Informed Consent

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Objectives

- Define and articulate informed consent
- Understand the need for both proper discussion and documentation of informed consent
- Identify the risks of an incomplete or absent informed consent process
- Acquire strategies to reduce risk of failing to obtain adequate informed consent

How is informed consent defined?

- A *process* that involves *discussions* with patients about the risks, benefits, and alternatives of procedures or treatments, as well as risks of foregoing procedures or treatments
  - Physicians have legal and ethical responsibility to provide adequate information to the patient so that the patient is able to make appropriate decisions
  - Physicians are required to document the elements of this discussion

Sources: UpToDate: *Informed Procedural Consent*; MedPro Group: *"You Never Told me!" Why Thorough Informed Consent is Paramount in Patient Care*; Code of Medical Ethics Opinion 2.1.1.

How does UpToDate define effective informed consent?

- Discussion between the provider and patient that includes the provider's disclosure of **material facts**
- Material facts are relevant to decision making, and usually include:
  - Diagnosis, when known (including method and alternative means of diagnosis when invasive, diagnostic techniques are utilized)
  - Proposed treatment or procedure
  - Risks/benefits of treatment
    - Information about events that occur frequently, even if complications would be considered minor
    - Rare events that represent major complications (i.e., death, loss of mobility)
  - Alternative treatment options (surgical or medical) with risks and benefits
  - Risks of refusing treatment/doing nothing

Source: UpToDate: *Informed Procedural Consent.*

Who can provide informed consent to patients?

- Informed consent is a non-delegable duty that the treating healthcare provider must perform
- Staff can reinforce the information shared by the provider, and provide supplemental information and education
  - The individual performing the procedure is responsible for conducting the actual discussion with the patient

Sources: UpToDate: *Informed Procedural Consent*; MedPro Group: *"You Never Told me!" Why Thorough Informed Consent is Paramount in Patient Care.*

Overview: What should the informed consent process look like?

Absent a medical emergency (i.e., incapacitation and life threatening disease/ injury requiring immediate medical treatment):

- Proper person to provide consent:
  - The physician should assess the patient's ability to understand relevant medical information and the implications of treatment alternatives and to make an independent, voluntary decision (i.e., minors must have parent's or legal guardian's consent).
- Discussion:
  - The physician should present relevant information accurately and sensitively. The physician should include information about:
    - The diagnosis (when known)
    - The nature and purpose of recommended interventions
    - The burdens, risks, and expected benefits of all options, including forgoing treatment
- Documentation:
  - The physician should document the informed consent conversation and the patient's (or surrogate's) decision in the medical record in some manner. This is separate from the signed general informed consent form that acknowledges the patient's consent.

Source: Code of Medical Ethics Opinion 2.1.1.

What should be included in the discussion?

- Material Facts:
  - The diagnosis (when known)
  - The nature and purpose of recommended interventions
  - The burdens, risks, and expected benefits of all options, including consequences of doing nothing
- General structure:
  - Use laymen's terms disclosing material facts relevant to the decision-making process while having a conversation with the patient – this is not a legal discussion
  - Provide the patient an opportunity to ask questions
  - Tailor the discussion to each individual's medical condition, and consider:
    - Current understanding of his/her own condition
    - Overall capacity to understand the information provided
    - Language barriers/interpreters
    - Educational materials

Source: MedPro Group: "*You Never Told me!" Why Thorough Informed Consent is Paramount in Patient Care.*

What should be documented?

- Document the content of the informed consent conversation, including all the **material facts** discussed:
  - Diagnosis
  - Nature and purpose of recommended intervention
  - The risks, burdens and expected benefits of all options, including consequences of forgoing treatment
  - Any education provided (written or verbal)
  - Any use of interpreters or family members present
  - Patient's opportunity to ask questions with satisfactory answers
  - Patient's acceptance or refusal of plan
    - If the patient refuses the recommended intervention, the physician must discuss and note the specific risks associated with delay or refusal – this is known as "informed refusal"
- Obtain patient's signature acknowledging discussion and confirmation of the plan at the time of the procedure
  - LMHS general consent form should be scanned into the record and used primarily for the purpose of patient's authorization of treatment

Sources: UpToDate*: Informed Procedural Consent*; MedPro Group: *"You Never Told me!" Why Thorough Informed Consent is Paramount in Patient Care;* ORC 2317.54.

What is considered insufficient documentation?

