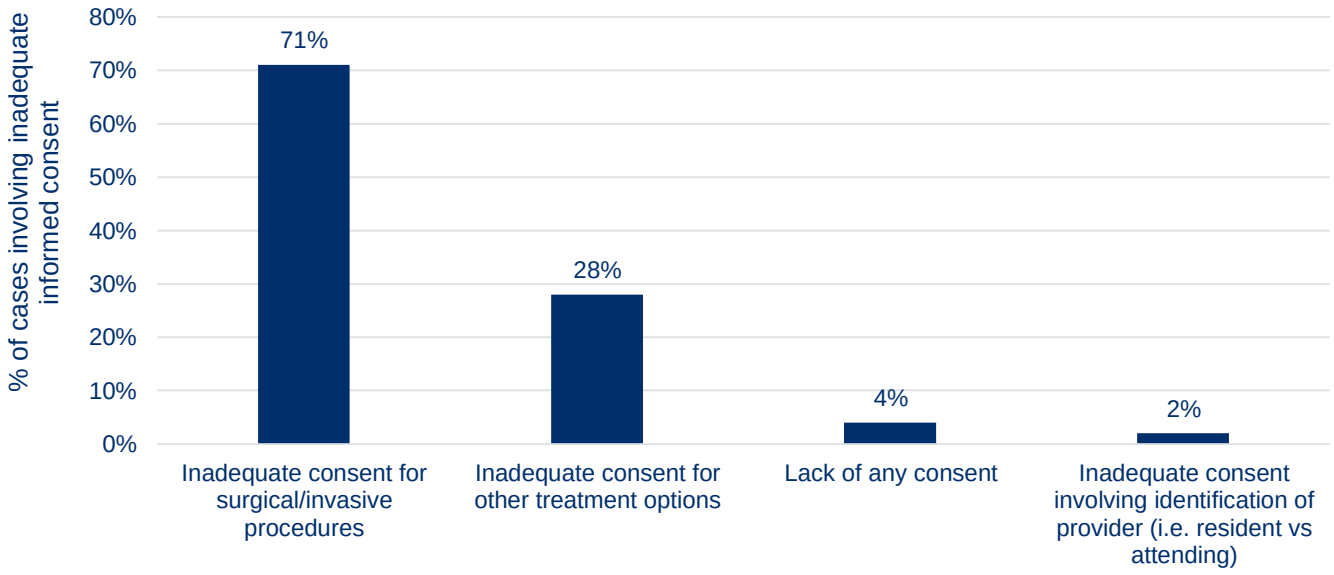
Cases Involving Inadequate Informed Consent

When a patient's expectation of the outcome of a surgical, medical or dental procedure isn't met, and a malpractice case is initiated, plaintiff's counsel will likely take a close look at the informed consent process. A non-delegable duty, this process is more than the mere signing of a form; it involves an interactive discussion between the patient and his/her provider. The patient must have an opportunity to ask questions and receive answers about the risks and benefits of the proposed treatment, the existence of alternative treatment options, and the risks of declining treatment altogether. The provider should also provide adequate information about the clinical rationale for treatment, and must ensure that the patient has the capacity to make a voluntary decision.

Inadequate, and even lack of, informed consent discussions between patients and their healthcare providers are recurrent risk factors in many cases (Figure 1). Contributing risk factors are multi-layered issues or failures in the process of care that appear to have contributed to the patient's outcome, and/or to the initiation of the case, or had a significant impact on case resolution. Multiple factors are identified in each case because generally, there is not just one issue that leads to these cases, but rather a combination of issues (therefore resulting in graphs with case volumes totals greater than 100% in some instances).

More than one-fifth (21%) of cases involving suboptimal communication between patients/families and providers reflect informed consent issues, and, as noted farther down in this report, other factors are at play as well. The presence or absence of an informed discussion is not the precipitating event which causes an adverse outcome, but the failure to manage patients' expectations is frequently the reason for initiation of a malpractice case when an unexpected outcome occurs.

