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"You Never Told Me!"

Why Thorough Informed Consent Is Paramount in Patient Care

Program speaker

Today's speaker is Arlene Luu, RN, BSN, JD, CPHRM, Senior Patient Safety & Risk Consultant, MedPro Group (Arlene.Luu@medpro.com)

Arlene provides comprehensive risk management services to policyholders in MedPro Group's Western Division. She has more than 20 years of experience as a registered nurse and has worked as a defense attorney representing doctors, nursing homes, nurses, and other healthcare providers in medical malpractice cases.

Arlene's experience in risk management and patient safety includes working in the hospital setting and providing risk consulting services to physicians in all specialties, dental providers, medical groups, and healthcare facilities. She has presented and published information on various patient safety topics, and she has provided risk management guidance and support related to healthcare law, quality improvement, and risk exposure.

Arlene earned her bachelor of science degree in nursing from San Diego State University, a certificate in public health nursing for the state of California, and her juris doctorate degree from California Western School of Law. She is a licensed attorney in California and a certified professional in healthcare risk management (CPHRM).

Program speaker

Russ Pride, MA, CPHRM
Senior Patient Safety & Risk Consultant, MedPro Group
(Russ.Pride@medpro.com)

Patient safety and clinical risk management have been the principal focus of Russ' career for the past 25+ years. Working as a patient safety and healthcare risk consultant for Princeton Insurance (a MedPro Group company) for 19 years, Russ provides an array of risk management services for physician practices, hospital systems, and professional healthcare organizations in New Jersey and New York, as well as for several national accounts.

Russ' previous experience includes serving as a risk manager for an urban acute care hospital; developing healthcare marketing programs for hospitals and pharmaceutical companies; and working with a regional health insurer in the areas of quality assurance, human resources, and corporate administration.

Russ is a certified professional in healthcare risk management (CPHRM) through the American Hospital Association. He earned his certificate in healthcare risk management through the New England Healthcare Assembly (Boston, MA) and is a chapter member of the Pennsylvania and New York societies of healthcare risk managers.

Russ is a workshop presenter for the Institute for Healthcare Communication (New Haven, CT), focusing on provider-patient communication. He earned a master's degree in psychology from LaSalle University (Philadelphia, PA) and has clinical experience as a behavioral therapist. An advocate for effective communication as the cornerstone for promoting safer patient care, Russ delivers workshops focusing on risk-prone issues such as informed consent, patient compliance, difficult relationships, the impact of social media, patient satisfaction, and more.

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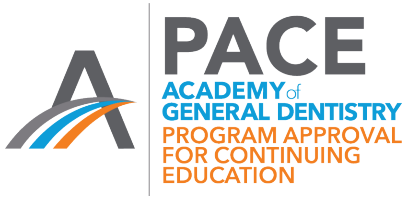
MedPro Group designates this enduring activity for a maximum of 1.0 AMA PRA Category 1 Credits™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.



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When there are relevant financial relationships, the individual(s) will be listed by name, along with the name of the commercial interest with which the person has a relationship and the nature of the relationship.

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.

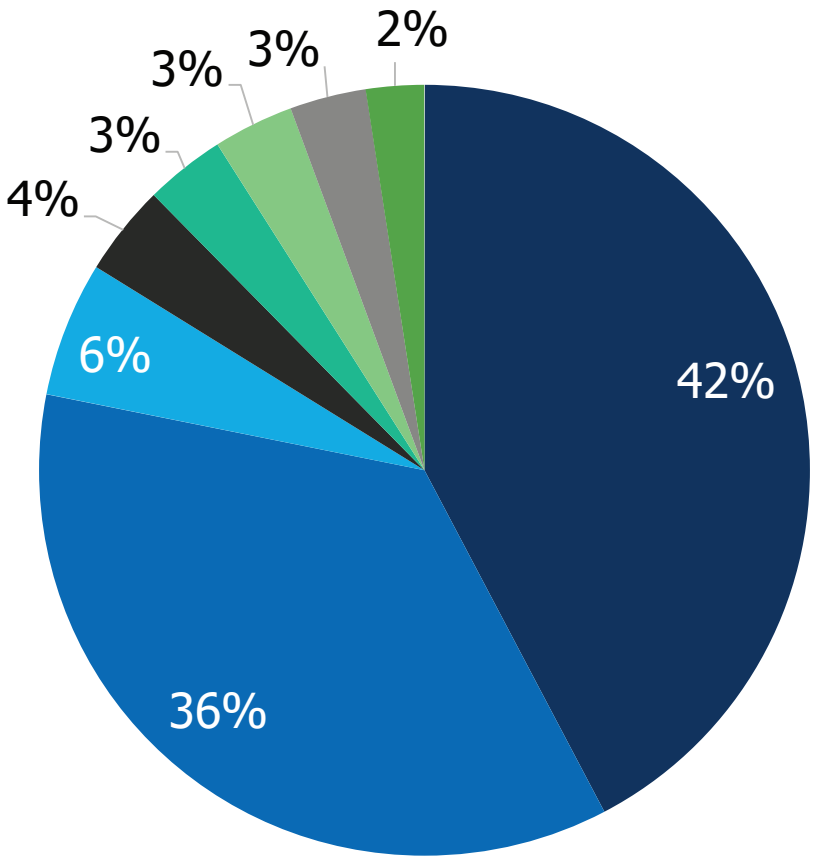
Objectives

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

- Articulate key elements of a thorough informed consent process
- Understand the need for comprehensive documentation of the informed consent process in the patient record
- Know the value of and difference between a consent form and an informed consent discussion
- Understand the risks of an incomplete or absent informed consent process
- Acquire strategies to minimize risk exposures relative to the informed consent process

