



## PATIENT SAFETY STRATEGIES

### BEYOND THE SIGNATURE

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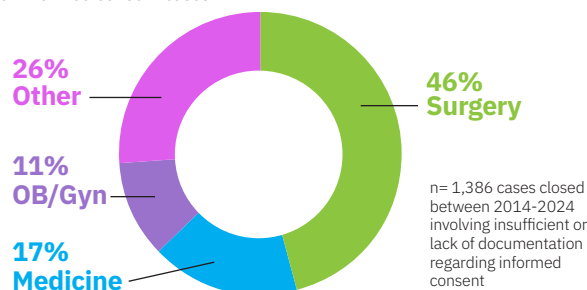
*Following an unsatisfactory outcome from finger surgery, a 38-year-old patient filed a malpractice claim alleging the wrong procedure was performed. However, thorough documentation of informed consent discussions supported the surgeon's care, leading to a defense verdict at trial.*

*A 25-year-old patient underwent Gamma Knife radiosurgery and suffered post-operative hearing loss in the left ear. Initially planned for the right ear, the procedure was intentionally changed to the left, but no documentation of informed consent or discussions about this change was recorded. Following a claim, the case was resolved with a settlement.*

When discussing informed consent, many think of a signed form or a simple checkbox in the patient record. However, as these cases demonstrate, adequate informed consent extends well beyond the paperwork. An analysis of more than 65,000 malpractice cases closed between 2014-2023 revealed that **insufficient documentation of informed consent increased the odds of a case closing with payment by 80 percent.** The majority of informed consent cases are related to surgery and occur in an ambulatory setting. Plastic and orthopedic surgery are the top surgery specialties with informed consent documentation issues.

#### Surgery accounts for nearly half of informed consent lapses

Percent of informed consent cases



Informed consent should be treated as a process rather than just a signed form. This critical communication between provider and

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### STRATEGIES TO IMPROVE INFORMED CONSENT PROCESS

- ✓ **Optimize Timing and Setting**— Conduct consent discussions in calm environments: [research](#) indicates engaging patients in informed consent discussions within an office setting, rather than in the preoperative holding area, enhances comprehension and decision-making. This approach allows patients to process information without the pressures of imminent procedures.
- ✓ **Enhance Documentation Practices**— Detailed documentation: beyond obtaining a signed consent form, thoroughly document discussions of risks, benefits, and alternatives in the patient's medical record—along with the patient's response or any refusals. This practice not only serves as a reference for future care decisions but also provides sound legal defense in the event of a claim.
- ✓ **Leverage Technological Innovations**—Video-assisted consent methods: utilizing educational videos as part of the consent process can significantly improve patient understanding. Clinical trials have demonstrated that video interventions enhance comprehension more effectively than written forms alone.  
  
Interactive digital resources: implementing digital tools that engage patients interactively can further bolster their grasp of medical information, leading to more informed decisions.
- ✓ **Implement Teach-Back Techniques**— Confirm understanding: employing the teach-back method, where patients are asked to reiterate the information in their own words, has also [proven effective](#) in informed consent processes. This helps ensure patients understand the details of their treatment options and associated risks accurately.
- ✓ **Address Language and Cultural Barriers**— Provide culturally sensitive materials: offering consent materials in the patient's preferred language and considering cultural nuances can bridge communication gaps, leading to better patient comprehension and comfort.
- ✓ **Assess Health Literacy Levels**— Simplify medical jargon: tailoring the complexity of information to match the patient's health literacy ensures that all patients, regardless of their background, can understand their treatment options.



patient aims to help manage patient expectations about the treatment outcome by carefully communicating the risks, benefits, and alternatives to the recommended course of action.

Informed consent is more than a legal requirement; it is a cornerstone of patient safety, trust, and effective care. As demonstrated by the case studies, comprehensive informed consent discussions—supported by detailed documentation—can make a critical difference in outcomes, both for patients and providers.

To learn more about how documentation influences risk beyond informed consent, [download a copy of Candello's 2024 Benchmarking Report](#): “For the Record: The Effect of Documentation on Defensibility and Patient Safety.”

## ADDITIONAL RESOURCES

**Case Study:** [MPL Defense Verdict Bolstered by Appropriate Consent Process](#)

**Case Study:** [A Failure to Document Patient's Refusal](#)

[Quick Safety 21: Informed consent: More than getting a signature \(Updated: April 2022\) | The Joint Commission](#)

[How Informed Consent Impacts Surgery Malpractice Outcomes](#)



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