Clinical Alert

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Maryland Department of Health and Mental Hygiene
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Wrong site procedures and retained foreign bodies: *Why are they still happening in Maryland hospitals?*

Lest anyone think that the issue of wrong site procedures and retained foreign bodies has bypassed Maryland, or that we have found solutions in our state to these vexing and preventable problems, we present the following cases of adverse events that occurred in the operating rooms of Maryland hospitals. These six cases of wrong site surgery were reported to the Office of Health Care Quality during the period from July 1, 2006 to June 30, 2007. While the outcomes of these cases were not immediately fatal, the fact that they occurred is very distressing to providers, hospitals, regulators, and -- of course -- patients. Given the widespread publicity surrounding the efforts of the Joint Commission and others to eradicate these "never" events, you might wonder if the events described below could happen in your facility.

Adverse event: outpatient esophagogastroduodenoscopy (EGD) performed instead of colonoscopy.
Root Causes: A wrong procedure was posted when two patients of the same physician were confused by posting staff. The patient signed the consent form for the correct procedure, but out-patient procedure staff did not note the discrepancy. Staff was afraid to question physician about the discrepancy because of his reputation for being difficult.
Result: The patient was subjected to an unnecessary procedure and had to undergo a colonoscopy prep twice.

Adverse Event: A PICC line was placed in an outpatient procedure instead of a Mediport.
Root Causes: The physician did not write orders that were clear and staff did not clarify the orders with the physician. The patient was not informed by the physician as to what was to be done. The patient had had several previous PICC lines inserted and staff and patient assumed this was to be the same. There was no discussion during the facility's RCA about failure of the physician's office to clarify what was to be done, or the failure of the outpatient staff to ensure the matter was clarified. Thus, not only was there a procedural error, but the follow-up root cause analysis was inadequate.
Result: A PICC line was inserted, then removed later in the day and patient re-scheduled for the desired Mediport insertion.

DISCUSSION: Root causes have varied in the wrong side surgery events reported to us in Maryland. Inadequate communication was the most frequent single cause. In one case, a patient even pointed out to the anesthesiologist that the surgical site marked was different than the site posted on the pre-operative form. The anesthesiologist wrote in the medical record that the patient was confused as to the site. In reality, the patient was the only person not confused. Sometimes patient information is posted incorrectly at the beginning and this erroneous information follows the patient throughout.

Hospitals should consider standardizing the information required for posting and then hold all physicians and their office staff, as well as hospital staff, to the requirements. Standardizing information content and format will help reduce the likelihood of procedures being posted with ambiguous information or without accurate laterality assigned in cases of bilateral disease. The patient may be afraid to question the surgeon, or the consent may have been signed so far in advance that the patient does not remember the discussion.

Resistance from the posting physicians to this standardization can be expected.

Adverse event: A patient's left kidney had a mass suspected to be cancerous. The patient's right kidney had a known benign cyst. The right kidney was removed at surgery. The consent form said right side, the site marking and a time-out confirmed the right side. The urologist had looked at

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one set of films preoperatively and assumed that the x-ray was mislabeled with "left." The patient was then posted for a wrong side procedure and this was done.
Root Causes: The urologist did not review all available films with the anesthesiologist and did not resolve the discrepancy before surgery commenced. The patient had had discussion with the urologist far in advance of surgery and knew he had disease in both kidneys, but did not realize that the left kidney was the one that needed removal.
Result: A second procedure had to be done wherein the left kidney was removed.

Adverse event: A patient had nodules on the left side of his thyroid but had a right thyroidectomy performed instead.
Root Causes: Neither the posting nor the consent form specified laterality. Diagnostic testing was not reviewed as part of a time-out.
Result: Patient underwent a second procedure for a sub-total thyroidectomy.

Adverse event: A patient was to have right inguinal and umbilical hernias repaired, but had a left inguinal repair instead.
Root Causes: Not yet provided by the hospital as of the date of this posting.
Result: The patient was still on the table prior to being taken to PACU when the surgeon realized he had not done an umbilical hernia repair and had done the inguinal procedure on the wrong side. The patient was put back under anesthesia and the correct inguinal hernia was repaired. However, the patient's condition deteriorated and the umbilical hernia could not be repaired.

DISCUSSION: It is human nature to try to make any job as simple as possible. We have found that in many hospitals, a gradual erosion of staff compliance with standards and policies occurs due to performance pressures based on a perception that production, or "through-put," is more important than safety. If bad things fail to happen early on, this erosion of compliance becomes institutionalized in a team or on a unit. A continued absence of adverse consequences confirms the utility of the deviant process. Without realizing that safety is being compromised, staff may cut safety activities to meet other goals (getting out on time, starting another case on time, etc.) Cumbersome, redundant procedures, like time-outs and counting, are not seen as "value added," especially if not following standards appears to have no immediate negative consequence.

David M. Gaba, in ***Human Error in Medicine***, cites several studies of team dynamics in the ORs.[1] He notes that status and hierarchy are important in team behavior and performance, and that the OR team is unusual because the surgeon and anesthesiologist are co-equal leaders, with some overlapping primary responsibilities. In addition, each other member of the team -- first assistants, nurses, etc. -- comes from a profession with its own standard behaviors. This situation may lead to an inability of the team to maintain required processes and thus respond effectively to inconsistencies in information and expectations. Status differential may lead team members of lower status to be reluctant to question the decisions of the surgeon and anesthesiologist. Is the atmosphere in the hospital such that staff feels they will be supported by management if they question a decision or action that seems unsafe?

