

Understanding Wrong Site/Wrong IOL Surgery

OMIC

OPHTHALMIC MUTUAL
INSURANCE COMPANY
(A Risk Retention Group)

Course Material

- Recent “wrong site” events in the news
- Joint Commission and Sentinel Event data
- OMIC statistics and case reports
- Audience response survey data from 2008 OMIC Forum on wrong site surgery
- “Surgical Confusions in Ophthalmology” – research by John Simon, MD
- AAO wrong site recommendations

“Surgeon operates on wrong eye
of a 4 year old boy”



April 13, 2011 Surgery

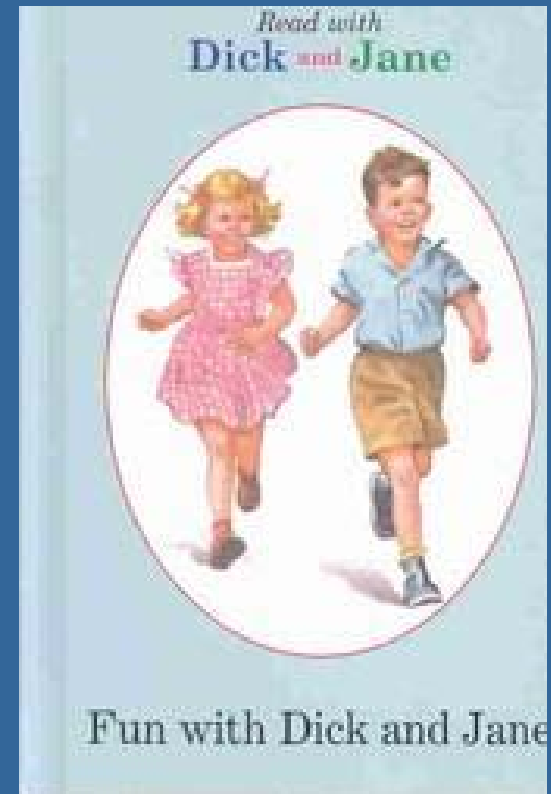
- 58 year old pediatric ophthalmologist
- 4 year old boy
- Plan: strabismus surgery OS; operates on OD
- Portland, OR – picked up on local television station and CNN and even reported in UK
 - Reporters interview parents and hospital Chief Administrative Officer

Please refer to handout material for full article

Washington Post – June 2011

The Pain of Wrong Site Surgery

- 2004 “This is not quite Dick and Jane, but it’s pretty close.” Dennis O’Leary, MD President Joint Commission



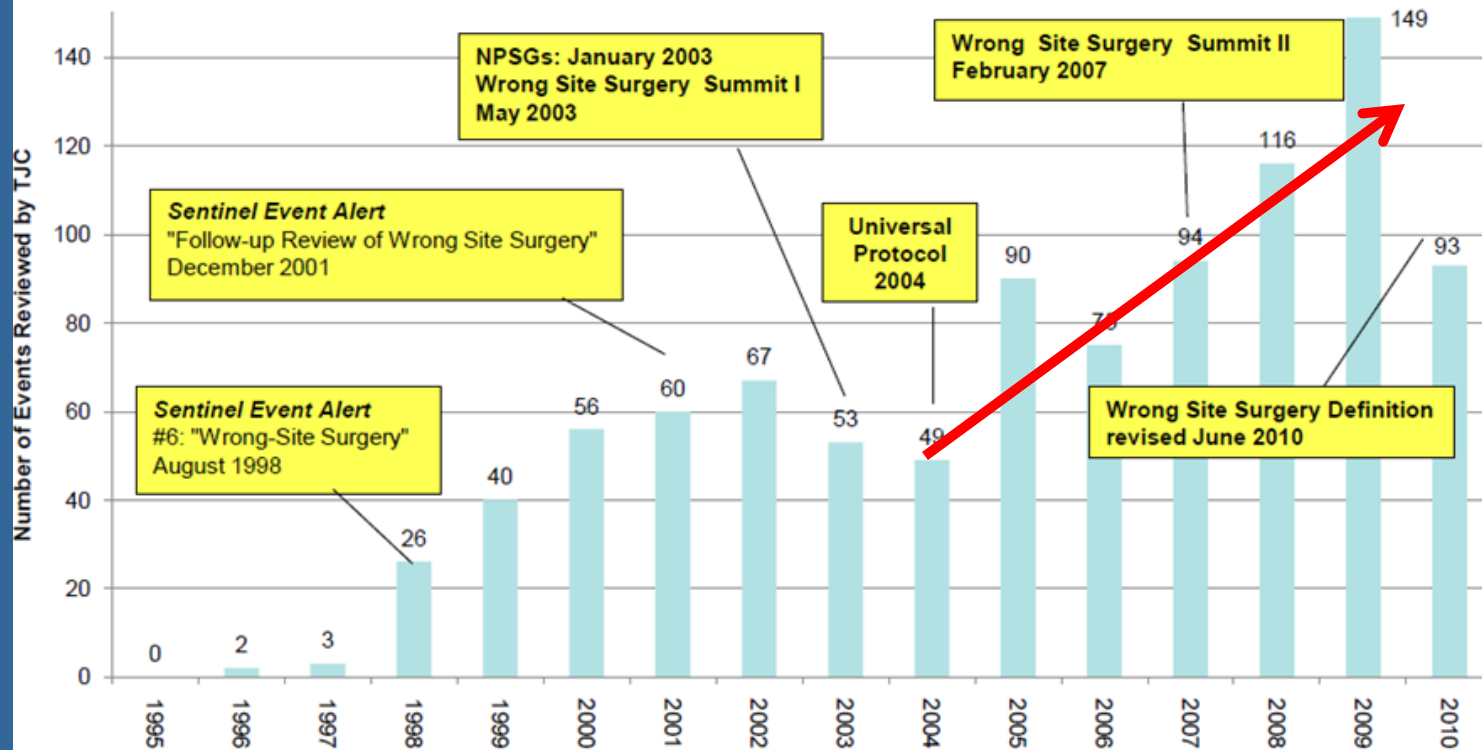
Please refer to handout material for full article

