Patient Safety Tip of the Week

November 9, 2021   Ensuring Safe Site Surgery

It seems we've been doing a lot of columns recently on wrong site surgery or procedures (see our Patient Safety Tips of the Week for September 14, 2021 "Wrong Eye Injections" and October 5, 2021 "Wrong Side Again"). Despite all our efforts to eliminate "wrong site surgery" (which includes both wrong procedures and surgery or procedures on the wrong site, side, or patient), such incidents have not disappeared.

The Pennsylvania Patient Safety Authority put forth "Draft Recommendations to Ensure Correct Surgical Procedures and Correct Nerve Blocks" (PPSA 2021) on October 23, 2021 to prevent wrong-site surgery. These recommendations were approved by the (Pennsylvania) Department of Health. Public comments will be accepted by Patient Safety Authority for 30 days from that date of publication. The recommendations are listed below:

Recommendations to ensure the correct surgical procedure is done on the correct site, side and patient:

Preoperative verification and reconciliation
- The site and side of procedure should be specified when the procedure is scheduled.
- The procedure, site and side should be noted in the medical record on the history and physical exam record.
- The procedure, site and side should be discussed and documented on the informed consent form.
- Verification and reconciliation of information on the schedule, consent, history and physical, and any office notes are the responsibility of all staff members— including scheduling staff, registration clerks, ancillary and nursing staff, and operating provider—and the patient themselves.
- All information to verify the correct patient, procedure, side and site, including the patient's or family's verbal understanding, must be verified by the circulating nurse, anesthesia provider and operating provider. This verification shall be documented in a manner determined by the healthcare facility.
- Verbal verification with the patient or their representative should be conducted whenever possible. All verbal verification must be done using questions that require active response of specific information rather than passive agreement. Example: Can you tell me your full name? What is your date of birth? What procedure are you having performed today?

- Patient identification must require at least two unique identifiers, for example, name and date of birth.
- Discrepancies must be reconciled and documented by the operating provider prior to the procedure.

Site Marking—Site marking recommendations apply to all procedures where there is more than one possible location for the procedure.
- The site must be marked by the provider responsible for the procedure, for example, surgeon or interventional radiologist, prior to the patient entering the procedure area. The mark must be confirmed by the attending nurse and an alert patient or patient representative. The mark must coincide with the schedule, history and physical, and consent.
- The site must be marked with the provider's initials with an indelible marker.
- The mark must be made as close to the incision site as possible, so that it is visible in the prepped and draped field.

Time-Out and Intraoperative Verification
- Prior to the induction of anesthesia, the circulating nurse and the anesthesia provider, verify the patient's identity, procedure, site, side, consent and site marking. The patient is included in this verification whenever possible.
- The provider performing the procedure should announce the time-out. This occurs after the patient is prepped and draped, and immediately prior to skin incision/puncture.
- Separate formal time-outs must be done for separate procedures, including anesthetic blocks, by the person performing that procedure.
- Noncritical activities in the procedure area must stop during the time-out, including music and nonessential talking that could distract team members.
- Relevant patient documents should be available and actively confirmed during the time-out process. Relevant documents include a history and physical, consent, operating room schedule, radiographic studies when applicable, and office notes.
- The site mark should be referenced in the prepped and draped field during the time-out.
- Members of the surgical team should actively and verbally verify agreement with the surgical site, side and relevant documents. Active participation should be used at all times. For example, "Which side is the surgery on?" instead of "The surgery is on the left side. Do you agree?"
- Staff should be engaged in the process and the operating provider should specifically encourage team members to speak up with any concerns during the time-out. The operating provider is responsible for resolving any questions or concerns based on primary sources of information and to the satisfaction of all members of the team before proceeding.
- Utilize intraoperative imaging whenever possible for procedures where exact site is not easily determined through external visualization, for example, X-ray and fluoroscopy, to verify spinal level, rib section level or ureter to be stented.

Accountability

- Incorporate accountability for these recommendations into the facility's quality assurance and formal evaluation process. This includes both individual and team performance evaluations, ongoing professional practice evaluations, and focused professional practice evaluations.

Recommendations to ensure nerve blocks are performed at the correct site and correct patient:

Preoperative Verification and Reconciliation
- Confirm patient identity using at least two forms of patient identification.
- Reconcile and verify the exact site and laterality of the surgical procedure and the perioperative nerve block site using all forms of available primary and confirmatory patient sources including surgical consent, patient or representative, or both, operative provider's notes (if available), surgical schedule and history and physical.
- If any sources differ, the process stops and a member from the anesthesia block team notifies the surgeon to resolve the conflicting information.

