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Ophthalmic Risk Management Digest

OMIC DIGEST

Wrong Eye, Wrong IOL, Wrong Patient

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To err is human, but in medicine, errors can have life and death consequences. Nearly a decade after it was published, a 1999 headline from an Institute of Medicine report on medical errors is still quoted: "98,000 Americans Dead Every Year from Medical Errors." The IOM report, *To Err is Human, Building a Safer Health System*, shone the media spotlight on the problem of medical errors and raised awareness of the shortcomings of the American health care system. Less publicized was a 2000 follow-up article by PBS health correspondent Susan Dentzer in *Effective Clinical Practice* (vol. 3, no. 6, American College of Physicians). In her article, "Media Mistakes in Coverage of the Institute of Medicine's Error Report," Ms. Dentzer notes that "all too frequently, errors in health care were the result of systems problems rather than of individual acts of malfeasance. In other words, to err really is human; at the same time, health care, like any other system in which we operate, is devised by and composed of humans. As a result, like any system that aims to minimize or eliminate error, health care must be designed to compensate for our inevitable human shortcomings."

All ophthalmologists have heard horror stories of wrong sided, wrong patient, wrong procedure, or wrong IOL cases. Most of us probably haven't read the IOM report, but we are all aware of the need to reduce systemic errors in health care delivery and improve patient safety. The American Academy of Ophthalmology has made a strong commitment to this problem, and in 2001, published "Eliminating Wrong Site Surgery" and "Minimizing Wrong IOL Placement." Both documents were revised in 2005 and are on the AAO web site. In addition, two related patient safety documents may also be found on the AAO web site, "Suggestions for a Checklist to Verify the Operative Eye" and "Suggested Multiple IOL Verification Procedures in the Operating Room for Minimizing Wrong IOL Placement." These documents were first developed by the AAO's Quality of Care Secretariat in collaboration with the American Society of Ophthalmic Registered Nurses and American Association of Eye and Ear Hospitals and were revised in 2005.

continued on page 4

MESSAGE FROM THE CHAIRMAN

Wrong site/wrong IOL surgery errors continue to plague our profession despite a concerted effort by OMIC to educate insureds and others about the circumstances that lead to such errors and provide risk management recommendations to help prevent them. A recent retrospective study of 42 OMIC claims and 64 New York state cases by John W. Simon, MD, et al, published in *Archives of Ophthalmology* (vol. 125, no.11) addressed the effectiveness of the Universal Protocol as a prevention tool. According to the study, even if the protocol were perfectly implemented, 15% of errors would remain. Recent events in Florida, where ophthalmologists have incurred substantial fines and penalties imposed by the state medical board, and the persistence of wrong site/wrong IOL errors has galvanized OMIC and its sponsor, the American Academy of Ophthalmology, to examine what can be done to eliminate these errors.

First, the problem must be put in perspective. Wrong site and wrong IOL errors are very low in frequency, indicating that proper safeguard systems are currently in place and working fairly well. In our 21 years of existence, approximately 4,679 lawsuits, claims, and incidents have been

continued on page 2

IN THIS ISSUE

Wrong Eye, Wrong IOL, Wrong Patient

continued from page 1

Universal Protocol for Wrong Events

In 2003, the Academy and 50 other professional health care organizations endorsed the Joint Commission's "Universal Protocol for Preventing Wrong Site, Wrong Procedure, and Wrong Person Surgery."™ There are four principal components to the Universal Protocol:

1. Completing a preoperative verification process;
2. Marking the operative site;
3. Taking a time-out immediately before starting the procedure; and
4. Adapting these requirements to non-operating room settings.

Wrong sided cases continue to occur, however, despite the best efforts of the Academy, the Joint Commission, and others. Current data seems to indicate that wrong site surgery is stubbornly defying solutions to eradicate it. (See Joint Commission and OMIC data, Graphs 1 and 2.)

In 2007, the Joint Commission received 5 to 8 new reports a month of wrong site cases nationally, and recently, wrong site surgery became the most frequently reported sentinel event in the commission's database (nearly 550 events reported since 1996). (Go to www.jointcommission.org/PatientSafety/UniversalProtocol/up_facts.htm for details.)

The Joint Commission convened a Wrong Site Surgery Summit in 2007. The organizations represented at the summit, including the Academy, agreed that the Universal Protocol is effective if properly implemented and consistently followed. Ophthalmic data support this conclusion. John W. Simon, MD, et al, concluded in a study for the American Ophthalmological Society that the Universal Protocol would have prevented 85% of the wrong incidents he analyzed had it been implemented ("Surgical Confusions in Ophthalmology," *Arch Ophthalmol.* 2007; 125(11): 1515-22).