Sentinel Events 1995 -2010

“Wrong” incidents trend up after Universal Protocol

Wrong-patient, Wrong-site, Wrong-procedure Events Reviewed by The Joint Commission

(Regardless of the magnitude of the procedure)



Incidence



The Wrong Site Surgery Project

- *Although reporting of wrong site surgery is not mandatory in most states, some estimates put the national incidence rate, which includes wrong patient, wrong procedure, wrong site and wrong side surgeries, **as high as 40 per week.***

Please refer to handout material for more information

Washington Post – June 2011

The Pain of Wrong Site Surgery

- 2011 “I’d argue that this really is rocket science.” Mark Chassin, MD President of Joint Commission



Washington Post – June 2011

The Pain of Wrong Site Surgery

- “I think we made a national policy (universal protocol) with a relatively superficial understanding of the problem”
– Peter Pronovost, Johns Hopkins
- “It’s very frustrating. If you can’t solve wrong-site surgery problem, what can you solve.”
– John Clarke, Pennsylvania Patient Safety Authority

Ophthalmology: “Wrong site” includes

- Wrong site
- Wrong side
- Wrong patient
- Wrong procedure

- Wrong IOL
- Wrong refractive settings



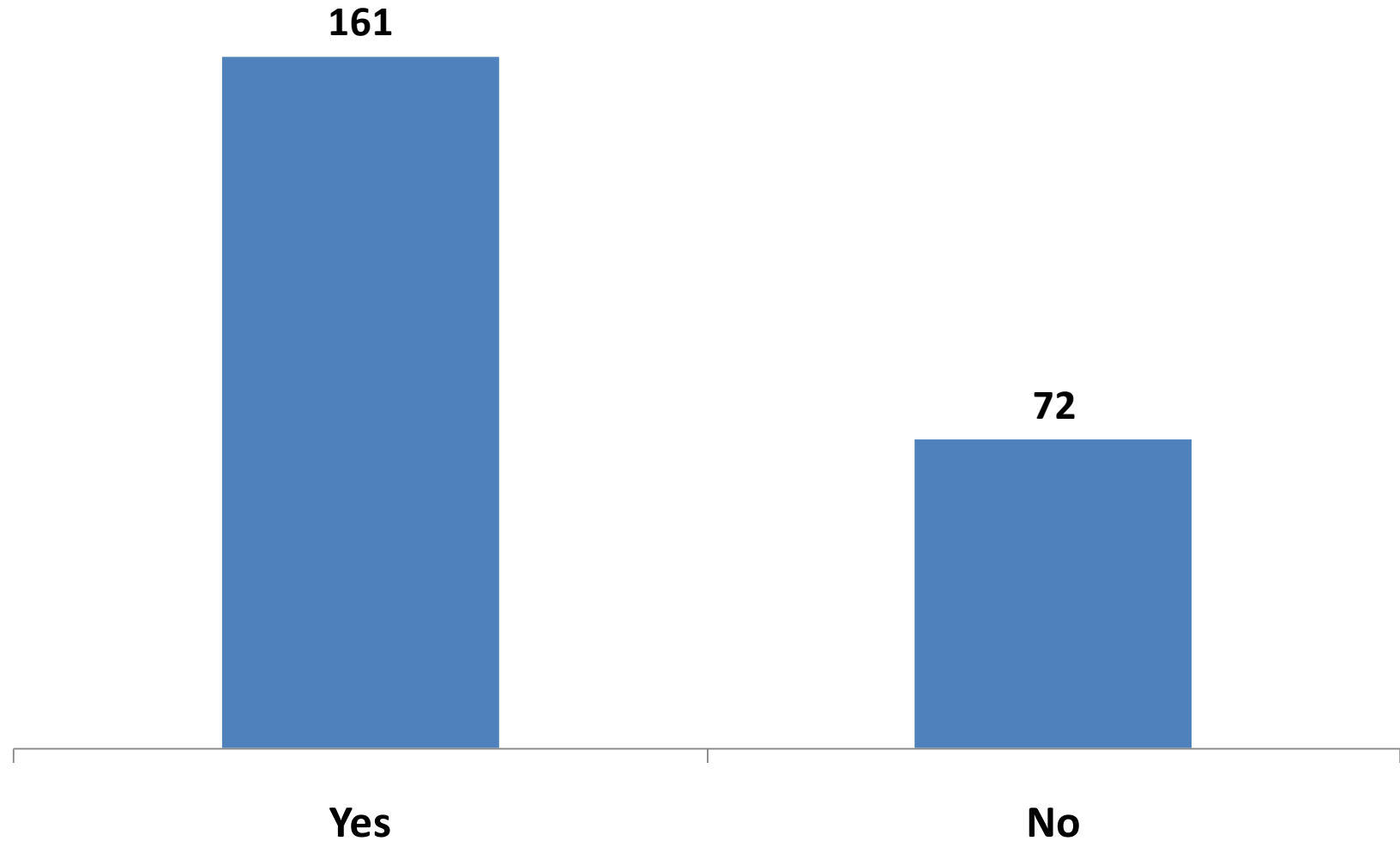
OMIC Forum -Wrong Site Surgery

**2008 American Academy
of Ophthalmology Annual Meeting**

Audience Reponses

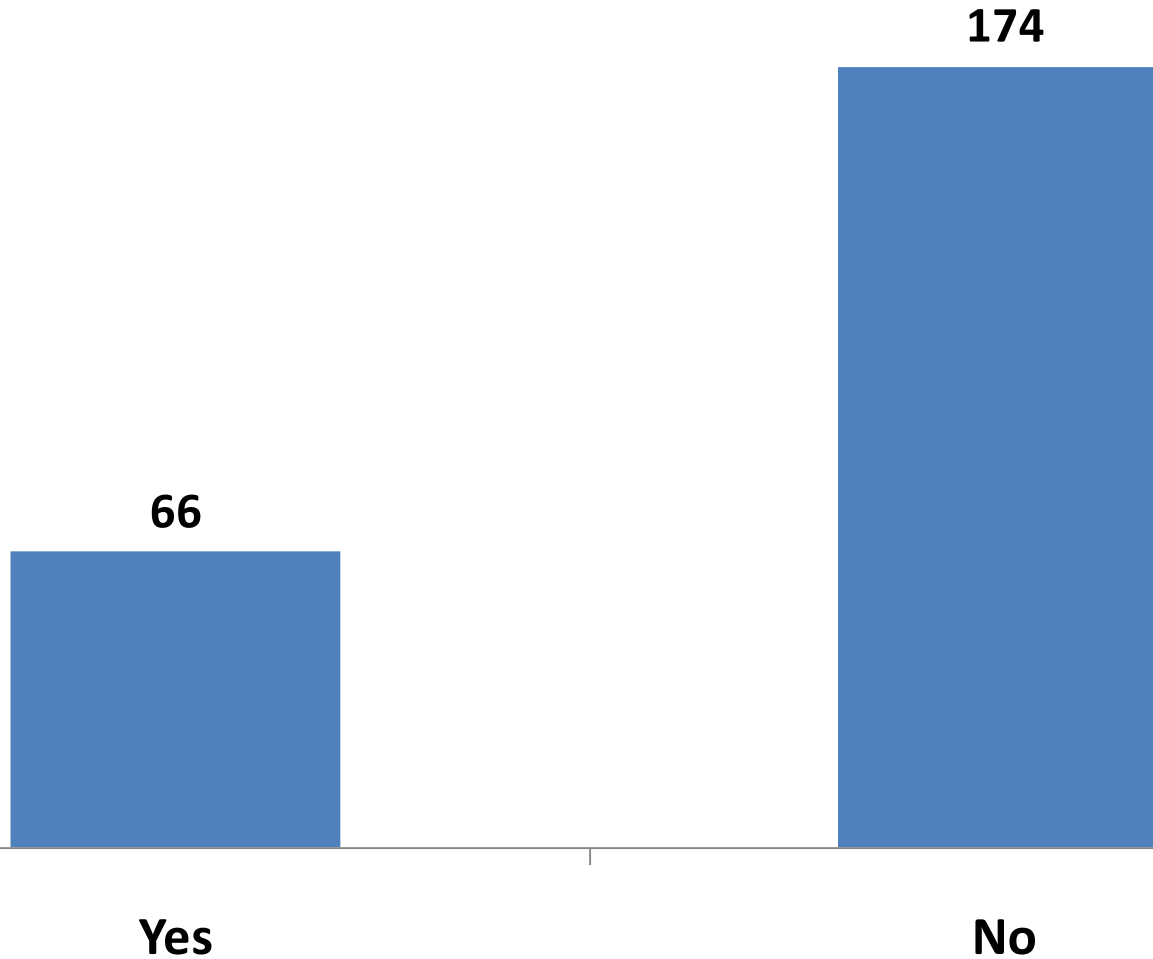
OMIC Forum 2008 Wrong Site Surgery

Do you know anyone who has done a wrong procedure, including IOL and refractive surgery?



OMIC Forum 2008 Wrong Site Surgery

Have you ever had a "wrong" procedure yourself?



