

The ICO's Global Call for Action to Eliminate Eye Surgical Errors

Goal

To eliminate mistakes related to eye surgery. These might include the wrong patient, wrong eye, wrong intraocular implants or injectable agents, or the wrong eye procedures.

Position

Patient safety is a high priority and fundamental responsibility of eye care providers. Unfortunately, errors may occur even in the most sophisticated environments. These are all preventable serious adverse events that may lead to loss of vision and so carry significant physical, emotional and economic consequences.

The root causes of these human errors are due to a lack of a strict protocol or to a breakdown in communication and the standard procedures prior to, during, or following eye surgery.

The World Health Organization (WHO) has identified patient safety as a major health priority, and the American Academy of Ophthalmology has been a strong advocate for safer surgical eye care. In support of resolution WHA66.4 endorsing the universal eye health global action plan 2014-2019, the ICO calls on all ophthalmologists to adopt patient safety practices that include the whole surgical eye care team. These practices should be in place wherever invasive procedures are performed on the eye, including settings outside of the operating room. Adherence to standard protocols and procedures to identify the correct patient, the correct surgical operation, the correct eye, the correct site, the correct implant, device or drug, will protect all patients undergoing eye surgery from avoidable harm and vision loss due to surgical errors.

Background

Surgical errors such as the wrong patient, wrong site, wrong procedure, or wrong implant, are among the most commonly recognized and reported medical errors [1]. These adverse patient safety events can affect people of all age ranges, the rich and poor, and occur throughout the world [2]. Ophthalmology is reported to have one of the highest rates of preventable adverse events [3, 4]. The need for multiple steps during eye surgery that often require pre-operative calculations and measurements, the reliance on a surgical team, and the use of specialized equipment and instruments may all play a role. Operating on the wrong person or the wrong eye are among some of the most serious of the "never ever" events [5-8], and carry the potential for disastrous consequences including the unthinkable removal of a healthy eye [9].

A recent US study noted that among 106 cases of surgical confusion during eye surgery, the insertion of the wrong intraocular lens implant accounted for 63% of adverse events. Another 14% were due to operating on the wrong eye, and another 8% to operating on the wrong person or performing the wrong procedure [10]. A Hong Kong study of a dozen sentinel events, reported 41% were operating on the wrong eye, 17% were both the wrong eye and the wrong procedure, and 17% were related to retained surgical items [11].

In cataract surgery errors related to intraocular lens implants are unfortunately common, with incorrect calculations, transcription or communication errors, and wrong lens selection among the most common factors [12-14]. In refractive surgery the errors include incorrect entry of patient specific data [15]. Serious errors of strabismus surgery may relate to pre-operative measurements, patient identification and intra-operative events[16].

Intravitreal injection of anti-VEGF agents also carry risk, and in one study of 166 serious incidents over a 7-year period, the wrong medication was injected in 16% of cases, the wrong person or eye was injected in 10%, and in 7% the medical records were missing [17].

It is recognized that human error is the root cause of such breaches in patient safety - either pre-operatively or intra-operatively, and that they are preventable. Major risk factors for mistakes related to surgery include a breakdown in communication between the surgeon and patient and team, the lack of verification procedures, inadequate validation of site marking procedures, inadequate preoperative checklists, incomplete patient assessment, staff distractions, limited or compromised information available in the operating room, and cultural or language barriers [18] [19].

The Joint Commission on Accreditation of Healthcare Organizations, in collaboration with professional organizations such as the American Academy of Ophthalmology (AAO), introduced and promulgated a Universal Protocol to prevent surgical errors [20]. The WHO Surgical Safety Checklist has also been shown to be effective in preventing such errors by introducing preoperative verification, site marking, and "time-out" procedures [21, 22]. The adoption of these steps has reduced the number of sentinel events during cataract and refractive surgeries [23-25]. However, according to a survey among ophthalmologists in the UK, only 54% of cataract surgeons use a checklist to address the selection of the correct intraocular implant [24]. The true extent of surgical mishaps is currently unknown as many of these "never events" go unreported.

Summary

The International Council of Ophthalmology calls on societies and ophthalmologists around the world to support and advocate for the elimination of human suffering from errors related to eye surgery. Educational programs to increase awareness will help to promote a culture of safety. Integrating safety promotion systems that involve the entire surgical team, and that include preoperative verification, site marking, and a surgical pause as part of a standard checklist are essential. The ICO also encourages

ophthalmology societies to develop a reporting system to measure events and to report on progress in the elimination of surgical eye errors.

