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Patient Safety Tip of the Week

September 14, 2021

Wrong Eye Injections

It was ophthalmology that actually introduced us to wrong site surgery. Our initial interest in surgical timeouts and checklists stemmed from a root cause analysis on an ophthalmology incident. That incident led to the development of one of the first formal surgical timeout policies, which later became a model for New York State's first foray into surgical timeout policies. Also, during a lull at one of the meetings of the statewide NYPORTS (New York Patient Occurrence and Report Tracking System) committee we asked attendees if they had ever seen implantation of incorrect lenses during cataract surgery. One hand after another shot up! Probably a third of attendees had experienced this at their hospital. John Simon and his colleagues at Albany Medical College subsequently analyzed all such cases in the NYPORTS database and an ophthalmology malpractice claims database. His work and the references are summarized in our March 11, 2008 Patient Safety Tip of the Week "Lessons from Ophthalmology".

Note that we use the term "wrong site surgery" to include not only a procedure on the wrong body part but also procedures on the wrong patient, wrong side, or wrong procedure.

But it's not just ophthalmologic surgery that runs the risk of wrong site errors. Intravitreous injections have become a very frequent ophthalmologic procedure and a recent report described several cases of errors related to such injections (Vora 2021). While the overall incidence of errors in such cases was very low, Vora et al. identified some important lessons from the four cases they found. Two cases involved injections in the wrong eye, one injection of the wrong medication, and one the wrong dose of the correct medication.

The 2 cases of wrong eye injection involved **failure to use (or failure to review) a surgical checklist** and **failure to perform a pre-procedure timeout**. Timeouts and surgical safety checklists should be required not only for "surgery", but also for any procedure being performed regardless of site of service. See our June 6, 2011 Patient Safety Tip of the Week "Timeouts Outside the OR" for a good discussion on that issue. And, of course, this also raises the question of how organizations that do have policies for use of timeouts and checklists for non-OR procedures actually audit adherence to those checklist and timeout procedures.

Also, in both cases, a new **consent form** was not obtained because the EMR contained an "active" consent form. Since age-related macular degeneration is commonly bilateral, it is not surprising that a patient might be scheduled for injections in each eye at one time or other. So, the presence in the EMR of consents for injections in both eyes may be a factor contributing to wrong eye errors. Also, since patients are likely to need recurrent injections, the issue of how long a consent should be "active" in the EMR is a serious consideration. How many of you have a process for "closing" a consent once the patient has the first procedure for which that consent was obtained? We'll bet probably none of you. We really need to develop a standard for somehow flagging in the EMR those consents that are no longer valid because the patient has already had the procedure for which that consent pertained. Just because a patient consented to a procedure the first time does not automatically mean they have consented to the repeat procedure.

The case in which the wrong medication was injected was interesting. This was a patient who had received previous injections of 3 anti-VEGF agents. There had been successful response to only one of those agents. "Active" consents for all 3 agents were present in the electronic medical record. Instead of reviewing the most recent medical record, the surgeon reviewed a past note where the patient received one of the failed medications. He then ordered that medication rather than the one that had been successful. Once again, the procedure team had not relied on a surgical checklist and it is unclear if a pre-procedure timeout was completed.

The fourth case involved injection of the wrong concentration of an anti-VEGF agent. At this site, all anti-VEGF agents were stored together in a refrigerator. The medical assistant, who was new to the service, erroneously pulled a box containing the higher concentration of the intended anti-VEGF agent and the surgeon injected that higher dose. As in the other cases, no checklist was used and there was no pre-procedure timeout performed.

The Vora study does not comment on two significant factors we've seen in ophthalmologic "wrong site" cases in the past – daily **volume of cases** and **throughput pressures**. Some of those cases involved ophthalmologic surgeons performing many procedures during a session and unexpected changes in the schedules on the day of the procedures. **Distractions and interruptions** are other factors leading to wrong-site errors. Since many of these procedures are being performed in the office, one wonders how often the surgeon gets interrupted or distracted by other activities in the office setting (phone calls, other patients, requests from other staff, etc.). In one of these cases, where the decision to inject an eye was made during a "routine" appointment, it was noted that the surgeon "re-entered" the room. Was he/she distracted by whatever he/she was doing outside that room?

