

Patient Safety Alert

Veterans Health Administration Warning System
Published by VA Central Office

AL13-03*

January 15, 2013

Item: Incorrect eye surgery adverse events in Veterans Health Administration facilities

Specific Incidents: VHA Directive 2010-023 “Ensuring Correct Surgery and Invasive Procedures” was updated and reissued on May 17, 2010 (see Reference 1). Between that time and June 30, 2012, there were reported preventable adverse events related to incorrect eye surgery in the Veterans Health Administration. The majority of events caused major harm (i.e., permanent lessening of bodily function, disfigurement, or required surgical intervention); no catastrophic events (i.e., death or major permanent loss of function) were reported.

Most of the events were wrong implants. A wrong implant is defined as “the implant determined by proper calculations in clinic is not the implant that is actually implanted (e.g., a 20.5 D lens is determined in clinic to be implanted, but a 25.0 D lens is actually implanted) or the implant that was implanted was not the implant that should have been implanted (e.g., an error occurred during the pre-operative period – where an incorrect A-constant was used in the power lens calculations)”. The remaining events consisted of wrong-side surgery events and expired lenses being implanted. The majority of these events occurred in operating rooms (ORs), but similar events have also occurred in non-OR settings.

NOTE: Refractive surprise cases are not part of this Patient Safety Alert. Refractive surprise is a case where preoperative measurements are obtained with accuracy and the planned implant is placed correctly, yet an unexpected post-operative refractive error results. Also not part of this Alert are events based on technique error.

General Information: A journal article presented a review of incorrect surgical procedures (i.e., wrong patient, wrong side, wrong site, wrong procedure, or wrong implant) reported within Veterans Health Administration from 2006 through 2009 (see Reference 2). During that time period, Ophthalmology had an in-OR rate for reported incorrect procedures of 1.06 per 10,000 procedures, while the overall VA in-OR rate for incorrect procedures was 0.4 per 10,000 procedures. (Rates are based on reported events and, as such, the rates could be even higher, as

events may be underreported.) Ophthalmology wrong implants accounted for 80% of all reported wrong implants in VHA. It is evident by the events described in the Specific Incident section of this Alert that Ophthalmology incorrect procedures related to wrong implants remain a challenge.

Veterans Health Administration facilities have completed Root Cause Analyses (RCAs) on the events reported in the Specific Incident section of this Alert. The root causes from these RCAs have been utilized in formulating the actions in this Alert. The most common root cause identified for Ophthalmology events was lack of standardization of processes. Time-outs, read backs prior to implantation, and double checks of calculations of power prior to lens implantation were some of the methods identified to prevent incorrect eye surgery, along with better team communication (e.g., questioning when things “just don’t feel right”).

Actions:

1. The **Chief of Surgical Services (or designee)** shall ensure that the following actions **regarding staff education** are completed by close of business (COB) March 1, 2013.
 - a. Ensure and document (in a manner fitting to your facility) that each staff member involved in eye surgeries and procedures (e.g., surgeon, resident, nurse, scrub tech, anesthesiologist, nurse anesthetist, nurse practitioner, ophthalmology tech, contractors, without compensation (WOC) Ophthalmologists, etc.) in ORs and clinics has reviewed VHA Directive 2010-023 “Ensuring Correct Surgery and Invasive Procedures” (see Reference 1).
 - b. Ensure, and document completion through the VA Learning University (VALU) Talent Management System (TMS), that each staff member involved in eye surgeries and procedures (as identified in 1a above) in ORs and clinics has taken the TMS course “Ensuring Correct Surgery and Invasive Procedures” (TMS Item #6573).
2. The **Chief of Surgical Services (or designee)** shall review and complete the following actions **regarding eye surgeries and procedures** by COB April 23, 2013.
 - a. Confirm that a standardized pre-operative process is in place for calibration of the equipment, performance of axial length and keratometry measurements, and preparation and transmittal of implant lens calculations. Standardized practice should include the following:

- a qualified staff member takes the measurement data (i.e., competency in this process would be current for this staff member)
- how specifically the lens measurement data is obtained (e.g., IOL Master)
- comparison of data obtained to prior implant surgeries (e.g., use of prior surgery implant information as a rough estimate of power based on refraction as a gross check for correct IOL power)
- documentation that the measurements, calculations, desired post-op refraction, and chosen implant style and power were reviewed by the credentialed and privileged surgeon and approved prior to surgery
- how the information is presented to the location of the surgery or procedure (e.g., the original printout from the IOL Master is presented to the OR).

NOTE: The term original within this Alert refers to the original source document or a copy/scan of the original source document. Hand-transcribed versions do not constitute original documents.