Figure 1. Inadequate Informed Consent Details

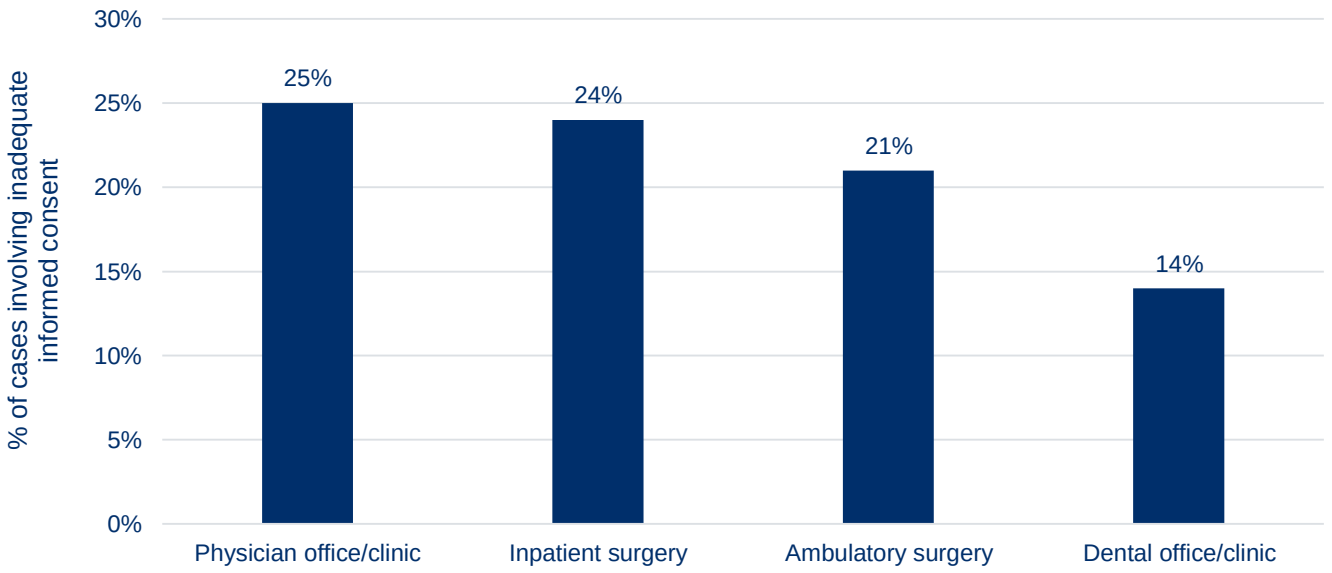


Almost three-fourths (71%) of cases involve consent issues specifically related to surgical/invasive procedures. Skin biopsies/excisions, total hip replacements, dental implants and root canals are among the top procedures noted in the data, but no one single procedure type accounts for more than 3% of the data. Therefore, there is ample opportunity to improve the content and timing of informed consent discussions across all procedure and treatment types.

Sixty percent of cases involving inadequate informed consent are noted as originating in an outpatient setting. Offices/clinics are the most often noted locations where the consent process is initiated (or should occur), followed by inpatient and ambulatory surgery settings (Figure 2).

Data source: MedPro Group + MLMIC cases involving inadequate informed consent opened 2012-2021 (N=1509)