In the endoscopy event noted above, the physician had a reputation for being difficult to deal with. The other staff assumed he would behave in an unpleasant manner if questioned, and were reluctant to firmly address the issue when he insisted on doing an EGD rather than a colonoscopy. Are your OR staff empowered to stop a process to resolve discrepancies, even with the physicians becoming displeased? Is it acceptable for the surgeon to merely grunt assent during the time-out, or is the response expectation more stringent?

According to Gaba, the dynamic environment of the OR is unique for another reason. The surgical process demands continuously balancing and refining various trade-offs between productivity and safety. We see this, not only in wrong site procedures where the staff are afraid to hold up the process for a properly interactive time-out, but also in cases where foreign bodies are left in the patient. Staff may know that counts are not correct, but fear to mention it to the surgeon, assuming they have made a mistake in counting. Or, if they are doing the count by rote, they are not actually thinking about what they are doing.

The Joint Commission's *Universal Protocol for Preventing Wrong Site, Wrong Procedure, Wrong Person Surgery*(TM) calls for using multiple, complementary strategies to eliminate wrong site procedures. This Protocol requires implementation of a consistent procedure throughout an organization to protect patients during any invasive procedure, anywhere in the facility. Specifically, the Protocol calls for a process that encompasses pre-operative verification, including the reviewing of all available diagnostics; reconfirming patient identity and site; marking the operative site so that the markings are visible when the patient is positioned and draped; and a time-out prior to incision to verify the patient, the site and the procedure.[2]

The American College of Surgeons released a practice statement in 2002 with ten guidelines to prevent wrong site surgery. These include verifying that the correct procedure is on the OR schedule, marking the site with the patient prior to administration of narcotics or sedation, and following the same checklist process with all surgeons for each procedure in a patient undergoing multiple procedures by more than one surgeon.[3]

The Veteran's Health Administration (VHA) has a five-pronged approach to preventing wrong site surgeries. These are: The consent form is properly executed; the operative site is marked; the patient is actively identified; a time-out briefing is conducted prior to starting the procedure; and two members of the OR team review pertinent radiological images prior to commencing the procedure. The VHA recommends that the anesthesia provider be the second person verifying the site since this provider may be the only person in the OR with the same physical orientation as the patient.[4]

Focusing on a single action, like site marking, will not prevent all wrong site surgeries. Conversely, trying to incorporate all of the various recommendations can make a needlessly complex procedure that is certain to become the subject of short-cuts.

However, even with all that, 100% of wrong site surgeries are preventable.

Suggestions:

Start early: The site verification process needs to start in the pre-op office visit. The National Association of Spine Society (NASS) advocates giving the patient a simple anatomic drawing with the pathology and the surgeon's notes about the site and procedure.[5] The patient is told to bring this information to the hospital on the day of surgery, and to share it with other providers. For procedures where marking is not useful, like endoscopy, patients might be given different color arm bands for each procedure. Also, as part of the pre-op process, the patient should be told that many people will ask him or her to state the site for surgery.

Adverse event: Anterior lumbar interbody fusion done on the wrong levels.
Root Causes: Surgeon relied on MRI films and had not done a regular film of the area. The surgical approach was insufficient to visualize the area.
Result: A second procedure had to be done.

Use all available information: If diagnostic studies have been completed, use them, and ensure that they are correctly labeled. The wrong kidney was removed in two cases in which pre-op films were not clearly labeled.

We have had events reported to us in which x-rays had been taken in the prone position, but when viewed in the OR, were assumed to show the patient supine. Do not ignore patient input by labeling the patient confused when he disagrees about which site. Confirm that all documentation matches, including the OR schedule and consent. Don't assume that the equipment has been set up in the OR for the correct side, or even that the patient has been correctly draped. A root cause of many wrong site events is that the wrong side has been prepped and draped or the equipment has been set up for the incorrect limb. One event reported to the Office of Health Care Quality involved a vendor in the OR handing the left side prosthesis to a surgeon who was doing a right-sided joint replacement.

Consistency: Staff on each unit performing invasive procedures should use the same procedure for verifying patient identification and site. It is no longer acceptable for each hospital department to determine how to confirm patient and site identification. Many of the OR events reported to the Office of Health Care Quality involve an unacceptable amount of individual variation within a facility. The issue of consistency of performance is also a part of individual accountability. Maintaining consistency among all participants in the invasive procedure is vital.

Monitoring: Frequent random monitoring of compliance is essential to inculcate new procedures, and improve the effectiveness of a protocol. Most surgical services already review outcomes like wrong site occurr-ences and close calls. Managers may also need to perform direct observation of the pre-procedure process to determine compliance with procedures and intervene in real time. Documentation also needs to be reviewed to ensure that all pre-procedure checks are being done. Surgeons who do fewer procedures at a facility may need more intensive monitoring until management can be satisfied as to their level of compliance.

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While none of these interventions are evidenced-based, they are low risk and inexpensive to implement. The return on investment for preventing even one wrong site procedure is immeasurable

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1.Bogner, M.S., ed. *Human Error in Medicine,* 1994.
2. *www.jointcommission.org/PatientSafety/UniversalProtocol/*
3. *www.facs.org/fellows_info/statements/st-41.html*
4.*www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=1106*
5. *www.spine.org/*

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