Informed consent data

Informed consent: allegation categories



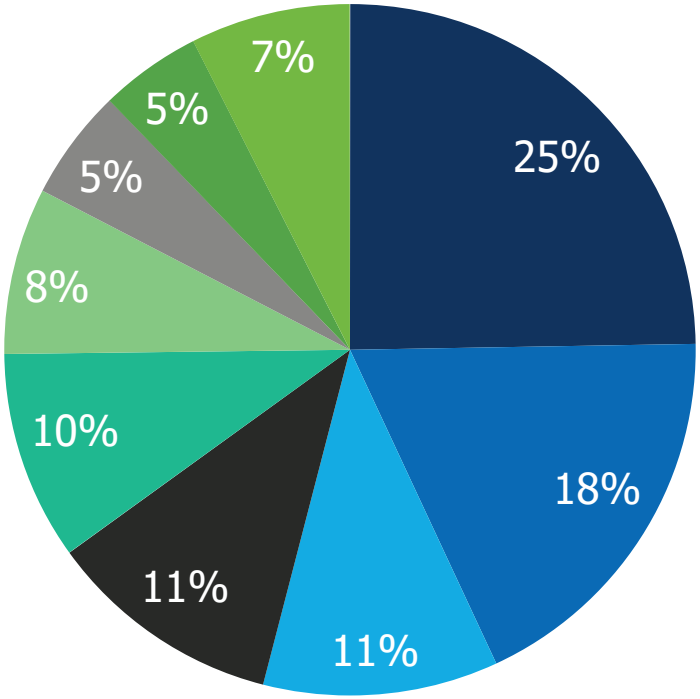
- Surgical Treatment
- Treatment-Related
- Communication
- Anesthesia-Related Treatment
- OB-Related Treatment
- Diagnosis-Related
- Medication-Related
- Other

Note: The "other" category includes allegations for which no significant claim volume exists. Any totals not equal to 100% are the result of rounding.

Source: MedPro Group closed claims data, 2005–2014.

Informed consent: responsible services

Responsible services are those specialty services that are alleged to be responsible for the resultant allegation(s) of the case



- Surgical Specialties
- Dentistry/Oral Surgery
- Medicine Specialties
- OB/GYN
- Orthopaedics
- General Surgery
- General Medicine
- Anesthesiology
- Other

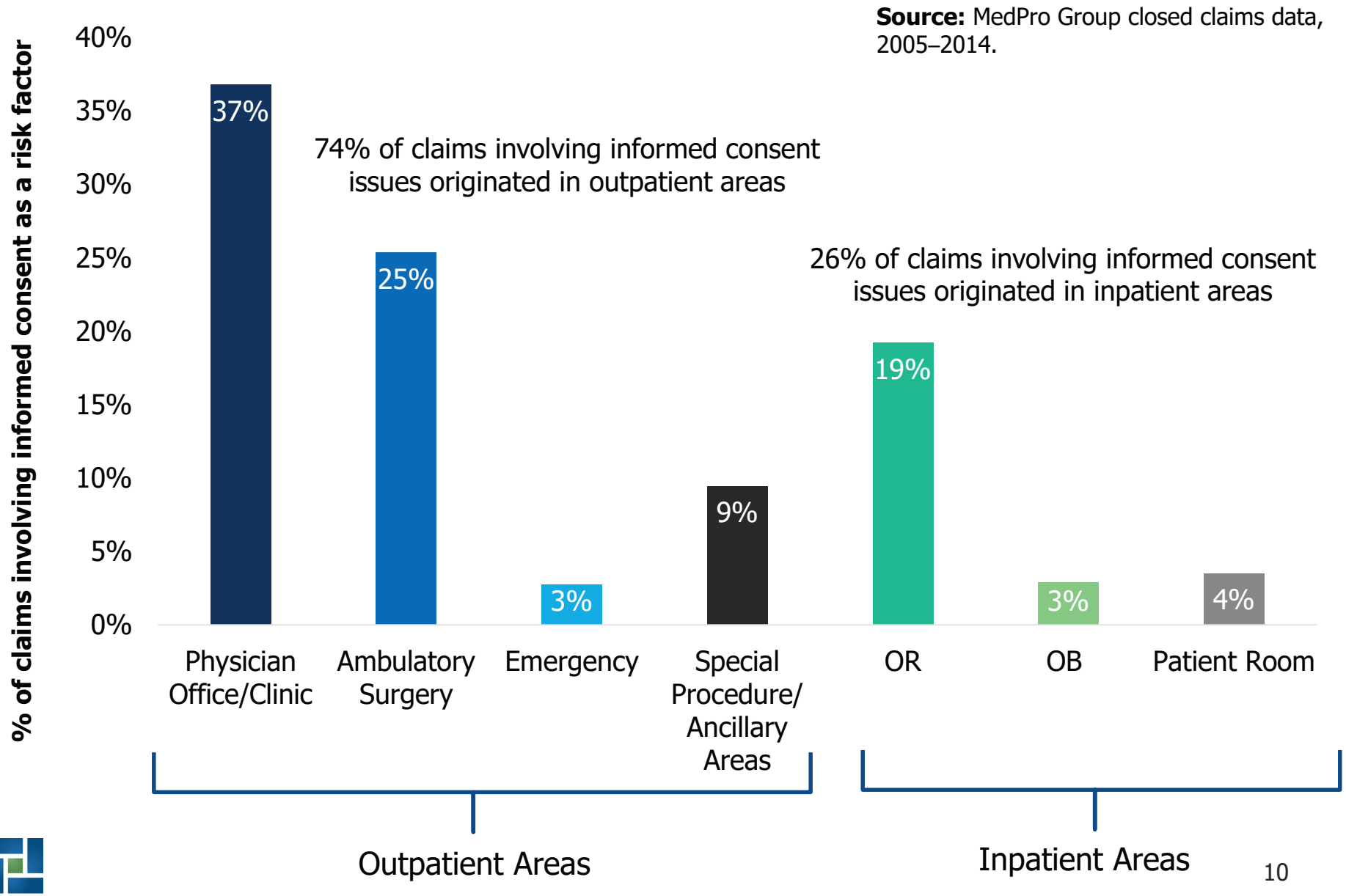
Top three specialties:
- Ophthalmology
- Orthopaedics
- Plastic