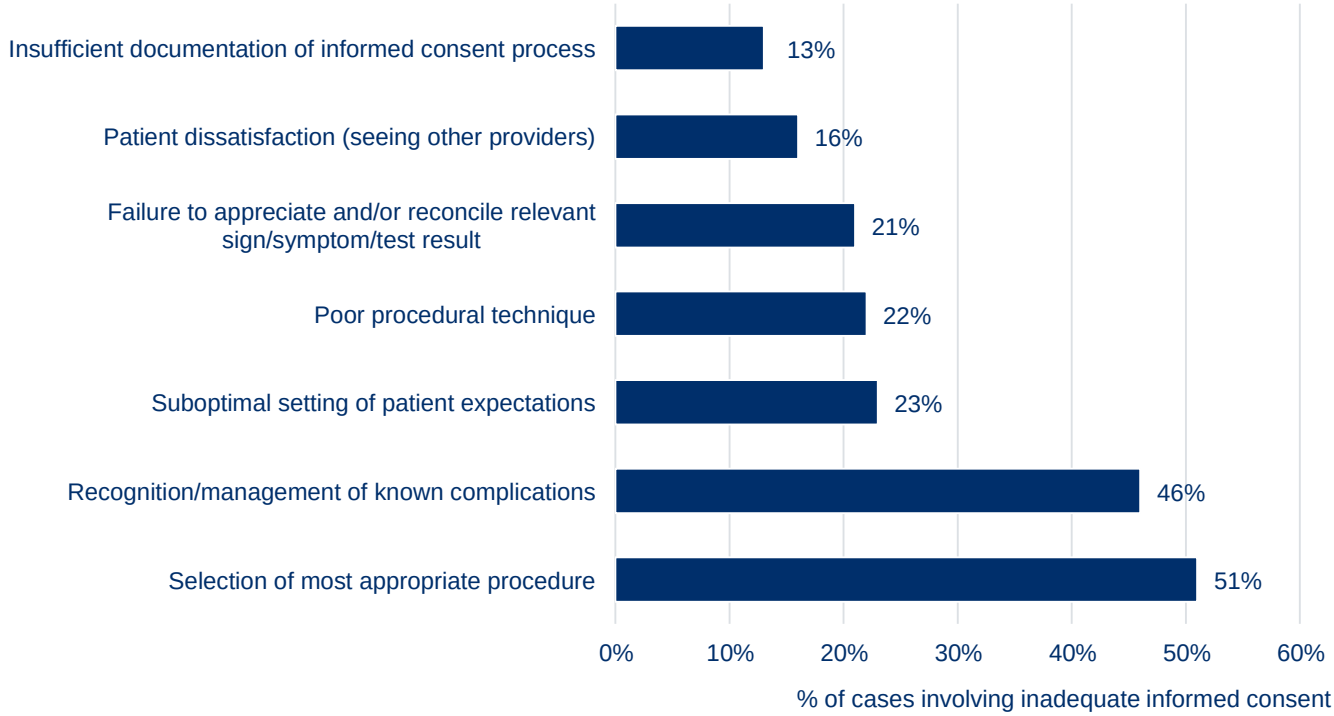
Figure 2. Most Common Locations



The Intersection of Events

Rarely is there just one underlying risk factor behind an adverse patient outcome. Cases involving inadequate informed consent are no different (Figure 3).

Figure 3. Additional Risk Factors in Informed Consent Cases



Data source: MedPro Group + MLMIC cases involving inadequate informed consent opened 2012-2021 (N=1509)

Case Studies

Several case studies follow, in an attempt to shed light on the importance of the content, documentation and timing of informed consent discussions.

Case Study: Failure to Obtain Informed Consent Prior to Third Molar Extraction

After several years of deferring recommended extraction of her third molars, the patient finally agreed to the procedure. Tooth #16 was extracted without complication. Two years later, she reported pain at a second third molar, tooth #17. The dentist prescribed a round of antibiotics and scheduled the extraction. A review of x-rays taken three years earlier showed the root of #17 close to a nerve. The dentist did not obtain a consent for anesthesia, nor for the extraction procedure.

A week after the procedure, the patient reported tongue numbness and a burning sensation. The dentist prescribed a Medrol dose pack and monitored the patient's symptoms. After five months with no improvement, the patient was referred to an oral surgeon. Imaging was obtained which revealed extensive bone removal and remaining tooth fragments.

The patient ultimately underwent neurolysis of the lingual nerve. The nerve had been partially transected, and then tethered to the adjacent tissue during the #17 extraction. Surgery failed to restore sensation, leaving the patient with persistent numbness and a burning sensation.