- how the information is entered into the electronic health record (e.g., staff scans the information).
- b. Ensure physical segregation of the records and lenses for each case from other cases to avoid inadvertent switching of lenses. This means that only the medical records and lens implant(s) for the current patient are present in the operating room or clinic at the time of the eye surgery/procedure (e.g., avoid stacks of paperwork or implants for all of the day's surgeries/procedures).
- c. Implement an eye-surgery-specific checklist to support pre-operative team briefing in the ORs and clinics. The pre-operative briefing checklist should include information normally on a pre-operative checklist (e.g., patient name and date of birth, procedure, surgical site and side, allergies and medications, anesthesia risks, special equipment required, etc.), as well as eye-surgery specific information, such as the following:
- original data (see the NOTE in Action 2a of this Alert regarding the term "original") used to determine the IOL power be available for review by the surgeon
 - correct lens has been selected (i.e., a double check of axial length and keratometry measurements and IOL calculations)

- a review of the style, power, and expiration date of the IOL
- verification of the correct patient and eye, and that the IOL calculation sheet matches the patient and eye
- marking of the surgical site

NOTE: See the Attachment of this Alert for additional eye-surgery specific elements that should appear in the checklist.

- d. Verify that the following five steps for ensuring correct surgery and invasive procedures are performed, **as described fully in VHA Directive 2010-023 (see Section 4b(1) of the Directive)**, prior to all eye surgeries and procedures:

- The consent process is administered and executed for the appropriate procedure.
- The operative site is marked.

NOTE: A uniform method should be used for marking the correct eye prior to operations (e.g., surgeon's initials); avoid ambiguous markings such as an "X" (e.g., "X" could be interpreted as "X marks the correct spot" or "X marks the spot not to be worked on"). Also, ensure that the operative site marking is visible after prep and drape.

- The patient and procedure site is identified using a standardized approach.
- All medical images, including original IOL data (see the NOTE in Action 2a of this Alert regarding the term "original"), are reviewed by two members of the procedure team prior to start of the procedure.
- A time-out must be facilitated by a checklist and occur immediately prior to the start of the procedure. During the checklist-guided time out, ensure that teams routinely verify the correct lens power, style, and expiration date, and that axial length and keratometry measurements and IOL calculations using original (see the NOTE in Action 2a of this Alert regarding the term "original") or source data information are checked and verified by the surgeon.

NOTE: A time-out must be completed prior to all nerve blocks.

NOTE: See the Attachment of this Alert for additional eye-surgery specific elements that should appear in the checklist.

- e. As prescribed in VHA Directive 2010-023 (see Section 4b(2)), ensure that a “read-back” is conducted immediately prior to implantation of the ophthalmologic medical device. **The privileged provider performing the procedure must confirm the correct style and power of implant with a team member, including a “read-back” of all relevant information. The expiration date must be verified as well.** Documentation of the correct medical implant must be placed in the patient’s health record.
3. By COB April 30, 2013, the **Patient Safety Manager** shall document on the VHA Hazard Alerts and Recalls website that medical center leadership has reviewed and implemented these actions, or that they are not applicable to your facility.

Additional Information:

The following additional educational resource specific to eye surgery is available:

- Simon, J.W. Preventing surgical confusions in ophthalmology (an American Ophthalmological Society thesis). *Trans Am Ophthalmol Soc* 2007 Dec; 105, 513-529).
<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2258113/>.

Sources:

Veterans Health Administration facilities and the NCPS Patient Safety Information System

References:

1. VHA Directive 2010-023: Ensuring Correct Surgery and Invasive Procedures, dated May 17, 2010.
http://www1.va.gov/vhapublications/ViewPublication.asp?pub_ID=2243
2. Neily, J. et al. Incorrect surgical procedures within and outside of the operating room: a follow-up report. *Arch Surg* 2011 Nov; 146(11), 1235-1239.
<http://archsurg.jamanetwork.com/article.aspx?articleid=1107203>

Attachment:

Checklist elements for checklist-guided preoperative briefing and time-out

Contacts:

Alerts and Advisory Team at the National Center for Safety (734) 930-5890

ATTACHMENT: Checklist elements for checklist-guided preoperative briefing and time-out

- Correct patient identity
- Procedure to be performed
- Site of procedure
- Laterality
- Valid consent form
- Patient position
- Procedure site marked
- Site mark visible after prep and drape
- Pertinent medical images confirmed (if applicable)
- Correct implant(s) available
 - Lens implant style
 - Lens implant power
 - Expiration date
 - Checked and verified by surgeon against calculation sheets available in the OR
- Antibiotic prophylaxis (if applicable)
- DVT prophylaxis (if applicable)
- Blood availability (if applicable)
- Special equipment available