Florida Medical Board Imposes Sanctions Against Violators

State medical boards have also responded to the problem. In Florida, the Board of Medicine requires that:

1. A very detailed mandatory "time-out" needs to occur in all surgeries (surgery is defined as an incision or curettage of tissue) in all settings, including the physician's office; and
2. All licensed facilities and physicians in their own practice must report wrong site/wrong patient incidents.

Penalties for violating these wrong site regulations and/or the time-out rule include fines, community service, and compulsory CME.

Florida recorded 33 ophthalmic wrong sided incidents between 2002 and 2006. Half of these incidents were related to IOLs. Ninety-two percent of the doctors were fined, all had to pay the cost of the investigations, and all but one had to perform community service. Additionally, these disciplinary actions were reported to the National Practitioner Data Bank and to states where the physicians had inactive licenses. One ophthalmologist faced penalties and sanctions in a state in which he had not practiced since residency, 20 years prior to the incident.

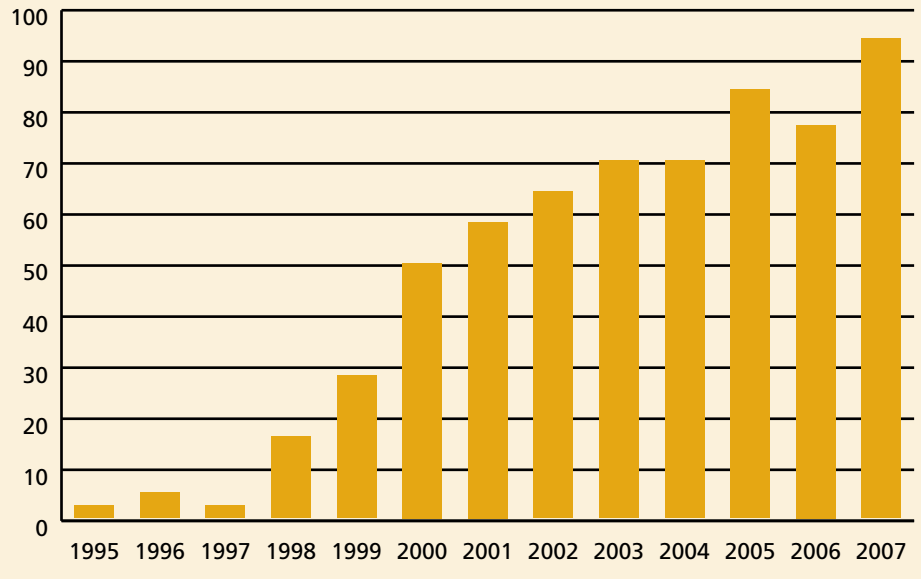
Earlier this year, the Florida Board of Medicine surveyed other states to find out what they're doing about the wrong sided IOL problem. None of the 10 states that responded (AL, ID, MD, NV, NM, NY, OK, TN, WV, and WY) has a separate state statute or medical board rule that addresses wrong site cases. Only New York tracks these incidents, and no New York ophthalmologist has been sanctioned for a wrong site case in the past 5 years.