3.5 year review of OMIC claims statistics (2008 – 2011)

- 1,997 reports to OMIC's claim department (lawsuits, claims, incidents, miscellaneous)
- 36 related to “wrong” events reported, i.e., < 2% of all matters reported

Types of reports to OMIC (2008 - 2011)

Type	# Reports	Wrong Reports
Lawsuits	492	3
Claims	292	7
Incidents	868	20
Miscellaneous	408	6
Total	1,997	36

OMIC's 36 “cases” include the following type of reports

- 27 - wrong IOL
- 7 - “wrong eye” surgery treatment
- 1 - wrong procedure
- 1 - wrong LASIK settings

*SAMPLE
OMIC
CASES*

Probing and Irrigation: 2010 Incident

- Patient 9 months post cataract surgery, chronic tearing
- Referred by cataract surgeon to insured; dx. punctal stenosis OU
- Discussed probing and irrigation with Crawford tubes OU;
- Dr. recommends “standard” bilateral simultaneous sx.; but **pt. only wants right side;**

Probing and Irrigation (cont.)

- Day of surgery:
 - In preop area insured allows anesthesia to talk with patient; goes to complete other paper work; patient moved to OR
 - In OR patient being induced with GA
 - Circulating nurse to **tape “nonsurgical”** eye; nurse tapes **right** eye; dispute whether time out occurred
 - Surgery done on **left** (wrong) eye; discovered by postop nurse; pt. returned to surgery for correct procedure

Errors and remedies

ERRORS: In pre-op area, no verification of procedure, patient, site; In operating room, no time out (or poorly executed time out).

REMEDIES: *Universal Protocol Policy Change*

“All other activity should pause allowing all attention to be focused on the time out process”

(Case reviewed by State Medical Board)

Wrong Procedure: 2008 Incident

- Clinic: Patient seen for LASIK consultation; had prior RK OU; thin corneas; **insured recommends and patient consented for PRK;**
- Surgery center – merger creating new facility and new routines; patient setup and room layout different
 - Patient on bed when insured comes to treatment room; insured checks numbers with VISX machine
 - Scrub tech hands insured “suction ring for Intralase procedure” and performs initial stromal separation part of the procedure; insured realizes error and stops

Errors and remedies

ERRORS: In pre-op area, no verification of procedure; In operating room, no time out

REMEDIES: *Universal Protocol Policy Change*
Color coded LASIK vs. PRK

(Case reviewed by State Medical Board)

Wrong Eye: 2010 Incident

- 68 y.o. female patient; referred for possible retinal tear in **left** eye
- Seen in office by insured (retina specialist)
- Places 3 shots in **right** eye and notices mistake and successfully treats left eye
- Subsequently, pt. complaining of slight decrease of vision in **right** eye

Wrong Eye: Incident (cont.)

- Refers patient back to primary doctor for care; letter to primary care doctor regarding laser to wrong eye
- Patient requests records and notes no mention of laser to wrong eye; thinks doctor is “hiding something”; **wants insured to change/add to his records fact that wrong eye was lasered**

Errors and remedies

ERRORS: In-office procedures; tend be less careful regarding marking of eye; insured also failed to document in patient's chart (although did mention in letter to referring physician)

REMEDIES: Universal Protocol for the office?

- (Medical Board Risk: fines up to \$10,000)

*Surgical Confusions
in Ophthalmology*

John Simon, MD

Archives of Ophthalmology

November 2007, Volume 125 (No. 11)

Surgical Confusions

METHODS

42 closed cases (40%)

OMIC, 1982-2003

64 NYPORTS (60%)

NYSDOH, 2000-2005

Masked pts, institutions, surgeons

Surgical Confusions

67 (63%) Wrong Lens Implant

17 errors preoperative

A-scan not programmed

Transcription errors in office

Unlikely preventable with UP

46 errors intra-operative

Failure to check lens spec's

Labels, training, storage

Changed schedules, R/L confusions

Workload, distraction

Surgical Confusions

15 (14%) Wrong Eye

Inadequate site verification

Drape covered mark, tape moved

- 5 lacrimal drainage surgeries
- 3 cataract procedures: 2 halted
- 2 YAG capsulotomies
- 1 retinal detachment: halted
- 1 lid procedure: halted
- 1 corneal transplant

Surgical Confusions

14 (13%) Wrong Eye Blocks

Inadequate site verification

- Site marking, time-out not done
- Purple mark on pigmented skin
- Some errors made in office

Surgical Confusions

8 (8%) Wrong Patient/Procedure

Inadequate patient identification

- Clinic laser procedures
- Two similar names

Exotropia repair for pt w/ esotropia

Surgical Confusions

2 (2%) Wrong Transplant

Corneal transplants

- Incorrect tissue in refrigerator
- Inadequate verification

Surgical Confusions

Ophthalmology Like Other Specialties

Switched schedules, personnel

Communication

Pre-op verification, site marking, time out

- Must take seriously
- Watch drape, color, tape
- Checklist: simplifies

Surgical Confusions

Ophthalmology vs. Other Specialties

Wrong site, pt/procedure rare

Wrong implant common: 64%

- 70% of wrong equipment cases
- IOLs look alike and pts can't help

16/106 cases likely unpreventable w/ UP

- Need vigilance throughout process
- Need special care with implants

*SAMPLE
OMIC
CASES*

IOI miscalculation: 2009 Incident

- Pt. has RD surgery with silicone oil; w/out complication; develops cataract
- Then - referred for IOI calculation
- Next - Remove silicone oil, vitrectomy and lensectomy with IOI implantation
- Later - optometrist notes 9 diopter difference between right and left eye
- Finally – lens exchange with good results

Errors and remedies

ERROR: The IOL calculations were based on the faulty assumption that the silicone oil was not going to be removed.