Apparently, none of these patients suffered harm from these errors. But the authors note these errors did have the potential to cause substantial ocular morbidity, particularly if a complication such as endophthalmitis might occur. They also comment on how such

errors can diminish trust in the treating physician and harm the physician-patient relationship.

The authors propose that retina surgeons standardize the injection pathway, with the following considerations:

- There should be a set way of communicating the injection plan with staff, which clearly communicates agent and laterality
- Patient consent and marking should be performed in a consistent manner
- The team member preparing the patient should reconfirm the intended patient, eye, and medication while marking off a checklist to ensure all variables have been reconciled with the treatment plan
- Finally, before injection, the surgeon should pause to perform a timeout

One of the most important facets in avoiding "wrong site" errors is a strong **scheduling policy and procedure** (see our October 30, 2012 Patient Safety Tip of the Week "Surgical Scheduling Errors"). At the time of scheduling a procedure, the appropriate primary source documents (including any relevant imaging studies) and current consent forms should be submitted along with a request delineating the exact procedure to be performed and laterality if appropriate. Requests for special equipment or supplies required should also be part of the scheduling process. We also recommend that the scheduling process include a comment or checkbox as to whether a surgical specimen for pathological examination is anticipated. That should be the process when a procedure is scheduled for an OR or facility-based procedure room. But many or most of these intravitreous injections are performed in the office. We suspect that such a formal scheduling process is not routinely performed for office-based procedures like these.

One problem we see during timeouts, whether they are in the OR or elsewhere, is failure of all staff to **review primary source documents**. All too often, staff merely nod agreement to items on the timeout checklist without themselves reviewing those documents.

Two other important opportunities to avoid wrong-site procedures are the **pre-procedure "huddle"** and the **site marking**. In cases being done in a hospital OR or an ambulatory surgery center, the pre-op huddle is done prior to the team entering the OR or procedure room. But we doubt such "huddles" are being done in most office-based procedures. The Vora study does not indicate whether site marking was used in any of these cases or whether it is routinely used during intravitreous injections in their organization. Our May 14, 2019 "Wrong-Site Surgery and Difficult-to-Mark Sites" had comments about site marking in eye procedure cases.

One important consideration in avoiding wrong-site procedures is **involvement of the patient** in the processes. But, since the majority of patients receiving intravitreous injections are elderly, problems with hearing, eyesight, and/or cognition may preclude full participation by the patient in those processes.

Lastly, how the anti-VEGF agents are **stored** may be important. Each office (or other site) should have a process in place to clearly segregate these medications to minimize the risk that the wrong one will be procured for a procedure. In the Vora paper there is a photo of the similar appearance of the medication-filled syringes for the two different doses of one of the anti-VEGF agents. Note that this is a similar problem to primary care practices storing multiple vials of different vaccines in their refrigerators.

While the incidence of such "wrong-site" procedures was low in this study, the increasing frequency of intravitreous injections will likely lead to occurrence of similar cases. The Vora study provides valuable lessons to avoid such incidents.

Some of our previous patient safety columns involving ophthalmology issues:

June 5, 2007	"Patient Safety in Ambulatory Surgery"
March 11, 2008	"Lessons from Ophthalmology"
June 8, 2010	"Surgical Safety Checklist for Cataract Surgery"
June 2012	"Tailored Timeouts for Ophthalmologists"
May 20, 2014	"Ophthalmology: Blue Dye Mixup"
September 2014	"Another Blue Dye Eye Mixup"
May 17, 2016	"Patient Safety Issues in Cataract Surgery"
December 5, 2017	"Massachusetts Initiative on Cataract Surgery"

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?"

References:

Vora RA, Patel A, Seider MI, Yang S. Evaluation of a Series of Wrong Intravitreous Injections. JAMA Ophthalmol. Published online August 26, 2021. https://jamanetwork.com/journals/jamaophthalmology/fullarticle/2783398