Patient Safety Tip of the Week

September 10, 2013

Informed Consent and Wrong-Site Surgery

In our August 27, 2013 Patient Safety Tip of the Week “Lessons on Wrong-Site Surgery” we discussed the importance of all parties reviewing primary source documents for verifying patient, procedure and correct site for invasive procedures. In that column and in our January 1, 2013 Patient Safety Tip of the Week “Don’t Throw Away Those View Boxes Yet” we focused especially on the unavailability of images or imaging reports as being problematic.

However, all the other documents are equally important. One that has received relatively little attention is the informed consent. While putting together our August 27, 2013 column we came across two papers on wrong-site surgery in which problems with informed consents contributed to the errors.

In a root cause analysis (RCA) of a case of removal of the wrong kidney in a patient in the UK (Tallents 2008) at least 3 issues related to informed consent were raised. One was that because the patients were often admitted outside normal working hours the admission workup was often done by members of a surgical team other than the surgical team which would actually be performing the surgery. Those team members often felt uncomfortable obtaining informed consent for the surgical procedure. Hence, they might obtain a general consent for hospitalization but not one for the specific surgery. Moreover, it was noted that the formal consent was generally taken by surgeons who were not competent to perform the procedure. These were often surgical house officers who had to rely on notes that were in the chart. Moreover, they were unlikely to review any relevant imaging studies before taking consent (since they often felt unqualified to read those imaging studies). A major recommendation coming from that RCA was that the hospital should implement a process for initiating formal consent in outpatients when the patient is seen by a clinician who is personally competent to do the procedure and review the imaging.

A second paper performed a common cause analysis (CCA) after a series of wrong-site surgical events in a US hospital (Mallett 2012). Basically, a common cause analysis
involves identification of themes common to events found in RCA’s done after the individual events. One of the themes they identified was related to documents used in verification. They found that the consents were not always placed in the correct location in the medical record, were not available to be reconciled, did not specify laterality, and were not obtained by the practitioner performing or involved in the procedure. One of their solutions was revision of the consent form to include a legend (right, left, and bilateral) next to where the practitioner writes the name of the procedure to be performed. That provides a visual cue to the practitioner to ensure laterality during the informed consent procedure. Secondly, they implemented a policy that informed consent must be only obtained by the physician/practitioner performing the procedure or by the resident/fellow who will be performing or assisting with the procedure.

A third timely paper from researchers at Johns Hopkins that does not deal with wrong-site surgery provides additional useful information about problems related to informed consent (Garonzik-Wang 2013). This study found that almost two thirds of patients were missing informed consent forms when they presented to the preoperative area. This required nurses to contact the attending surgeon or resident to perform the informed consent. It led to delays in case start times in 14% of cases. Moreover, often the individual responding to the nurse request was a resident, who was pulled away from other patient care responsibilities or teaching rounds and typically spent less time performing the consent than expected. Residents typically spent less time obtaining informed consent in all locations and the vast majority spent only 5 minutes or less when obtaining it in the preoperative area. And, to top it off, the majority of attending surgeons were not satisfied with the performance of the residents on informed consent and felt that patients preferred being asked for their consent by an attending surgeon. The paper has an excellent discussion on the dilemma of doing informed consent appropriately yet also ensuring that residents learn how to do it. Based on their findings they are implementing 3 things to improve the informed consent process:

1) Creating a centralized single streamlined electronic process to be used by all attending surgeons to ensure that all consents obtained in clinics reliably make it to the medical record

2) Standardize the consent forms for commonly performed procedures

3) Include specific educational initiatives for surgical residents on informed consent