It is insufficient to:

- Provide only a signed general informed consent form without entering a note to document the contents of the informed consent discussion with the patient
  - The consent form itself means little in its generic form, but rather is used to document the patient's acknowledgment of the discussion
- Document only "Risks and benefits were discussed," without further description of the specifics somewhere in the patient's medical record

Sources: UpToDate: "Informed Procedural Consent;" *MedPro Group*: *"You Never Told me!" Why Thorough Informed Consent is Paramount in Patient Care.*

General form should be used to show patient authorization, but cannot rely solely on form for documentation of informed consent.

INFORMED CONSENT FOR LICKING MEMORIAL HOSPITAL

The purpose of this form is to verify that full disclosure has been made to the patient or patient's legal representative regarding:

- the nature and purpose of the proposed procedure(s)
- the anticipated benefits, the alternative therapies
- the material risks and / or complications with having the procedure
- the risks of not having the procedure

Patient name: _____ Primary Surgeon / Proceduralist: _____

Proposed procedure(s): _____

Other significant surgical tasks may be conducted by: _____
(practitioners other than primary surgeon / proceduralist)

Examples: Opening and closing, dissecting tissue, removing tissue, harvesting grafts, transplanting tissue, implanting devices and placing invasive lines.

☐ Check if applicable: **Additional Information Documentation (Form # 1600-0214, 1600-0215, 1600-0217 or 1600-8025)** follows.

☐ This case is an emergency. The operation must proceed immediately to protect the safety of the patient. Delay to obtain consent would constitute an unacceptable detriment to the patient.
Reason this case is an emergency: _____

Informed consent information was discussed with the patient or patient's legal representative. All questions were answered and consent was obtained.

Physician name: _____ Physician signature: X _____

Date: _____ Time: _____

I understand this procedure / treatment:

- may require the use of a sedative or drug which results in conscious sedation / anesthesia
- may be performed by an operating team consisting of an operating / administering physician, other participating physicians, anesthesia physician or associates, nurses, technicians and other necessary personnel
- may include participation or observation by product or vendor representatives
- may require the administration of blood or blood components and derivatives and bone grafting, if determined necessary during the course of the operation or procedure
- may require pathology evaluation with eventual disposal of any tissues or body parts removed as a necessary part of the operation or procedure
- may reveal unforeseen conditions requiring the performance of additional procedures

Note: *Any objection to any of the above must be discussed with the physician and noted on this form:* _____

I understand this information has been presented to me regarding the procedure / treatment and all of my questions about the procedure have been answered in a satisfactory manner. I understand that all procedures involve risks. These risks include allergic reactions, bleeding, blood clots, infections, adverse side effects of drugs, blindness and even loss of bodily function and death as well as risks of transfusion reactions and transmission of infectious disease such as Hepatitis and Acquired Immune Deficiency Syndrome from the administration of blood or blood products. I have been advised as to the reasonable alternatives and possible consequences of remaining untreated. I have also been advised of the associated risks and possible complications. I further understand the experience my physician has in performing this procedure. I acknowledge that no guarantees or promises have been made to me concerning the results of any surgery or procedure. **I authorize and consent to the performance of the procedure / treatment.**

Patient (or patient's legal representative) signature: X _____ Date: _____ Time: _____

Relationship to patient: ☐ Self ☐ Other : _____

Place patient label here.