REMEDIES: Careful communication between physicians

(Case reviewed by State Medical Board)

Wrong LASIK Settings: 2007 Lawsuit

- 6/14/07 – LASIK evaluation; VA 20/80 OD and 20/200 OS; moderately high astigmatism OS, and little astigmatism OD
- 6/25/70 – Bilateral simultaneous LASIK; blurred vision first post-op day
- Patient had -4 diopters of cylinder at 160 degrees and he was treated at 70 degrees ...90 degrees off axis doubling amount of astigmatism

Wrong LASIK Settings (cont.)

- Subsequent treatment : 2 additional LASIK surgical procedures and VA in left eye restored back to 20/20 uncorrected
- No note in medical record acknowledging error or discussion with patient regarding the problem.

Errors and remedies

ERRORS: surgical plan should have been visibly available to surgeon and team during procedure; failure to document error in chart

- Case settled with \$26,000 payment to patient

AAO Wrong Site Task Force

*Recommendations of American
Academy of Ophthalmology Wrong-
Site Task Force*

Published November 2008

(Please refer to handout material for Academy
recommendations)

Task Force Members

AAO – American Academy of Ophthalmology

AAPOS – American Association of Pediatric Ophthalmology and Strabismus

AGS – American Glaucoma Society

ABO – American Board of Ophthalmology

ASCRS – American Society of Cataract and Refractive Surgery

ASOPRS – American Society of Ophthalmic Plastic and Reconstructive Surgery

ASORN – American Society of Ophthalmic Registered Nurses

OMIC – Ophthalmic Mutual Insurance Company

OOSS – Outpatient Ophthalmic Surgery Society

AUS – American Uveitis Society

AUPO – Association of University Professors of Ophthalmology

RS – Retina Society

AAO Wrong Site Task Force

Goal: To develop recommendations that are designed to minimize the incidence of preventable surgical errors regarding surgical site(e.g. wrong eye) and surgical procedure(e.g. wrong intraocular lens implant).

Help surgeons evaluate their own systems.

Three Areas to Address

- 1) Steps Taken Prior To Surgery Day
- 2) Steps Taken On Day Of Surgery
- 3) Pre-Operative Calculation Procedures

Steps Prior To Surgery

The Order For Surgery:

- 1) Written Order In The Medical Record
- 2) As Specific As Possible
(e.g. procedure, eye, IOL, etc.)

Steps Prior To Surgery

Communication With Surgery Staff:

- 1) Information between the Clinic and Surgical O.R. should pass as seamlessly as possible.
- 2) Data between locations via Written Documentation rather than Verbal
- 3) EMR

Steps Day Of Surgery



Consent Process:

- 1) Patient Actively Involved
- 2) Procedure Defined
- 3) Written So Patient Can Understand
- 4) Proper Eye Clearly Notated On Form

Steps Day Of Surgery



Hard Stop:

- 1) Any Member of the Staff can halt the process of preparing the Patient for Surgery if an Inconsistency or Error is discovered.
- 2) No Staff Punishment for calling a Hard Stop

Specifics Points Re: Marking The Operative Eye



- 1) Follow the Guidelines of the Accreditation Bodies that apply to your specific Hospital Or ASC
- 2) If only one Eye is to have Surgery, it should be clearly marked before Surgery
- 3) Protocols designated by the Surgeon should define who can mark the Eye

Specific Points Re: Time-Out



- 1) Performed typically in the OR
- 2) Patient involved if possible
- 3) All Members of the Surgical Team should be engaged (Surgeon, Scrub Person, Circulating Nurse, and Anesthesia)

Specific Points Re: Time-Out

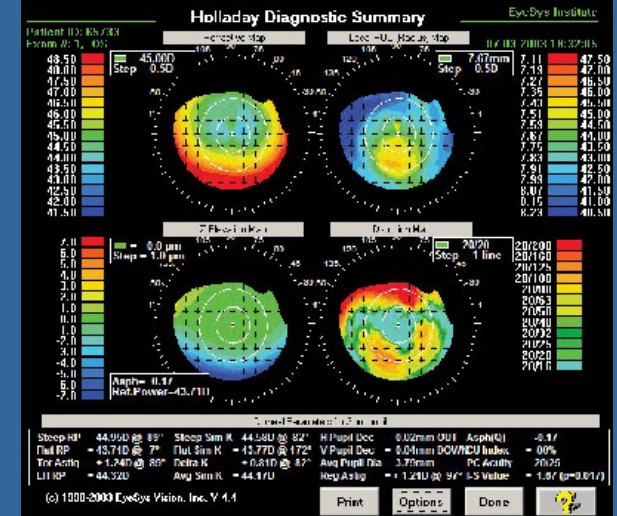


- 4) Any Discrepancies while performing the Time-Out should result in a Hard Stop
- 5) Typical Data Reviewed: Patient Name, Birthdate, Operative Eye(s), Procedure, IOL or Settings
- 6) Two Patient Identifiers