Top three specialties:
- Cardiology
- Dermatology
- Gastroenterology

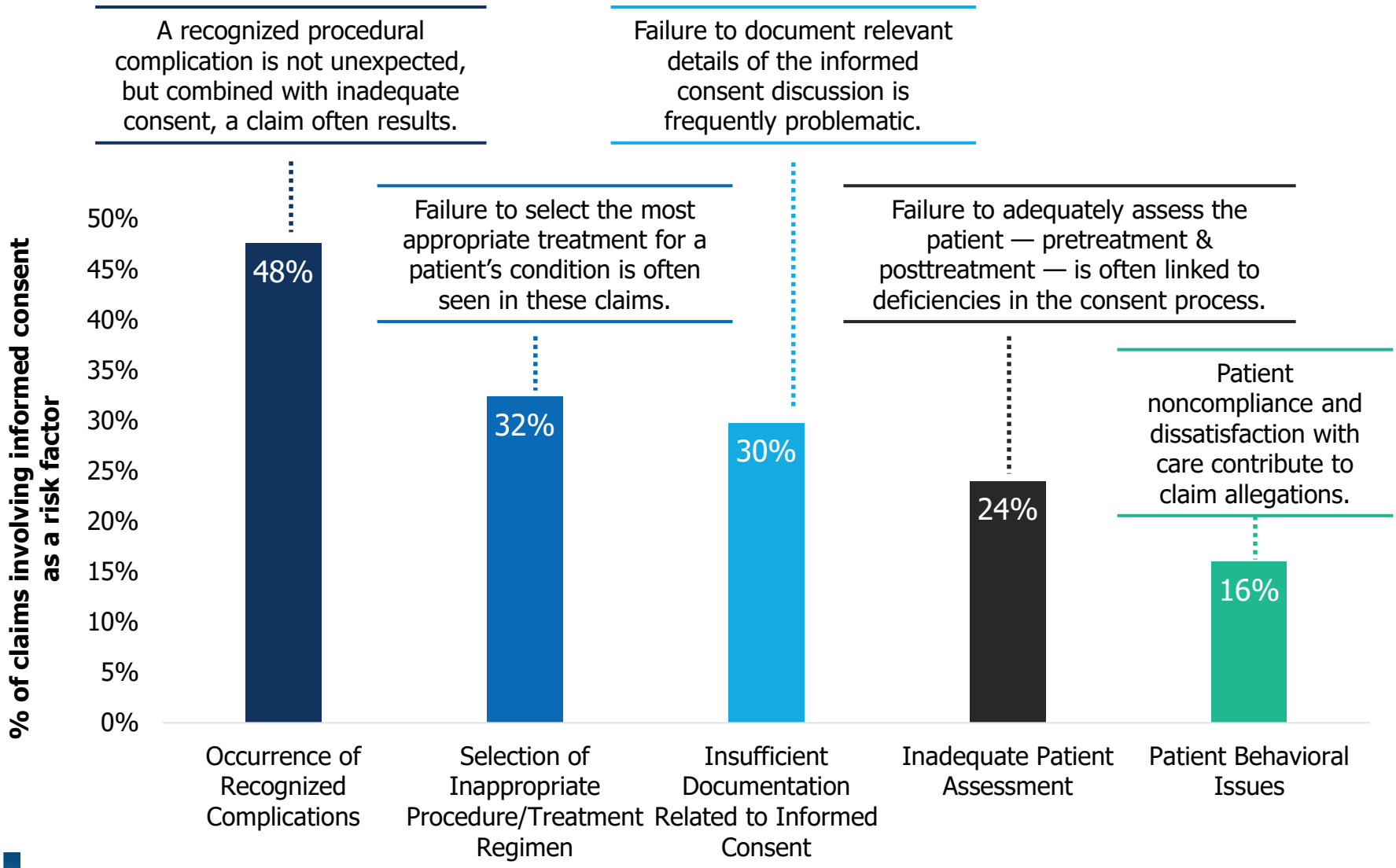
Note: The "other" category includes allegations for which no significant claim volume exists. Any totals not equal to 100% are the result of rounding.

Source: MedPro Group closed claims data, 2005–2014.