Cataract Surgery, IOLs Involved in Most Wrong Cases

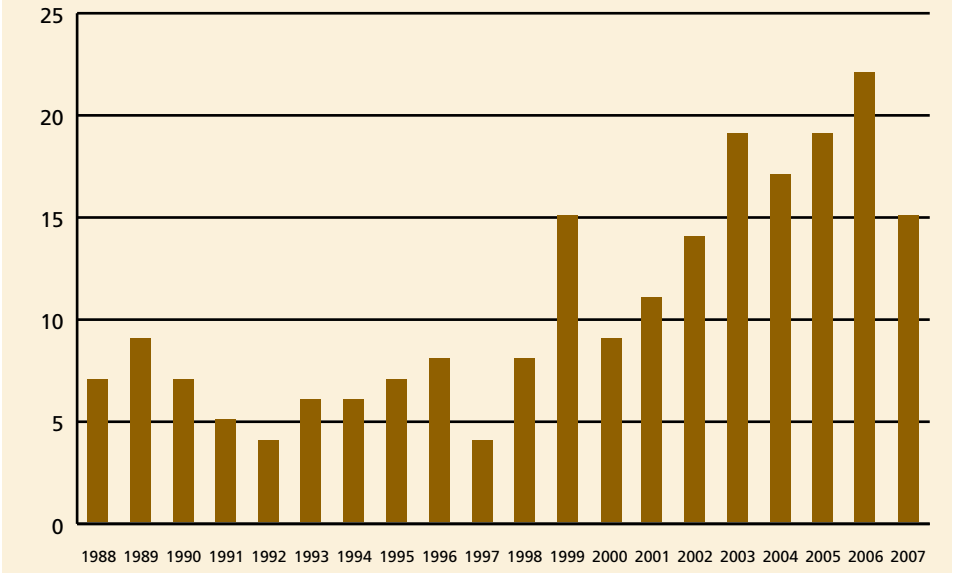
With cataract surgery by far the most commonly performed ophthalmic procedure in this country (1.8 million annually), it's not surprising that most wrong sided cases relate to cataract, and most involve problems with IOLs. Indeed, over 80% of wrong sided eye cases reported to OMIC over the course of 20 years have resulted from wrong IOL implantation, wrong power, or wrong measurement (see

GRAPH 1

INCIDENCE OF "WRONG" CASES REPORTED TO THE JOINT COMMISSION



GRAPH 2
INCIDENCE OF "WRONG" CASES REPORTED TO OMIC



Graph 3). In 1997, Dean Brick, MD, then chairman of OMIC's Risk Management Committee, found that 25% of cataract claims involved an IOL. He recommended the following loss prevention strategies, which remain relevant today:

- Employ one or two technicians who are well trained to perform keratometry and biometry.
- Review the scans and keratometry data when choosing the IOL.
- Use one or two styles of IOLs regularly to prevent confusion about constants or model numbers.
- Use a third generation formula for IOL selection.
- Keep a list of IOL choices for that day's patients on the side of the phaco machine and check it just prior to insertion.
- Use a checklist preoperatively to document data, informed consent, and any preop and postop instructions given to the patient.

Zero Tolerance by Joint Commission

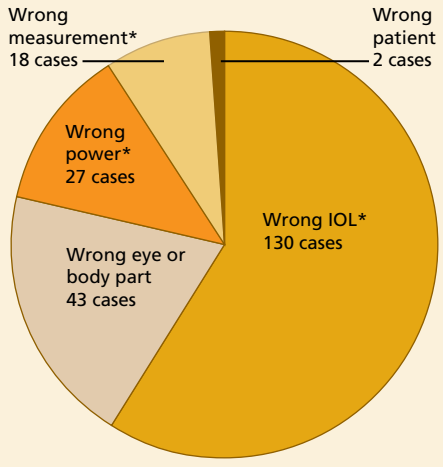
At this time, Florida appears to be the only state to strictly penalize wrong site cases. The state's position is in keeping with the following statement from the Joint Commission's 2007 Wrong Site Surgery Summit:

> "There should be 'zero tolerance' for failure to follow the Universal Protocol as a short term goal and there should be 'zero tolerance' for occurrence of these events."

In the move toward "zero tolerance," the Joint Commission is changing the Universal Protocol to provide more flexibility to hospitals, ASC's, and health care providers in its implementation. In addition, there will be more details on implementing the "who, what, when, and how" of the pre-procedure verification process, marking the procedure site, and the time-out. These guidelines are on the Joint Commission's web site at www.jointcommission.org/PatientSafety/UniversalProtocol.

OMIC participates in the AAO's drive to eliminate wrong site, wrong IOL, and wrong patient surgery. This year's OMIC Forum at the Annual Meeting in Atlanta will focus on these "never events." We will review OMIC's claims and lawsuits, discuss the faulty systems and processes that led to them, discuss state board actions, and review the Joint Commission's latest Universal Protocol. The panel will include James B. Sprague, MD, a member of OMIC's Risk Management Committee, and William J. Knauer III, MD, chairman of OMIC's Marketing Committee. Dr. Simon will discuss his findings and Peter Angood, MD, vice president and chief patient safety officer of the Joint Commission, will review the Universal Protocol. The OMIC Forum will be held Sunday, Nov. 9, at 1:00 pm in the Georgia World Congress Center. Preregistration is not required, but participants must complete an attendance form on-site to receive CME credit and an OMIC premium discount.

GRAPH 3
TYPE OF "WRONG" CASES REPORTED TO OMIC 1987–2008



* IOL-related cases = 80% of total