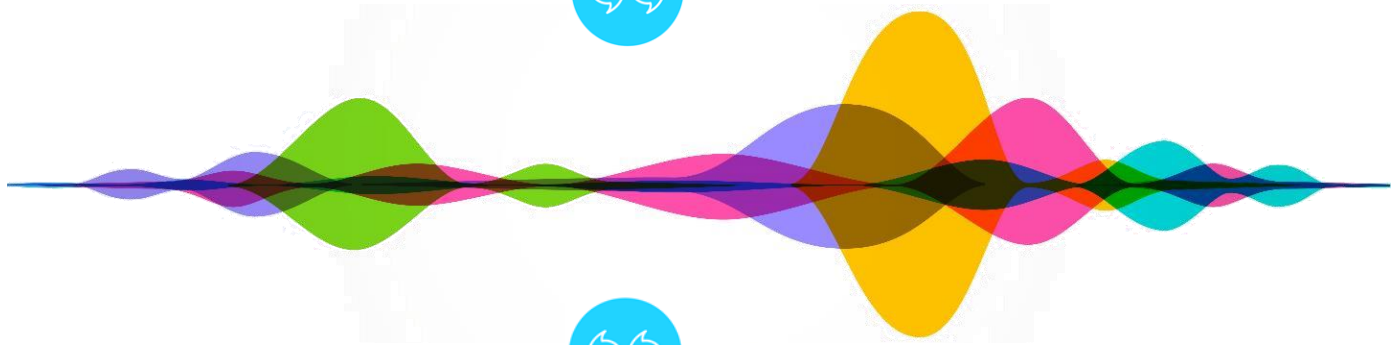
Communication and delivery

Allow time between the informed consent discussion and the proposed procedure to allow for:

- Understanding of material information and recommended plan
- Seeking answers to questions
- Researching proposed procedure using:
  - Websites
  - Patient education handouts
  - Multimedia

Patient comprehension

Even after signing a consent form, many patients do not fully understand the nature, risks, benefits, and alternatives of their treatments.



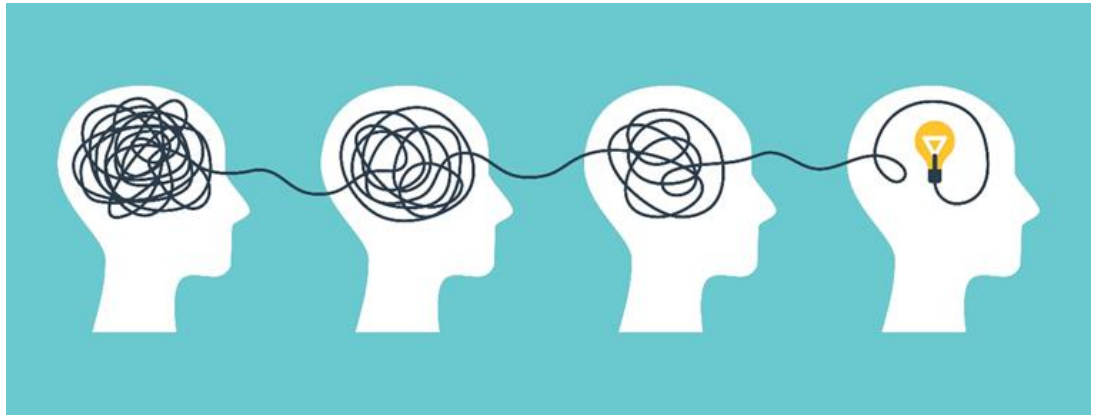
Lack of adequate understanding is particularly common for vulnerable populations such as those who face language barriers or those with limited education or health literacy. Current practices also generally fail to define adequate patient comprehension and to ensure its assessment as part of the informed consent process.

Becker's Hospitals Review. (2017, January 19). *Joint Commission offers courses to improve informed consent.* Retrieved from www.beckershospitalreview.com/patient-experience/joint-commission-offers-courses-to-improve-informed-consent-process.html; Glaser, J., et al. (2020). Interventions to improve patient comprehension in informed consent for medical and surgical procedures: An updated systematic review. *Medical Decision Making, 40*(2), 119–143. https://doi.org/10.1177/0272989X19896348

Reinforce the informed consent discussion: health literacy

Clear communication can improve a patient's comprehension.

- Speak slowly and clearly.
- Focus on and repeat "need to know" concepts and information.
- Avoid clinical jargon.
- Use visual aids to explain important concepts.
- Use plain language educational materials.
- Encourage interactive dialogue.
- Use the "teach-back" technique to gauge comprehension.
- Provide treatment and follow-up care instructions verbally and in writing.