Licking Memorial Hospital

INFCONS

Informed Consent Hospital

1600-0075
06/17/08, 5/25/09, 8/2/16, 7/11/17

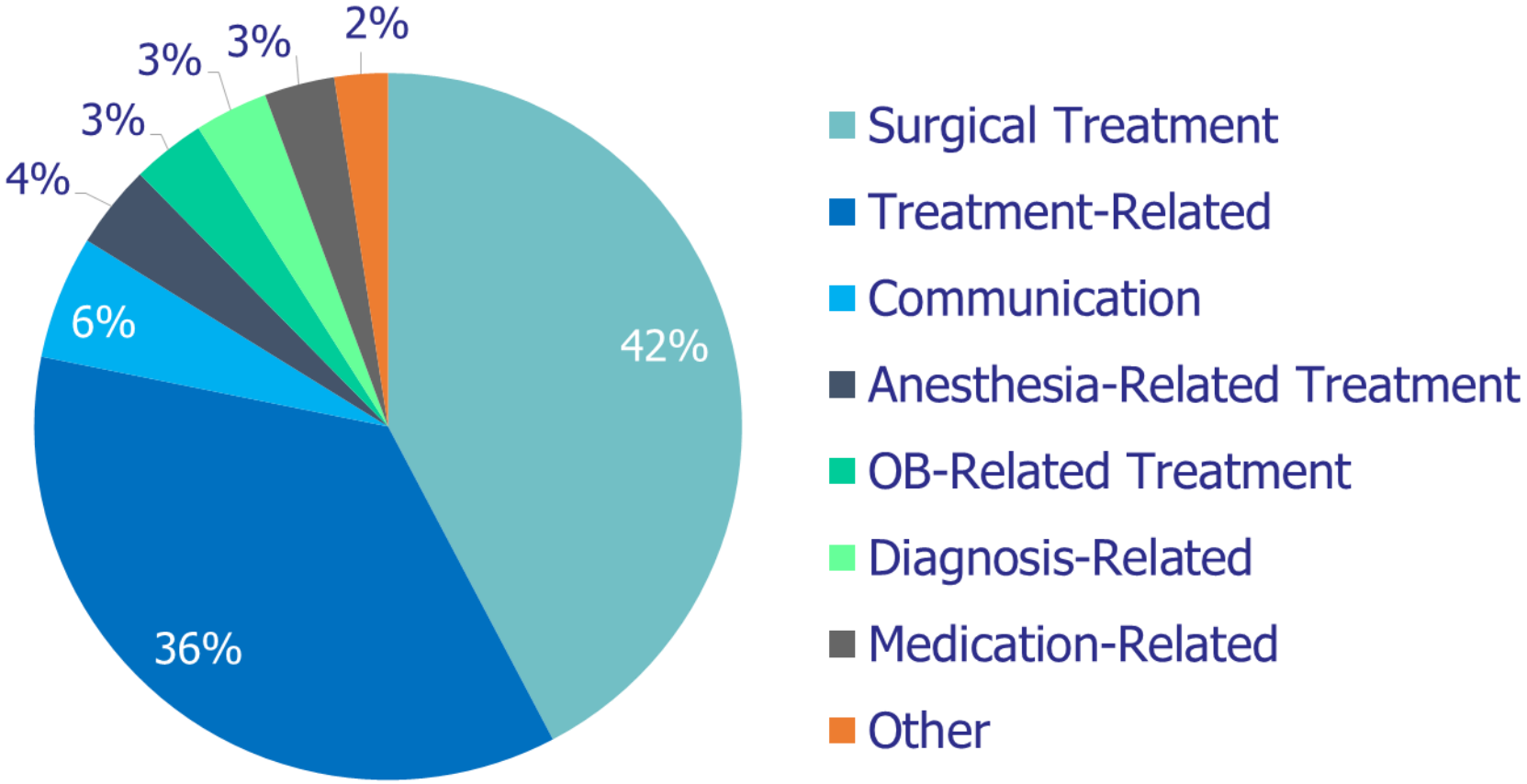
Why is it important to have sufficient informed consent?

- Enhances the physician-patient relationship
  - Fosters cooperation in the planned intervention/procedure and reduces resentment in event of complications
- Avoids criminal liability
  - Allegation of battery for unlawful touching of another
- Lowers chances of civil liability
  - Malpractice suit more likely to be filed when an unexpected outcome occurs and the patient is unprepared for results
  - If no documentation exists, you are relying on a jury to determine if you or the patient is accurate about the discussion occurring
- Maintains compliance:
  - Professional governing bodies and licensing/accrediting bodies and LMHS policy and procedures

Source: UpToDate: *Informed Procedural Consent.*

Informed Consent Data:

Where do informed consent allegations occur?

