Verbal and Written: Claims Involving Informed Consent Issues

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). Risk factors are broad areas of concern identified during the clinical claims data coding process that may have contributed to patient injuries or to the initiation of malpractice cases.

More than one-fourth (27%) of communication-related cases (the “parent” risk factor of informed consent) identified in our malpractice claims data involve 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.
More than half (67%) 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 ambulatory and inpatient surgery settings. (Figure 2).

As expected, informed consent issues tend to be most prevalent in surgical and dental cases; 64% of all cases involve surgical and dental specialties. Total hip replacements and root canals are among the top recurrent procedures noted in the data, but there is ample opportunity to improve the content and timing of informed consent discussions across all procedure and treatment types.
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. Frequency of Additional Risk Factors in Informed Consent Cases

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 Manage Patient Expectations Prior to Orthopedic Surgery

A total left hip replacement was recommended and performed on a female patient in her early 60’s. Post-operative charting by the orthopedic surgeon revealed that there was a “very slight increased leg length on the left.” Nursing documentation entered in the chart after the patient ambulated for the first time indicated that the patient was concerned that her left (operative) leg felt longer. Two days later, she was discharged and given orders to begin physical therapy.

During physical therapy, the patient complained that her leg felt “much longer” and that she was extremely disappointed in her surgical outcome. She told the therapist that she had not been informed that this was a potential outcome of surgery. X-rays taken during a follow-up visit with the surgeon revealed a 15mm difference in length between her left and right legs. She was advised that she would need a hip revision surgery to correct the discrepancy.
The same orthopedic surgeon performed the revision, and unfortunately, the patient suffered a hip dislocation three weeks post-op from the second surgery. The dislocation was reduced, but two months later, she suffered a second dislocation while seated and shifting her weight slightly in the chair. She underwent a second revision surgery performed by a different orthopedic surgeon.

A malpractice case was filed, alleging improper performance of surgery. In addition to criticizing the surgeon’s operative technique, plaintiff’s counsel focused on the patient’s expectations and surgeon’s failure to conduct a truly informed consent discussion. The case settled in the low six-figure range, due in part to expert opinions indicating that the surgical outcome was likely the result of ‘cutting the femoral neck too high” and the surgeon’s failure to use a larger prosthetic ball in the femoral socket. Several risk factors were noted as follows:

- **Clinical judgment**: failure to appreciate significance of patient’s post-operative symptoms; surgeon’s decision to proceed to revision surgery less than three weeks after the initial surgery (which ultimately contributed to the subsequent hip dislocation)
- **Communication**: inadequate informed consent for the procedure (patient’s expectations were not managed pre-operatively)
- **Technical performance**: surgeon’s surgical technique and occurrence of known complication

**Case Study: Failure to Obtain Informed Consent Prior to Dental Extraction**

Following evaluation of a new patient, the dentist recommended that the patient have a root canal on molar #3. She agreed, but because her insurance wouldn’t cover the cost of a root canal, the patient opted instead for extraction. The dentist’s chart contains no documentation as to any type of pre-procedure informed consent discussion, nor does it contain a signed consent form. Extraction was performed under local anesthesia, but the procedure was difficult, resulting in a triangular fracture of the patient’s jaw due to fusion of the lingual nerve root to the jaw bone (a rare condition). Perforation of the
sinus cavity also occurred, causing significant bleeding. The patient was informed of the complications, and was discharged with instructions for treating the wound and prescriptions for an antibiotic and pain medication.

The patient called the office several days later complaining of pain radiating from the extraction site to the other side of the mouth. She refused the dentist’s referral to an oral surgeon, and never returned to this dentist’s office for follow up.

Ultimately, the patient required maxillary reconstruction using bone grafts and a sinus perforation repair. She claimed permanent facial nerve damage (trigeminal neuralgia and Bell’s palsy), right-sided facial droop, chronic pain, sinus problems, and difficulty breathing.

A malpractice case was filed, alleging improper performance of the extraction. Lack of any evidence of an informed consent process was a significant reason behind setting this case in the low six-figure range.

Several additional risk factors were noted as follows:

- **Behavior-related**: patient dissatisfaction with care/failure to return for follow-up evaluation
- **Documentation**: lack of documentation of informed consent discussion
- **Technical performance**: dentist’s procedural technique and occurrence of known complication

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**Case Study: Failure to Advise of Alternative Treatment Options**

A patient in her mid-sixties presented to an interventional radiologist for a kyphoplasty intended to treat a lumbar compression fracture. During the procedure, the patient suffered an intrathecal hemorrhage (a recognized complication). Post-procedure, questions were raised as to whether the patient was truly a candidate for the procedure, given her co-morbidities and other available alternative treatment options.
Chart documentation revealed that the patient was duly advised of the risks and consented to the treatment, knowing that the radiologist made no guarantee of success. However, the patient was not advised of alternative treatment options, and given the outcome, she initiated a malpractice case alleging failure to advise of other treatment methods.

The case was settled in the upper five-figure range, in part due to the informed consent issue and also due to:

- **Clinical judgment**: radiologist’s decision to recommend and proceed with the kyphoplasty
- **Technical performance**: occurrence of known complication

**Risk management note**: adverse outcomes don’t necessarily equate to malpractice. If the patient’s pre-procedure expectations are managed, and a full informed consent discussion is conducted and thoroughly documented in the chart, many times cases are dismissed even when complications occur.

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**Case Study: Failure to Ensure Patient Comprehension of Recommended Procedure**

A male patient in his early thirties presented to a clinic complaining of a sebaceous cyst on the left side of his neck. The patient did not speak fluent English, and later alleged that he was not provided with a translator (chart documentation is unclear as to whether or not this was true). The patient was evaluated by the office’s physician assistant who recommended incision and drainage of the cyst.

A nurse explained the procedure to the patient while the physician assistant was preparing for the procedure. There is no evidence of a formal informed consent discussion between the physician assistant and the patient documented in the chart.

Unfortunately, the procedure resulted in transection of the spinal accessory nerve. The patient was left with weakness of the trapezius muscle, and neck pain radiating into his arm. The case was settled in the mid-six figure range, primarily due to the physician assistant’s improper performance of the procedure, but also due to the failure to send
the incised tissue for pathology examination, failure to document the procedure with any clear details in the patient’s chart, and failure to obtain appropriate informed consent - including lack of explanation of the risks of the procedure, failure to ensure that the patient understood the procedure to be performed, and failure to offer any alternative treatment options.

Several risk factors were at play in this case, including:

- **Clinical judgment**: failure to seek diagnostic confirmation of the specimen; failure to refer patient for follow-up after the patient’s immediate complaints of pain; practicing beyond the scope of expertise
- **Documentation**: lack of documentation of the adverse event and informed consent discussion
- **Technical performance**: misidentification of anatomical structures and poor technique

**Resources**

- Risk Management Strategies for Informed Consent
- Checklist: Informed Consent
- On-Demand Webinar: “You Never Told Me!” Why Thorough Informed Consent is Paramount in Patient Care

**Data Source**

MedPro Group closed claims data, 2008-2017
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