The case was settled for $100,000. Additional risk factors were noted as follows:

- **Clinical judgment:** failure to appreciate and reconcile relevant sign/symptom/test result (implication of tooth #17's proximity to the nerve)
- **Technical skill:** failure to recognize/properly manage known complication (transection of the nerve)

Case Study: No Informed Consent for Cosmetic Procedure

The patient presented for a cosmetic procedure during which a dermal filler was injected into her lower face and forehead. Afterwards, she developed a persistent infection which resulted in a scar. The patient presented to the same provider for a repeat dermal filler procedure to "fix" the scar, but developed a recurrent infection. IV antibiotics were required, and the patient was advised by an ENT surgeon that surgery might be an option to address the now present facial asymmetry.

Expert review noted criticism of the treating physician due to poor documentation. Several office visits during which the facial abscess was drained were not documented. The provider's contentions that the patient was non-compliant with antibiotics and wore "a lot of makeup" over the infected site were not documented. The patient contended that the provider never gave her any after-care instructions, and failed to conduct an informed consent discussion with her prior to the procedure. She now has bilateral temporal and brow "drooping", and facial nerve weakness resulting in mid-face asymmetry.

The case was settled for $300,000. Several additional risk factors were noted as follows:

- **Administrative:** credentialing issues (the physician, a pediatrician, was not credentialed to perform the dermal filler procedures)
- **Behavioral-related:** patient's non-adherence to antibiotic regimen impacted the ultimate outcome
- **Clinical judgment:** narrow diagnostic focus, failure to appreciate/reconcile relevant signs/symptoms, failure to order diagnostic test (no cultures of the abscess were performed), delay in obtaining consult/referral to manage persistent symptoms
- **Documentation:** insufficient/lack of documentation of the adverse outcome, the provider's clinical rationale for treatment decisions, and patient discharge instructions
- **Technical skill:** failure to recognize/properly manage known complication

Case Study: No Informed Consent for Colon Resection

A patient with a strong family history of colon cancer presented for her first colonoscopy in her early 50's. A large tumor, documented as 30 cm from the anal verge, was identified, biopsied and tattooed for subsequent surgical identification. The pathology report noted an adenocarcinoma of the sigmoid colon. During the subsequent laparoscopic-assisted colon resection, the colorectal surgeon was unable to see or palpate the tumor, nor did she see the tattoo marks. She resected the sigmoid colon in the area she "thought" the tumor was but upon opening that section in the operating room, no tumor was seen. The surgeon then blindly resected additional sigmoid colon with no tumor found. She then performed a colonoscopy, which revealed the tumor to be in the descending colon at approximately 45 cm.

The tumor was found to be Stage 1, meaning the patient is likely "cured", however, she was left with frequent bowel movements which have been unresponsive to medications. No informed consent documentation was present in the medical record

The case was settled for $200,000. Several additional risk factors were noted as follows:

- **Clinical judgment:** concerns with the surgeon's decision-making intra-operatively
- **Documentation:** lack of documentation of the informed consent process
- **Technical skill:** poor surgical technique

Resources

- **The Essential Elements of Informed Consent**
- **Informed Consent in Dentistry**
- **Informed Consent: An Ethical and Legal Imperative**
- **Risk Resources: Informed Consent**
- **Risk Management Strategies for Informed Consent**

About MedPro & MLMIC Data

MedPro and MLMIC are partnered with Candello, a national medical malpractice data collaborative and division of CRICO, the medical malpractice insurer for the Harvard-affiliated medical institutions.

Derived from the essence of the word candela, a unit of luminous intensity that emits a clear direction, Candello's best-in-class taxonomy, data, and tools provide unique insights into the clinical and financial risks that lead to harm and loss.

Using Candello's sophisticated coding taxonomy to code claims data, MedPro and MLMIC are better able to highlight the critical intersection between quality and patient safety and provide insights into minimizing losses and improving outcomes.

Leveraging our extensive claims data, we help our insureds stay aware of risk trends by specialty and across a variety of practice settings. Data analyses examine allegations and contributing factors, including human factors and healthcare system flaws that result in patient harm. Insight gained from claims data analyses also allows us to develop targeted programs and tools to help our insureds minimize risk.