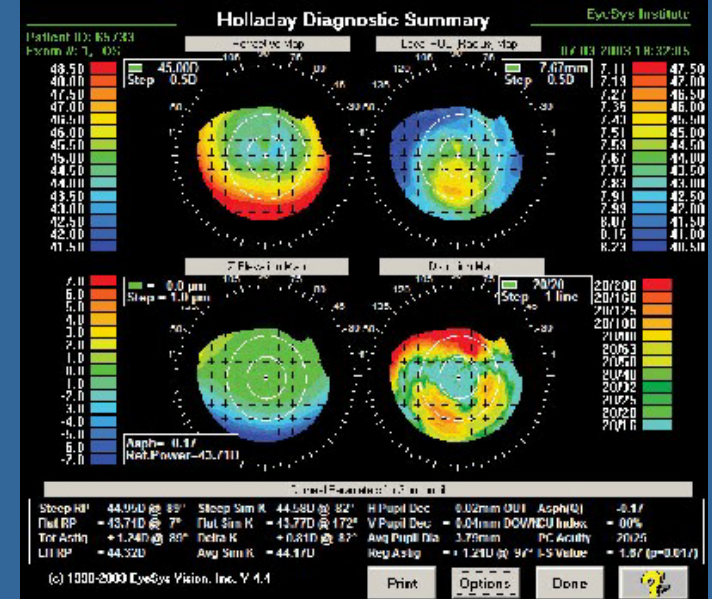
Specific Points Re: Pre-Operative Calculations

Intraocular Lens:

- 1) Lens Power Double-checked
- 2) IOL Calculations for Both Eyes
- 3) Surgical Order should designate the IOL Type and Power
- 4) Written Documentation available to the Surgeon in the OR



Specific Points Re: Pre-Operative Calculations



Keratorefractive Surgery:

- 1) Surgeon may include PO Refractive Target in Time-Out
- 2) Surgical Plan should be visually available for Surgeon and Team

Specific Points Re: Strabismus and Pre-Operative Calculations

- 1) Surgeon should consider having Written Documentation regarding Case available to view when scrubbed and gowned

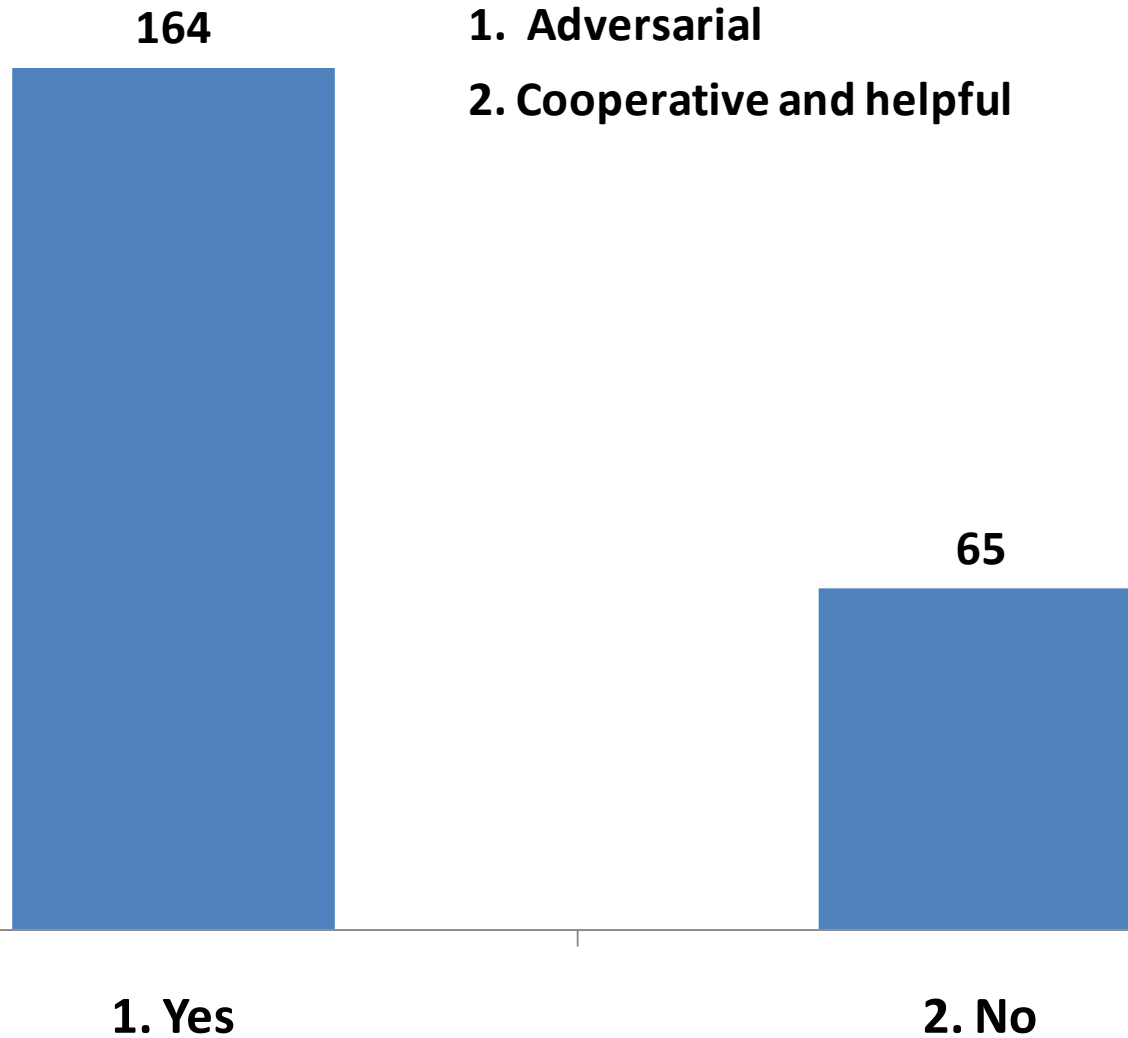
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*Audience Reponses
and
Faculty Overview*