Informed consent: location

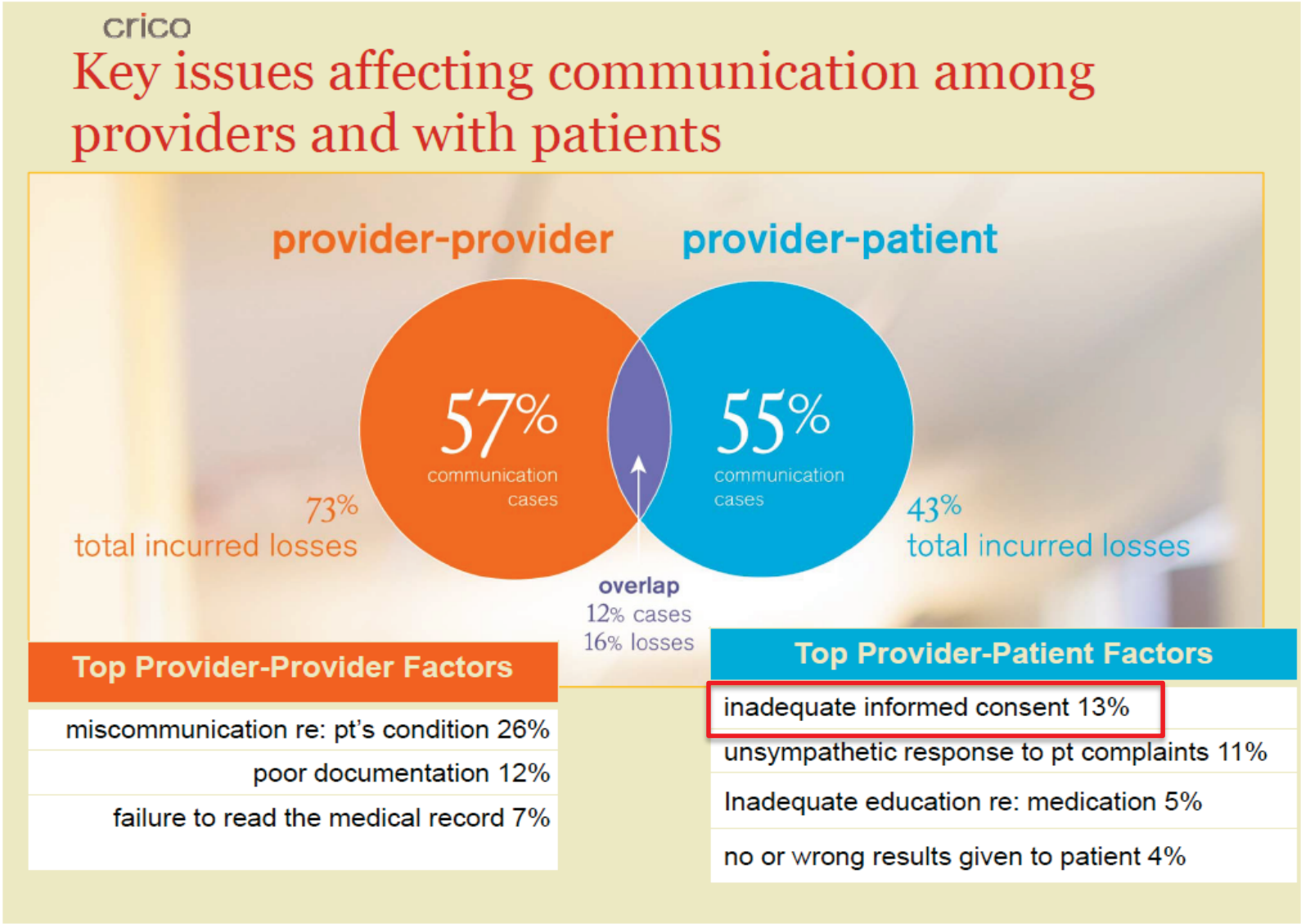


Informed consent: associated risk factors



Note: Totals do not equal 100% because more than one factor is associated with each claim.

Informed consent: communication breakdown



Source: Malpractice Risks in Communication Failures (2015). Annual Benchmarking Report, CRICO Strategies, a division of The Risk Management Foundation of the Harvard Medical Institutions Incorporated)

What is 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."

Source: Faden, R. R., Beauchamp, T. L. (1986). *A History and Theory of Informed Consent*. New York, NY: Oxford University Press, 101.

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."

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

An informed discussion

Discuss the risks, benefits, alternatives/options, as well as the risks of withholding treatment.

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

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

An authorization form

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

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

Patient comprehension

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

Salome Chitavi, PhD, Project Director
Division of Healthcare Quality Evaluation
The Joint Commission

Informed consent in depth

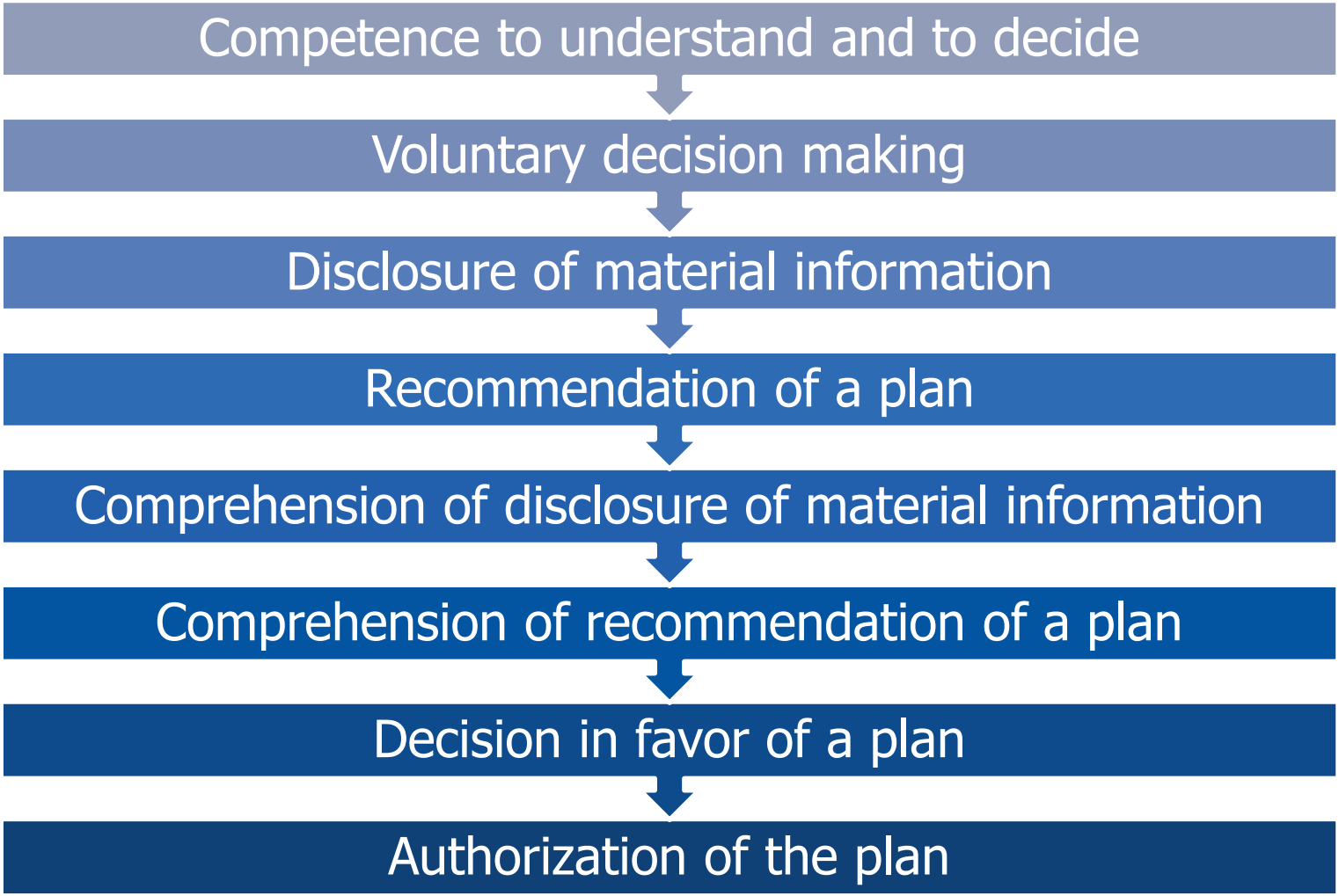
Is consent always necessary?