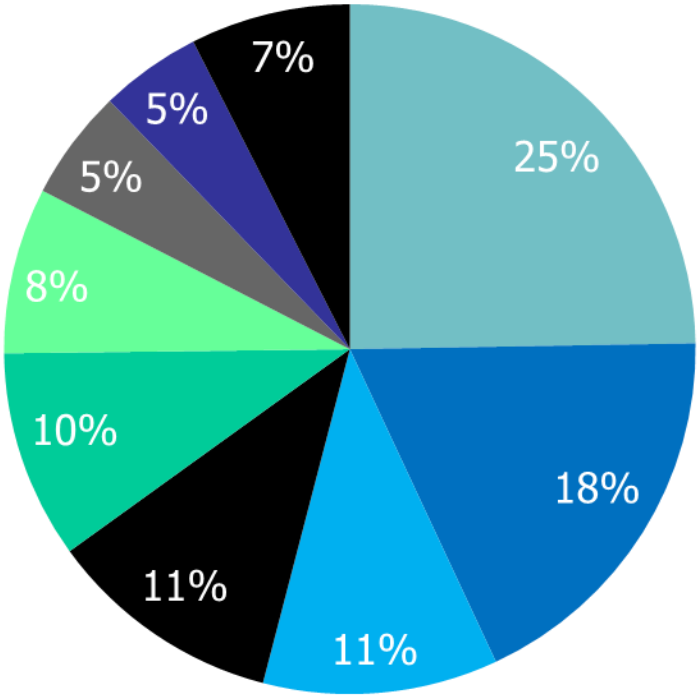


Source: MedPro Group closed claims data, 2005–2014.

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

Informed Consent:

What services are most likely to have informed consent issues?



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

Top three specialties:
- Ophthalmology
- Orthopaedics
- Plastic

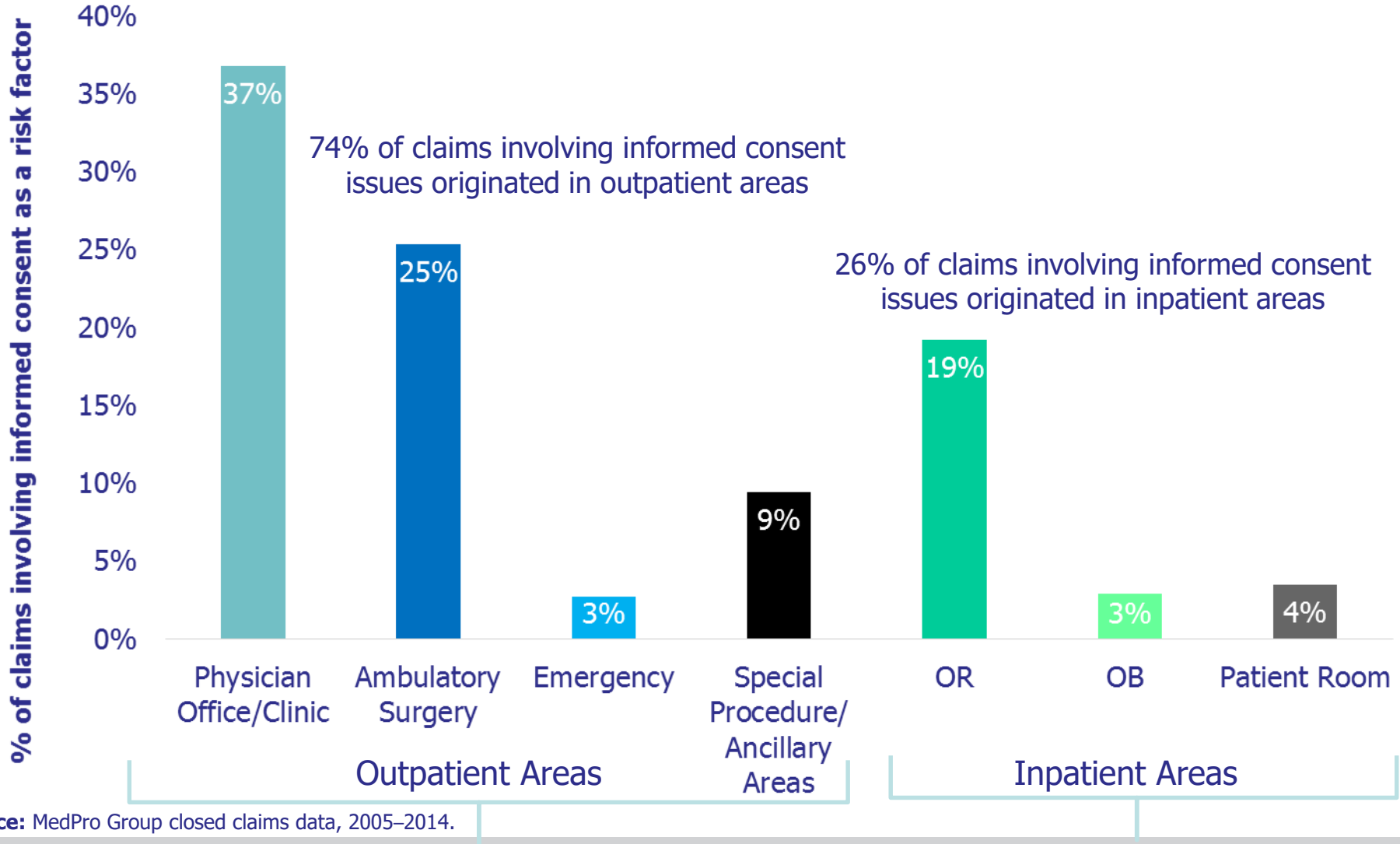
Top three specialties:
- Cardiology
- Dermatology
- Gastroenterology