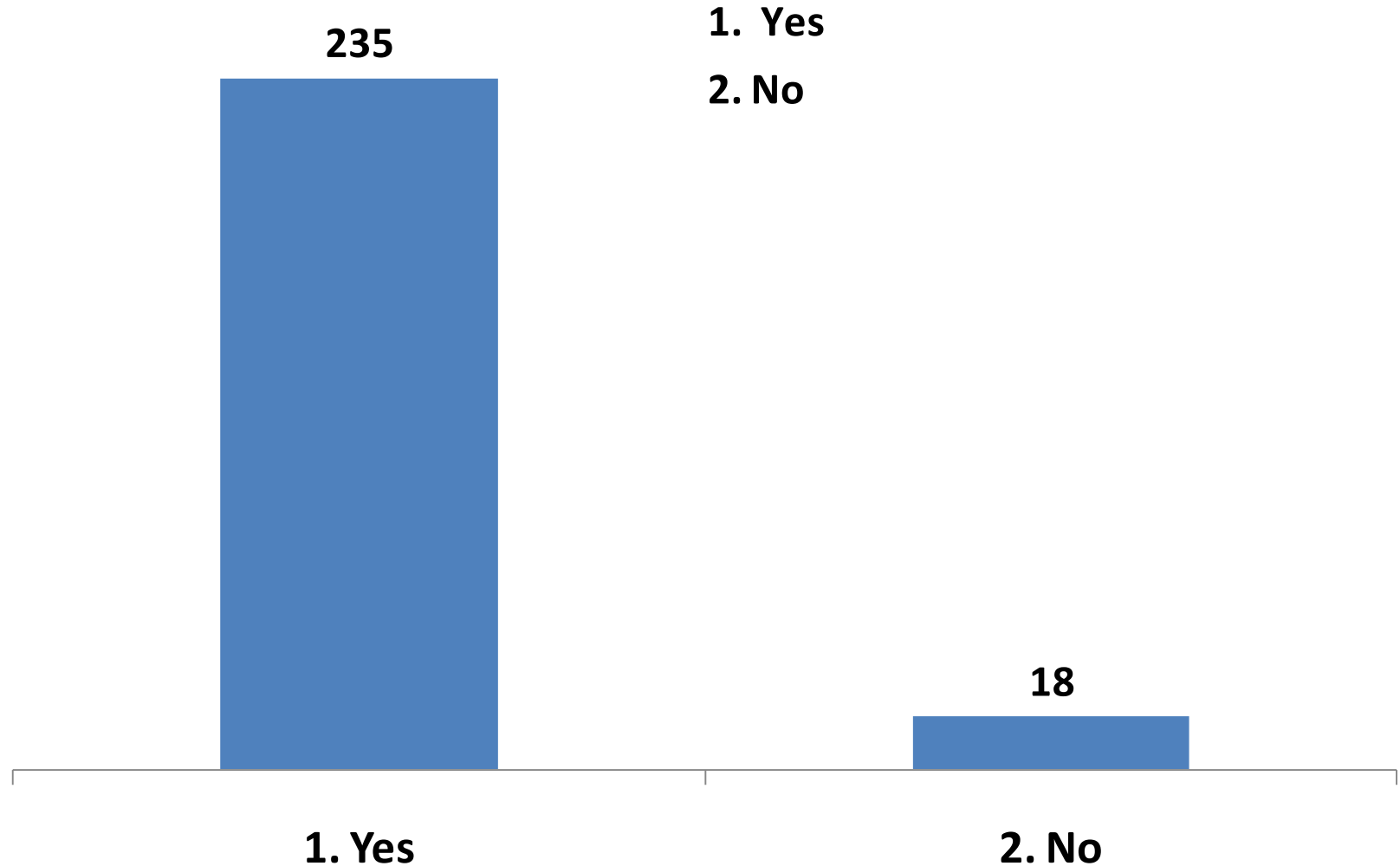
OMIC Forum 2008 Wrong Site Surgery

The State Medical Board is primarily :



OMIC Forum 2008 Wrong Site Surgery

Does the current approach by the medical boards discourage individuals from self reporting?