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 life-threatening disease or injury requiring immediate treatment

Source: Rosovsky, F. A. (2005*). Consent to Treatment: A Practical Guide, 3rd ed*. Gaithersburg, MD: Aspen Publishers.

Criteria for informed consent



Source: 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 (illness?)
- Emotional or mental issues
- Religious or cultural influences
- Situational influences

Capacity to decide

- Able to communicate clearly?
- Understand the information given?
- Able to reason using the information?
- Appreciate implications of the decision?

Responsibility for consent

Provider

- Generally, this is a nondelegable duty.
- 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.

Failure to obtain consent — potential consequences

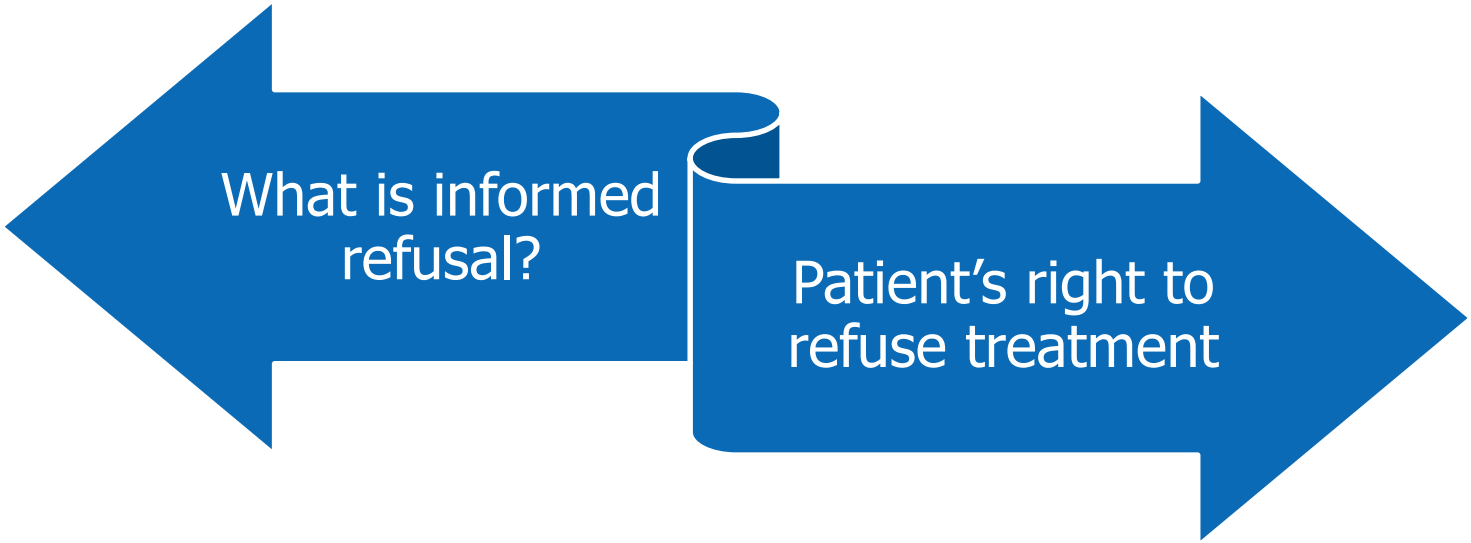
Potential allegation of battery (criminal offense)

Unexpected outcome — patient unprepared for results

Civil liability

May be in violation of (a) state statutes/regulations, (b) organizational policies and procedures, or (c) governing professional bodies' ethics (AMA, ADA, etc.)