Source: MedPro Group closed claims data, 2005–2014

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

Informed Consent:

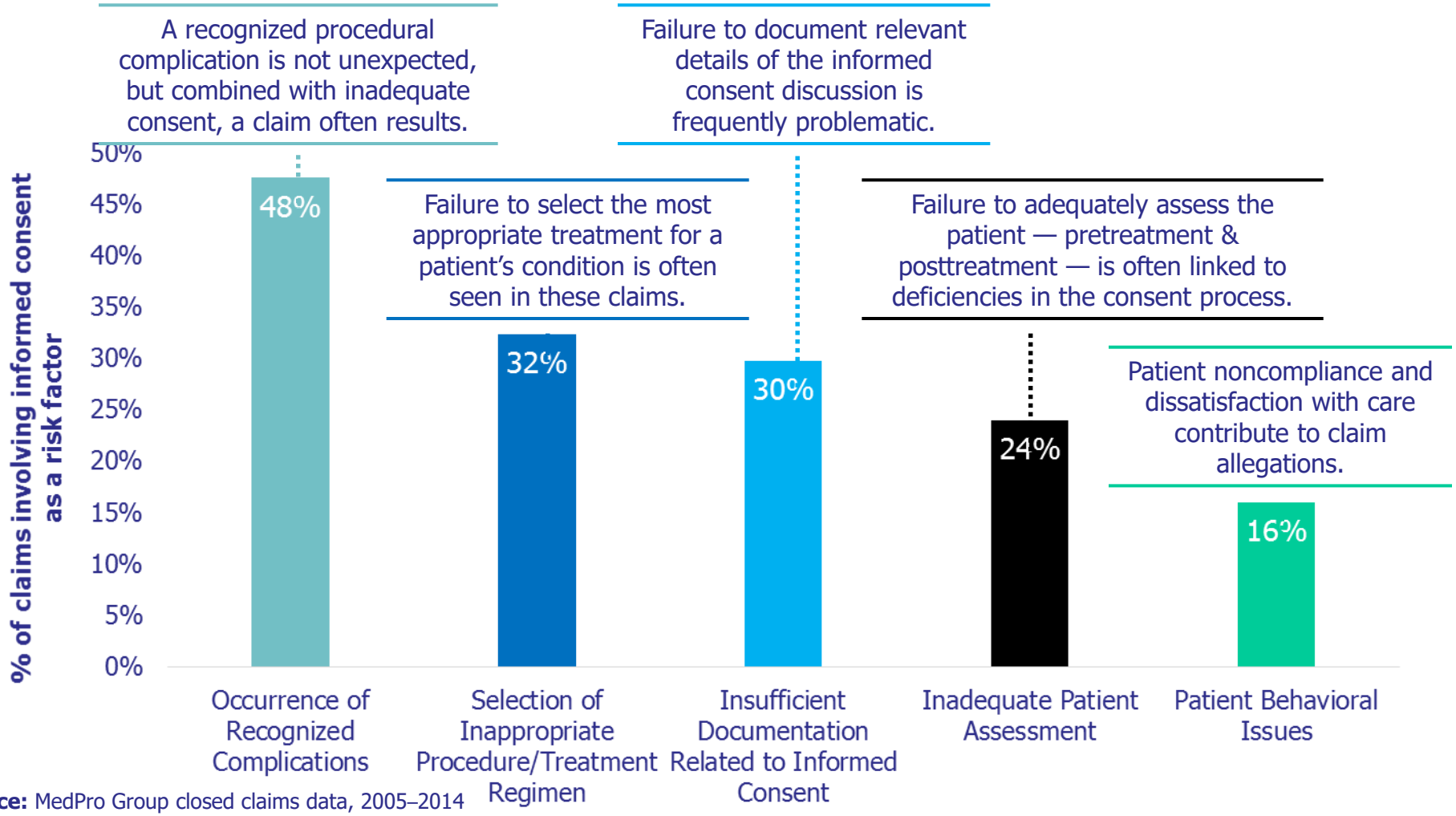
What locations are most likely to involve informed consent issues?