OMIC Forum –Faculty Overview

Culture of shame prevails in medicine:

- Stresses individual culpability
- Assumes incompetence, poor judgment
- Ignores systems errors
- Encourages secrecy
- Prevents analysis

OMIC Forum –Faculty Overview

How effective is culture of shame?

- Cases continue to be (under)reported
- Inconsistent use of recommendations
- Inconsistent thresholds, denominators
- Rarity makes statistical significance hard to see
 - Need a system that reports “near misses”

OMIC Forum –Faculty Overview



Need to move to “culture of safety”

- Assume human error, be proactive
- Create structures to reduce it
- Encourage honest, accurate reporting with a blame-free environment
 - Stow. AORN 84:406, 2006
- Legislation to protect voluntary reporting
 - IOM: To err is human. 1999

OMIC Forum –Faculty Overview



Culture of safety

- Must understand how problem occurred
- Root cause analysis
- Are conclusions used?

OMIC Forum –Faculty Overview



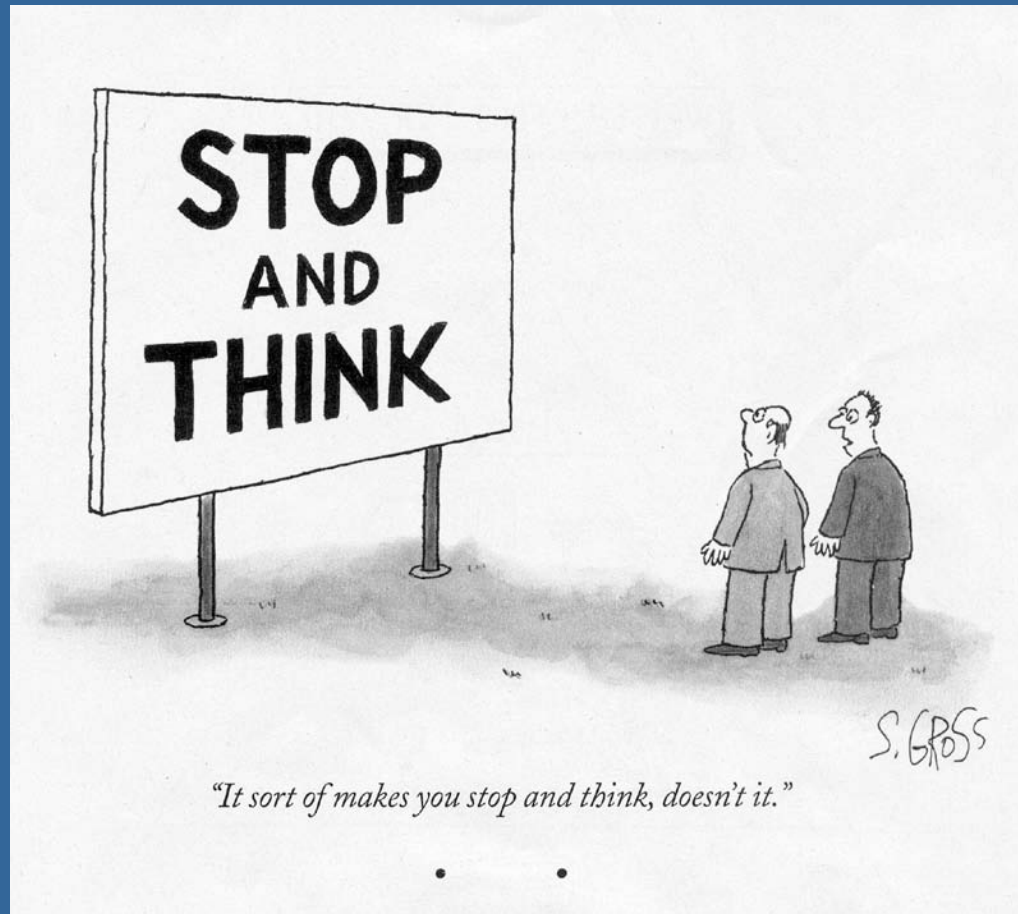
Enlightened Approach

If error: treat patient

Prompt, full, honest disclosure

- Explain what happened
- Acknowledge harm
- Take responsibility
- Show remorse
- Make amends: won't recur

What do you think?



next slide re discount

How to Get OMIC Risk Management Premium Discount

- In order to receive your OMIC risk management premium discount you must complete an online survey.
- Please use the link below to go to the survey.

[Link to survey http://tiny.cc/jdjg6](http://tiny.cc/jdjg6)