Informed refusal



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 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

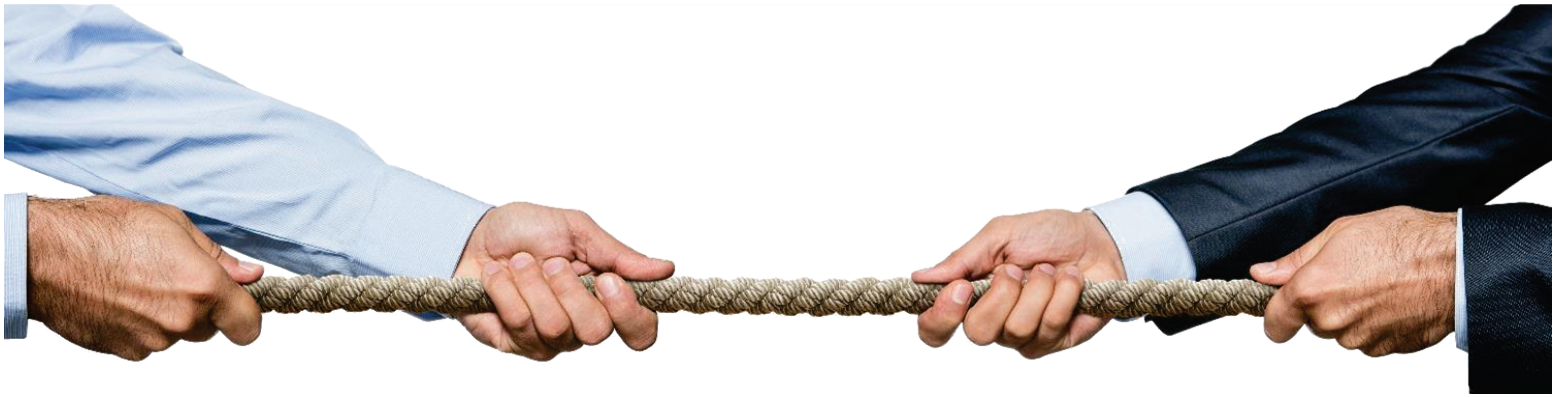
Revocation/withdrawal

- 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.

Additional considerations

Minors and adults with diminished capacity

- Guardianship: Who has legal authority to give consent?
  - Family/friend/clergy/other?
  - Group home staffer?
  - Show me the paperwork! (by what authority?)
- Issues related to divorce:
  - Who has custody? Sole custody vs. joint custody?
  - Who is paying for minor's treatment?
- Be sure to comply with your state's regulations



Consent for minors

In most states, minors can consent to:

- Contraceptive services
- Sexually transmitted infections services
- Prenatal care
- Adoption
- Medical care for a child
- Confidentiality of health record for these services

Source: State policy updates. Guttmacher Institute. Retrieved from https://www.guttmacher.org/state-policy/explore/overview-minors-consent-law

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:
- PT
- OT
- Speech

Other treatments:
- Nutrition
- Hypnotherapy
- Massage
- Acupuncture

Diagnostic tests:
- Stress tests
- EMGs

Radiology:
- Films
- Scans
- MRIs

Chiropractic:
- Manipulations
- Acupuncture
- MUA
- Tx equipment

Note: ECT: electroconvulsive therapy; EMG: electromyogram; MRI: magnetic resonance imaging; MUA: manipulation under anesthesia; OT: occupational therapy; PT: physical therapy; Tx: treatment

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."

Dr. John Spertus
Mid-American Heart Institute,
Co-Developer of PRISM

"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."

Reed Miller
Customized Informed Consent Improves Communication
(Medscape, November 15, 2011)

Case studies

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

Case study I — surgery

Patient	32-year-old male law enforcement officer in auto accident while on the job; accident resulted in back injury.
Summary	The patient had complaints of lower back pain and was treated conservatively over several months including receiving three epidurals providing some pain relief. The patient returned to work. The patient presented to the emergency department the next day with complaints of leg numbness and loss of 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; once in the OR, the orthopaedic surgeon determined the patient needed three disc fusions and completed same.
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: Consented to single-level fusion, but 3-level fusion done in OR. (2) Negligent performance of procedure.