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

Informed Consent:
What are the associated risk factors?

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



Source: MedPro Group closed claims data, 2005–2014

Case Study: Informed Consent

- **Patient summary:** 55-year-old female underwent a bronchoscopy during an admission to the hospital for COPD and right lung nodule. Patient developed a pneumothorax during the procedure and had a chest tube placed, resulting in prolonged hospitalization in ICU for 4 days. Physician discussed r/b/a, such as bleeding, infection, lung collapse, and death, and documented the same. Physician also obtained a signed general consent and documented patient agreed with the plan and was agreeable to proceed.

- **Outcome:** No money was paid out on behalf of physician or the hospital when the patient made a $250,000 demand. The physician discussed and documented the risk of lung collapse with the patient prior to procedure, and also obtained the signed general informed consent form at time of procedure.

Source: LMHS Closed Claim Data

Case Study: Informed Consent

- **Patient Summary:** 46-year-old patient with history of migraines, rhinoplasty, prior tobacco use, and prior corneal surgery was seen by the ENT for treatment of head congestion and decreased hearing in right ear. CT scan done and patient was diagnosed with mucosal disease of paranasal sinuses. ENT recommended surgery for "blocked sinuses" and performed a bilateral endoscopic sinus surgery with removal of large amounts of soft tissue & purulent material. The next day patient called the ENT and reported double vision. The patient was referred to an ophthalmologist the following day who diagnosed the patient with a perforated inferior rectus muscle in orbit of right eye (known complications of sinus surgery). Patient required multiple surgeries to correct and has permanent vision impairment.

- **Outcome:** Significant six figure payment paid out due to failure to discuss and document: 1) risk of surgery other than bleeding and 2) other treatment options.

Source: MedPro Closed Claims

Case Study: Informed Consent

- **Patient Summary:** 48-year-old female who had a left femoral artery embolectomy; seen regularly by primary care physician (PCP) for monitoring of warfarin. The patient's PCP not available for one office visit; the patient was seen by another provider in the office. 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 provider okayed it, without discussing the risks, benefits, and alternatives regarding warfarin discontinuation or other options, such as Plavix. The provider never saw the patient again.

Case Study: Informed Consent
(continued)

- **Patient Summary (Cont.):** 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.

- **Outcome:** Indemnity payment to the family because there was a lack of adequate discussion and documentation of the risks of discontinuation of warfarin, lack of discussion and documentation of alternatives, and lack of documentation of communication with other providers about approval of discontinuation of warfarin.

Source: MedPro Group*: "You Never Told me!" Why Thorough Informed Consent is Paramount in Patient Care.*

Risk Reduction Strategies

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

Other Risk Reduction Strategies: Discussion

- When possible, allow **time** between the informed consent discussion and the proposed procedure for the following:
  - Understanding/comprehending
  - Seeking answers to questions
  - Reviewing the education research provided

Source: MedPro Group: *"You Never Told me!" Why Thorough Informed Consent is Paramount in Patient Care.*

Other Risk Reduction Strategies: Documentation

- Do not provide patients exhaustive lists of every conceivable issue
- Transmission of material facts requires more than just a list and signed form
  - It is a discussion of truly relevant data for the patient and should contain information the patient needs to know to make an educated decision

Source: UpToDate: *Informed Procedural Consent.*

Summary

- Ensure proper person for consent
- Provide time for discussion with the patient/patient's family in advance of carrying out treatment/ procedure
- Document the discussion about r/b/a/c somewhere in a note in the chart, or on the general consent form that the patient signs

Panel Discussion

Questions for panel members?

Resources

- American Medical Association, *Code of Medical Ethics Opinion 2.1.1.*
- MedPro Group (Malpractice Insurance Liability Carrier): *"You Never Told Me!" Why Thorough Informed Consent is Paramount in Patient Care.*
- Ohio Revised Code Section 2317.54.
- UpToDate: *Informed Procedural Consent.* Authors Marsha Ryan MD, JD FACS, Michael Sinha, MD, JD, MPH. *Literature Current Through Dec. 2018.*