Anesthesia Site Marking
- After confirming the information in the preoperative verification, the responsible anesthesia provider will use a standardized, institutionally approved mark that is distinct from the one used for the surgical site to mark the perioperative nerve block site.
- Place the mark close to the injection site to ensure it is visible in the prepped and draped field.
- Repeat the marking process when there are multiple injection sites.

Time-Out
- Secure a block team consisting of at least two people with independent roles (for example, responsible anesthesia provider and pre-operative or holding area nurse or circulating nurse):
- Engage the anesthesia provider to initiate the time out.
- The anesthesia provider should be present during the time-out and during the nerve block.
- Conduct a time-out before:
  a. Sedating the patient, when possible.
  b. Inserting the needle or as close to the procedure as possible.
  c. Each nerve block.
- Minimize distractions and stop all unrelated activity before conducting the time-out.
- Both the anesthesia provider and block team member verify the procedure that is documented and on the surgical consent (and anesthesia consent if used).
- Locate and visibly confirm the anesthesia site mark during the time-out.
- Repeat the time-out process when there are changes to:
  a. Block team.

      b. Patient location within the perioperative area.
      c. Patient positioning.
      d. Planned nerve block site

Accountability
- Incorporate accountability for these recommendations into the facility's quality assurance and formal evaluation process. This includes both individual and team performance evaluations, ongoing professional practice evaluations and focused professional practice evaluations.

An article on wrong site surgery in ophthalmology last year (Parikh 2020) illustrates the importance of many of these recommendations. That study expands upon work previously done by John Simon that we've also discussed before (see our Patient Safety Tips of the Week for March 11, 2008 "Lessons from Ophthalmology" and May 17, 2016 "Patient Safety Issues in Cataract Surgery"). The new study reported on 143 cases of "confusion" in ophthalmic surgery cases in New York State between January 1, 2006, and December 31, 2017. Two-thirds (66.4%) involved cases of incorrect implants being used during cataract surgery (cataract extraction and intraocular lens implantation). Wrong eye blocks or anesthesia accounted for 14.0%, incorrect eye procedures accounted for 7.00%, incorrect refractive surgery measurements accounted for 4.20%, incorrect patient or procedure accounted for 3.50%, incorrect intraocular gas concentration accounted for 2.80%, and incorrect medication in surgery accounted for 2.10%.

Of all cases, 92 (64.3%) were deemed preventable by the Universal Protocol in its current format. The leading root cause of surgical confusions among all the cases was an inadequately performed time out, which accounted for nearly one third of all surgical confusions (32.2%).

However, one salient feature of their work was that 33 of the incorrect implant cases (34.7%) were **not** preventable by the Universal Protocol. Many were the result of "upstream" errors, originating in the clinic or office before surgery. Errors from incorrect orders or calculations before the day of surgery were the second most common cause, accounting for nearly one quarter of surgical confusions (21.7%). They also noted a contributing factor we have emphasized in the past – change in the OR schedule. Other contributing factors included multiple lenses present in the OR, staff accidentally obtaining the incorrect lens power from the storage room, poorly labeled lenses, human error leading to errors despite properly performed time outs, and incorrect decisions by surgeons regarding toxic medications.

Our original foray into wrong site surgery 25 years ago that led to development of a timeout process followed cases of wrong intraocular lens implantation that included several of those root causes (change in the surgical schedule, presence of multiple lenses in the OR, etc.). We discuss the issue of change in surgical schedule later. And we extend the issue of multiple lenses in the OR to the presence of multiple records in the OR. Any time you have charts or records or images of more than one patient in the OR, you are

vulnerable to using records from the wrong patient. If a surgeon brings all his office notes for the day's cases, make sure they are kept somewhere outside the OR and that only those records on the case at hand are allowed in the OR one at a time.

Parikh et al. note that the Universal Protocol and time outs typically are performed before the case begins and key aspects may be forgotten at the time of lens implantation, which occurs toward the end of the surgery. For the time out to be maximally effective, it must occur shortly before the intended action.

Problems with site markings also contributed to some cases. Seven cases involved ambiguous site markings, which were washed off during surgical preparations, were covered, or otherwise were not visible. Another was simply not marked, and 2 were marked incorrectly. Patients themselves sometimes contributed by mistakenly affirming that they were having a procedure on the incorrect eye.

The authors stressed that "upstream" errors, originating in the clinic or office before surgery, and ineffective communication during time outs suggest a need for modification of the Universal Protocol. We discussed many of those "upstream" issues in our October 5, 2021 Patient Safety Tip of the Week "Wrong Side Again".