Case study II — pain management

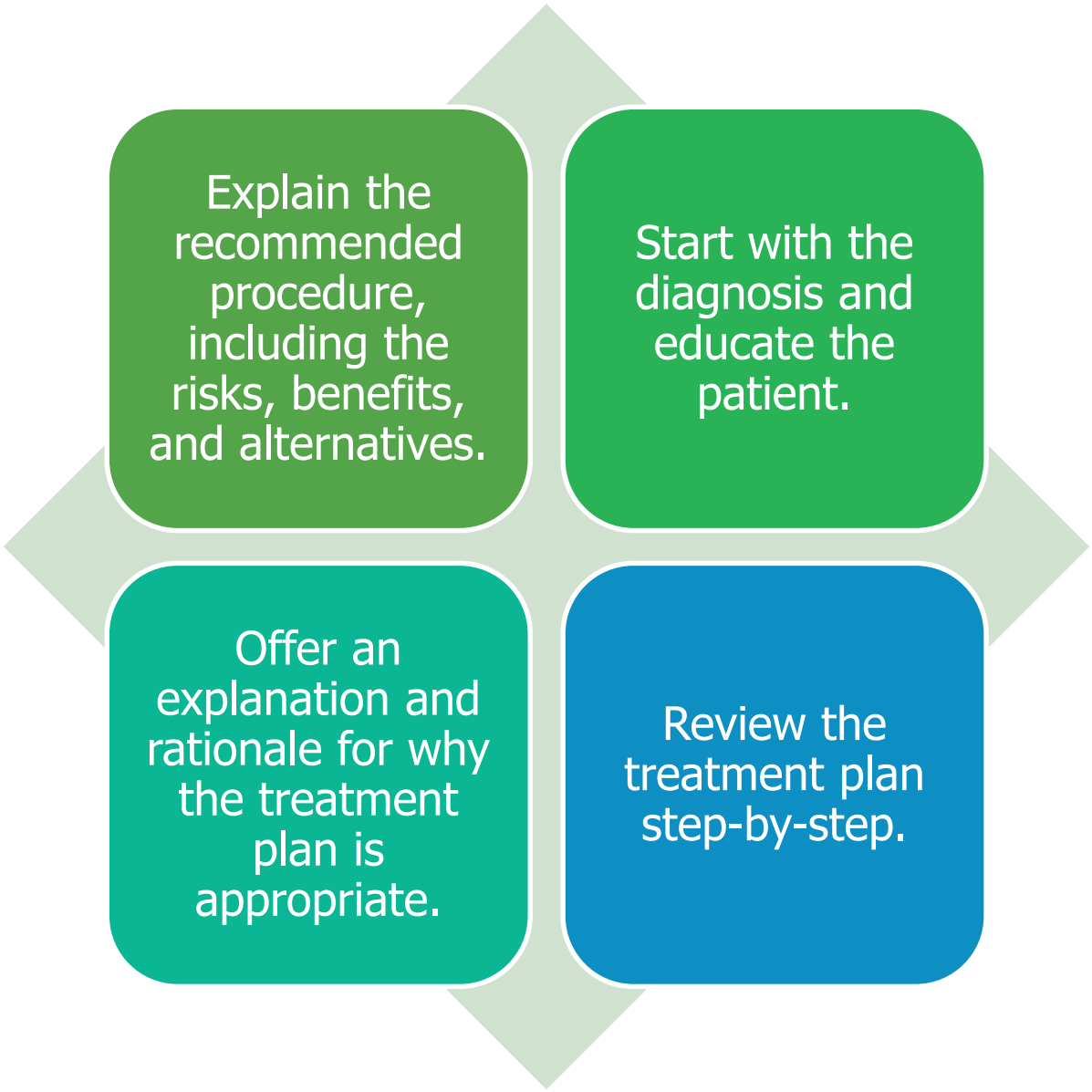
Patient	Female in her mid-thirties postfall with reflex sympathetic dystrophy (RSD) referred by orthopaedist to anesthesiologist.
Summary	The anesthesiologist treated the patient conservatively with opioids and anticonvulsants without relief. Then the anesthesiologist treated the patient with three to 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. (3) Improper performance of anesthesia procedure.

Case study III — medications

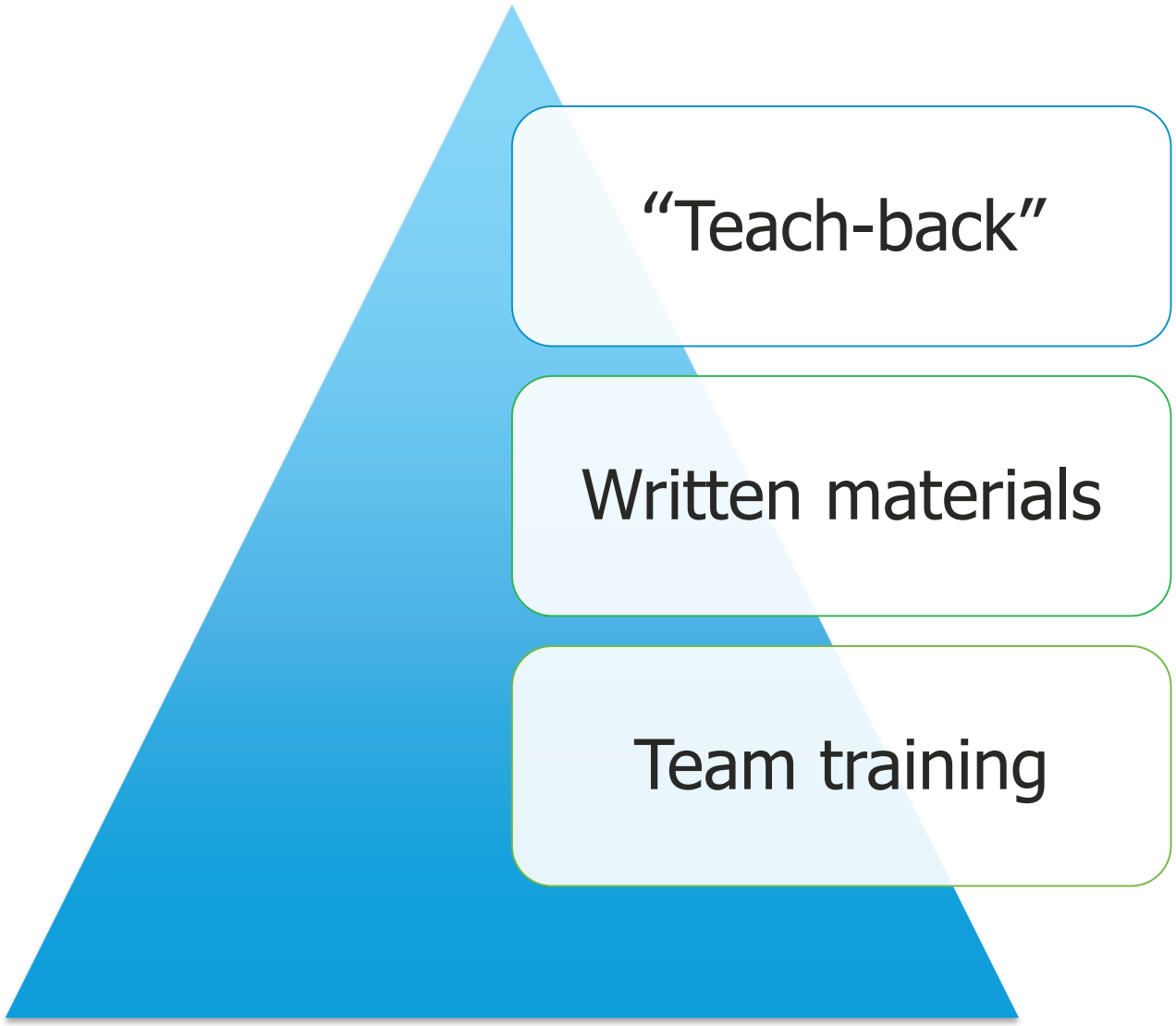
Patient	48-year-old female who'd had a left femoral artery embolectomy; seen regularly by primary care physician (PCP) for monitoring of warfarin.
Summary	The patient's PCP not available for one office visit; the patient was seen by the PCP's associate. The patient complained of stomach upset from warfarin prescribed by a vascular surgeon; she wanted to discontinue it and begin an aspirin regimen instead. The associate okayed it, without discussing the risks, benefits, and alternatives regarding warfarin discontinuation or other options, such as clopidogrel bisulfate. The associate never saw the patient again.
Outcome	4 months after this 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 another stroke and died.
Allegations	(1) Lack of consent related to risks of discontinuing blood thinner. (2) Inadequate consent related to other treatment options. (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.