Yes, the above 3 descriptions all come from teaching hospitals but problems with availability and accuracy of informed consents occur even in non-teaching hospitals. It is extremely common even in community or rural hospitals for surgeons to obtain the informed consent in the preoperative area. Our June 5, 2007 Patient Safety Tip of the Week “Patient Safety in Ambulatory Surgery” noted that ambulatory surgery is particularly vulnerable to missing documents because those documents are usually in the surgeon’s office rather than at the hospital. That is why you need to be firm in your requirement for such documents before cases are scheduled. And, yes, we still continue to encounter some surgeons who look at the document as some sort of regulatory requirement foisted upon them!
The preoperative area is not the appropriate place for the informed consent process to take place. Proper informed consent requires the physician or practitioner provide the patient with details of the procedure, the potential benefits and potential harms, and the alternatives (including what might happen with the alternative of doing nothing). That discussion takes time and there must be adequate opportunity for the patient (and any surrogate) to ask questions. The pressures in the preoperative area cause considerable truncation of the informed consent process. Moreover, once a patient has committed to coming to the hospital or ASC for a procedure, they are very unlikely to say no. So the more appropriate place for the informed consent to be performed is the physician’s office, clinic, or inpatient bedside if the patient is already admitted.

We strongly recommend that you not schedule surgery until you (the hospital or ASC) have in hand copies of the H&P, the booking form, the consent form, and imaging studies. While you might provide a tentative date and time for surgery you must have a “drop dead” date on which you will cancel that tentatively scheduled slot if you have not received these items. Things like the H&P may need updating to meet regulatory time frames but you should have available at least the H&P from the office at the time the case was originally scheduled.

Having the consent form ahead of time will help in the preoperative verification process. It should prompt the surgeon to address the issues well before the day of the procedure and allow preoperative personnel to spot discrepancies long before the day of surgery so they can be resolved. The study from Hopkins also would suggest that, in addition to helping prevent wrong-site surgery, you will also likely improve OR efficiency and throughput.

We also like the recommendation in the paper by Mallett et al. (Mallett 2012) to include on the informed consent form a legend (right, left, and bilateral) next to where the practitioner writes the name of the procedure to be performed. Our October 30, 2012 Patient Safety Tip of the Week “Surgical Scheduling Errors” has many recommendations about scheduling and booking. In that column we also mentioned a paper by Wu and colleagues (Wu 2012) that did a qualitative and quantitative analysis of errors occurring during the surgical booking/scheduling process and identified not only patient safety issues but also analyzed the costs associated with the delays such errors end up causing. The Wu paper noted the Minnesota Alliance for Patient Safety sample booking form that contains a section which must be filled out by the physician performing the surgery (i.e. that cannot be delegated to staff). Though that is a booking form it also utilizes the visual cue to force the physician to verify laterality of the procedure. The Minnesota Alliance for Patient Safety has several other valuable resources as part of its Surgery Scheduling and Verification Pilot Project. These include algorithms for scheduling for either the hospital or ambulatory surgery center and for the clinic or physician office, and verification checklists for both sites.

You should do your own simple audit of availability of the informed consent document when the patient arrives in your preoperative area. You will probably find some issues
that make you vulnerable not only to wrong-site surgeries but also day-to-day OR inefficiencies.

Some of our prior columns related to wrong-site surgery:

Patient Safety Tip of the Week columns:
September 23, 2008 “Checklists and Wrong Site Surgery”
June 5, 2007 “Patient Safety in Ambulatory Surgery”
March 11, 2008 “Lessons from Ophthalmology”
July 1, 2008 “WHO’s New Surgical Safety Checklist”
January 20, 2009 “The WHO Surgical Safety Checklist Delivers the Outcomes”
September 14, 2010 “Wrong-Site Craniotomy: Lessons Learned”
November 25, 2008 “Wrong-Site Neurosurgery”
January 19, 2010 “Timeouts and Safe Surgery”
June 8, 2010 “Surgical Safety Checklist for Cataract Surgery”
December 6, 2010 “More Tips to Prevent Wrong-Site Surgery”
June 6, 2011 “Timeouts Outside the OR”
October 30, 2012 “Surgical Scheduling Errors”
January 1, 2013 “Don’t Throw Away Those View Boxes Yet”
August 27, 2013 “Lessons on Wrong-Site Surgery”

What’s New in the Patient Safety World columns:
July 2007 “Pennsylvania PSA: Preventing Wrong-Site Surgery”
August 2011 “New Wrong-Site Surgery Resources”
December 2011 “Novel Technique to Prevent Wrong Level Spine Surgery”
January 2013 “How Frequent are Surgical Never Events?”

References:


http://ajm.sagepub.com/content/27/1/21.full.pdf+html


sample OR scheduling form

http://www.patientsafetysolutions.com/

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