Resources:

World Health Organization. Universal Eye Health: A Global Action Plan 2014-2019. Geneva, Switzerland: WHO; 2013. Available at www.who.int/blindness/actionplan/en/

http://www.who.int/patientsafety/safesurgery/checklist/en/

https://www.jointcommission.org/assets/1/18/UP_Poster1.PDF

http://www.aao.org/patient-safety-statement/recommendations-of-american-academy-ophthalmology-

http://www.aao.org/patient-safety-statement/ophthalmic-surgical-task-force-surgery-checklist-2

References:

- 1. Commission, T.J., Summary Data of Sentinel Events Reviewed by the Joint Commission. February 4, 2016, in Available at https://www.jointcommission.org/assets/1/18/2004-2015_SE_Stats_Summary.pdf. Accessed July 3, 2016.
- 2. Haynes, A.B., et al., A surgical safety checklist to reduce morbidity and mortality in a global population. N Engl J Med, 2009. **360**(5): p. 491-9.
- 3. Neily, J., et al., *Incorrect surgical procedures within and outside of the operating room.* Arch Surg, 2009. **144**(11): p. 1028-34.
- 4. Neily, J., et al., *Incorrect surgical procedures within and outside of the operating room: a follow-up report.* Arch Surg, 2011. **146**(11): p. 1235-9.
- 5. Fraser, S.G. and W. Adams, *Wrong site surgery*. Br J Ophthalmol, 2006. **90**(7): p. 814-6.
- 6. Lum, F. and A.P. Schachat, *The quest to eliminate "never events".* Ophthalmology, 2009. **116**(6): p. 1021-2.
- 7. Pikkel, D., A. Sharabi-Nov, and J. Pikkel, "It is the left eye, right?". Risk Manag Healthc Policy, 2014. **7**: p. 77-80.
- 8. Elghrably, I. and S.G. Fraser, *An observational study of laterality errors in a sample of clinical records.* Eye (Lond), 2008. **22**(3): p. 340-3.
- 9. Traquair, H.M., Removal of the Wrong Eye. Br J Ophthalmol, 1947. **31**(1): p. 8-12.
- 10. Simon, J.W., et al., *Surgical confusions in ophthalmology.* Arch Ophthalmol, 2007. **125**(11): p. 1515-22.

- 11. Mak, S.T., Sentinel events in ophthalmology: experience from Hong Kong. J Ophthalmol, 2015. **2015**: p. 454096.
- 12. Steeples, L.R., et al., Wrong intraocular lens events-what lessons have we learned? A review of incidents reported to the National Reporting and Learning System: 2010-2014 versus 2003-2010. Eye (Lond), 2016.
- 13. Kelly, S.P. and A. Jalil, *Wrong intraocular lens implant; learning from reported patient safety incidents*. Eye (Lond), 2011. **25**(6): p. 730-4.
- 14. Zamir, E., K. Beresova-Creese, and L. Miln, *Intraocular lens confusions: a preventable "never event" The Royal Victorian Eye and Ear Hospital protocol.* Surv Ophthalmol, 2012. **57**(5): p. 430-47.
- 15. Moshirfar, M., et al., Sources of medical error in refractive surgery. J Refract Surg, 2013. **29**(5): p. 303-10.
- 16. Simon, J.W., *Complications of strabismus surgery.* Curr Opin Ophthalmol, 2010. **21**(5): p. 361-6.
- 17. Kelly, S.P. and A. Barua, *A review of safety incidents in England and Wales for vascular endothelial growth factor inhibitor medications.* Eye (Lond), 2011. **25**(6): p. 710-6.
- 18. Committee on Quality of Health Care in America, Institute of Medicine: To Error is Human. Building a Safer Health System DC. National Academy Press. 2000, 1-2.
- 19. Simon, J.W., Preventing surgical confusions in ophthalmology (an American Ophthalmological Society thesis). Trans Am Ophthalmol Soc, 2007. **105**: p. 513-29.
- 20. Joint Commission on Accreditation of Healthcare Organizations. Universal Protocol for preventing wrong site, wrong procedure. JCAHO Perspective on Patient Safety. 2003. **3**: p. 1-11.
- 21. Haynes, A.B., et al., Changes in safety attitude and relationship to decreased postoperative morbidity and mortality following implementation of a checklist-based surgical safety intervention. BMJ Qual Saf, 2011. **20**(1): p. 102-7.
- 22. World Allliance for Patient Safety Implementation Manual Surgical Safety Checklist (First Edition) Safe Surgery Saves Lives. Available at: http://www.who.int/patientsafety/safesurgery/tools-resources/SSSL Checklist fin-alJun08.pdf?ua=1 Accessed July 4th, 2016.
- 23. Neily J1, C.A., Orcutt J, Paull DE, Mills PD, Gilbert C, Hemphill RR, Gunnar W., Examining Wrong Eye Implant Adverse Events in the Veterans Health Administration With a Focus on Prevention- A Preliminary Report. Journal of Patient Safety, 2015, March epub ahead of print 000000000000170 [doi].
- 24. Kelly, S.P., et al., Surgical checklist for cataract surgery: progress with the initiative by the Royal College of Ophthalmologists to improve patient safety. Eye (Lond), 2013. **27**(7): p. 878-82.
- 25. Robert, M.C., et al., Avoidance of serious medical errors in refractive surgery using a custom preoperative checklist. J Cataract Refract Surg, 2015. **41**(10): p. 2171-8.

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