Risk strategies

Elements of the informed consent discussion



Reinforce the informed consent discussion



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: RBAC

- Risks
- Benefits
- Alternatives
- Consequences of doing nothing

Document patient's understanding

Note 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

Communication and delivery

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

- Understanding
- Comprehending
- Seeking answers to questions
- Researching proposed procedure using:
  - Websites
  - Practice handouts
  - CDs, DVDs, etc.

Supplemental information

Use supplemental information to reinforce the informed consent discussion

- Provide the patient with a written summary of consent discussion to share with his/her support network
- Enhance the discussion with visual aids
- Reinforce the discussion with web resources

Sample consent language

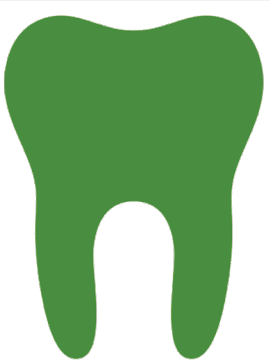
National Institutes of Health

Medical and dental schools

Professional organizations

State medical associations

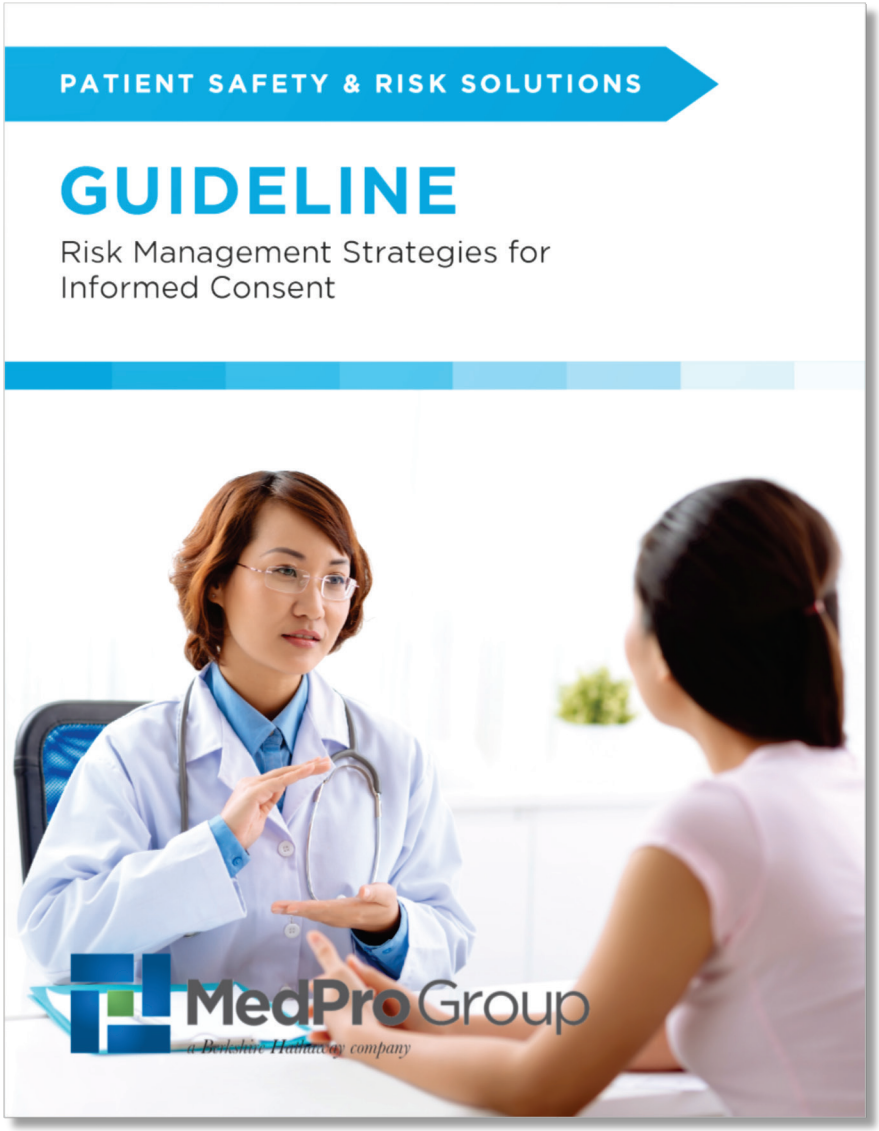
State dental associations



Summary

- Data tell the story.
- Consent is a process, not just a discussion or a form.
- Understand the elements of consent: RBAC.
- Documentation is crucial.
- Know how to respond to informed refusal (revocation/ withdrawal).
- Determine who may provide consent.
- Educate your patient.
- Use resources to supplement your consent discussion.

Resources



Risk Management Strategies for Informed Consent