Reinforce the informed consent discussion: teach-back

The teach-back technique is a research-based health literacy intervention that improves patient–provider communication and patient health outcomes. Teach-back is a helpful method for gauging patient comprehension.

"I want to be sure that I did a good job explaining your problem. Can you tell me:

- What your condition is?
- What you need to do?
- Why you need to do it?"

Resource

Always Use Teach-Back! Training Toolkit www.teachbacktraining.org/

Reinforce the informed consent discussion: plain language

Key plain language concepts:

- Use a font size of 12–14 points.
- Use concrete nouns and active voice.
- Avoid excessive use of *italic font,* ALL CAPS, and underlining — all of which are hard to read.
- Limit information to no more than three to four key messages.
- Put the most important information at the beginning and repeat it at the end.
- Avoid lengthy lists.
- Use simple one- or two-syllable words when possible (e.g., “heart attack” instead of “myocardial infarction”)
- Eliminate clinical jargon.
- Use visuals to reinforce concepts and help clarify information.

Document the informed consent discussion

The quality, not the quantity, of the documentation is important.

- Entry should be objective, factual, and concise.

Record essential elements: risks, benefits, alternatives, consequences of doing nothing.

Document patient's understanding and use of any comprehension techniques (e.g., teach-back).

Note any questions that the patient asked.

- How were these questions answered?
- Was the patient satisfied with the responses?

Other considerations:

- Mention educational pieces given to patient to reinforce consent process.
- Note patient refusal of proposed treatment and reasons given.

Sample consent language

- National Institutes of Health
- Medical and dental schools
- Professional organizations
- State medical associations
- State dental associations

Summary

Summary

Data tell the story of the role of informed consent in malpractice claims.

Consent is a process, not just a discussion or a form.

Understand the elements of consent: risks, benefits, alternatives, consequences of doing nothing.

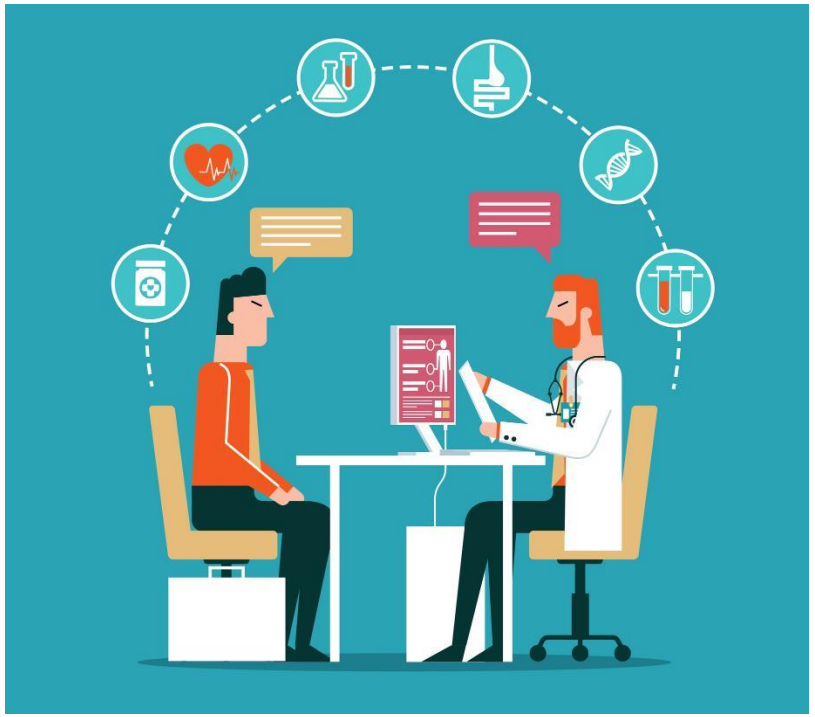
Documentation is crucial.

Know how to respond to informed refusal (revocation/withdrawal).

Determine who may provide consent.

Educate your patients and make sure they understand the information provided.

Use resources to supplement your consent discussion.



Resources

Article: Informed Refusal: A Review
www.medpro.com/documents/10502/2820774/Article_Informed+Refusal_A+Review.pdf

Checklist: Informed Consent
www.medpro.com/documents/10502/2899801/Checklist_Informed+Consent.pdf

Checklist: Strategies to Support Patient Comprehension
www.medpro.com/documents/10502/2899801/Checklist_Patient+Comprehension.pdf

Guideline: Risk Management Strategies for Informed Consent
www.medpro.com/documents/10502/2837997/Guideline_Risk+Management+Strategies+for+Informed+Consent.pdf

Risk Resources: Informed Consent
https://www.medpro.com/documents/10502/2824311/Risk+Resources_Informed+Consent.pdf

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