Wrong-site nerve blocks have actually become the most common type of wrong-site surgery, accounting for 25.7% of cases of wrong-site surgery reported to the Pennsylvania Patient Safety Reporting System (PA-PSRS) from July 2004 to September 2017 (Arnold 2018).

Balocco et al. (Balocco 2019) described risk factors for wrong-side nerve blocks. These included both physician-related factors, patient-related factors, and procedure-related factors.
Physician-related factors:
- High-pressure environment; overbooked list
- Other personal time pressures
- Fatigue
- Multiple team members with no clear hierarchy or accountability
- Poor communication or interpersonal relationships
- Change of staff during the procedure
- Failure to mark the site
- Failure to check the site
- Poor recording (inappropriate or misinterpreted abbreviations)

Patient-related factors:
- Sedated or confused, or block sited after induction of anesthesia
- Similar patient names
- Language/communication difficulties
- Abnormal anatomy
- Multiple blocks needed in the same patient

- Hemodynamic instability causing distraction and time pressure

Procedure-related factors:
- Change in patient position
- Change in the OR or procedural environment
- Changes in the order of operating list
- Wrong site marked
- Mark erased or covered
- Distractions (phone calls, verbal, staff teaching, entry of other staff, alarms)

Notice that changes in the OR schedule again showed up as a significant risk factor. We cannot overemphasize the need to communicate to all parties when such changes take place. In that case that got us started over 25 years ago on preventing wrong-site procedures, a patient had complained he had expected to be the first case of the day. Staff sought to accommodate him by inserting him earlier into the schedule and that was a primary factor in leading to 2 consecutive patients receiving wrong intraocular lens implants. We recommend that you somehow flag that changes have occurred on your OR white board or electronic surgical schedule and especially communicate to all when such changes occur after the day's original schedule was published.

Balocco et al. went on to discuss the use of checklists to help avoid wrong-side nerve blocks.

Vandebergh et al. recently described strategies to prevent wrong-side nerve blocks (Vandebergh 2021). They discuss the roles of checklists, procedural markings, the "Time Out" or "Stop Before You Block", influence of the environment and team, and use of simulated procedures. They also discuss how new technologies, such as a USB device that attaches to the ultrasound probe and senses when the patient's skin is touched, triggering an audible alert ("Check the side of the block") that can only be stopped by pressing a confirmation button on the device.

They also discuss another intervention that we've discussed in multiple columns. That is including on the procedure kit or tray a sticker that requires a checklist be completed before the contents of the kit/tray can be removed.

Wrong-site surgery and wrong-site procedures are sentinel events that should never occur. We have a whole variety of tools and procedures to prevent such occurrences, but you have to use them and do so religiously. Failure to comply with the time out process or have everyone fully participate remains a major factor in wrong-site surgeries. And such participation must be active. Staff cannot simply nod concurrence. They must be able to go to primary source documents and confirm that the patient, procedure, site and laterality are correct.

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

September 23, 2008 "Checklists and Wrong Site Surgery"
June 5, 2007 "Patient Safety in Ambulatory Surgery"
July 2007 "Pennsylvania PSA: Preventing Wrong-Site 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"
August 2011 "New Wrong-Site Surgery Resources"
December 2011 "Novel Technique to Prevent Wrong Level Spine Surgery"
October 30, 2012 "Surgical Scheduling Errors"
January 2013 "How Frequent are Surgical Never Events?"
January 1, 2013 "Don't Throw Away Those View Boxes Yet"
August 27, 2013 "Lessons on Wrong-Site Surgery"
September 10, 2013 "Informed Consent and Wrong-Site Surgery"
July 2014 "Wrong-Sided Thoracenteses"
March 15, 2016 "Dental Patient Safety"
May 17, 2016 "Patient Safety Issues in Cataract Surgery"
July 19, 2016 "Infants and Wrong Site Surgery"
September 13, 2016 "Vanderbilt's Electronic Procedural Timeout"
May 2017 "Another Success for the Safe Surgery Checklist"
May 2, 2017 "Anatomy of a Wrong Procedure"
June 2017 "Another Way to Verify Checklist Compliance"
March 26, 2019 "Patient Misidentification"
May 14, 2019 "Wrong-Site Surgery and Difficult-to-Mark Sites"
May 2020 "Poor Timeout Compliance: Ring a Bell?"
September 14, 2021 "Wrong Eye Injections"
October 5, 2021 "Wrong Side Again"

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http://www.patientsafetysolutions.com/

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