

OMIC DIGEST

Ophthalmic Risk Management Digest

Wrong Eye, Wrong IOL, Wrong Patient

By Paul Weber, JD
OMIC Vice President of Risk Management/Legal

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.

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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.

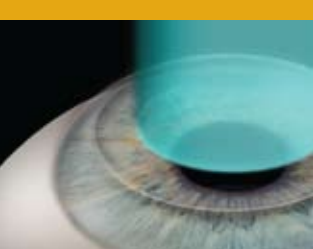
A recent retrospective study of 42 OMIC claims and 64 New York state cases by John W. Simon, MD, et al, published in *Archives of Ophthalmology* (vol. 125, no.11) addressed the effectiveness of the Universal Protocol as a prevention tool. According to the study, even if the protocol were perfectly implemented, 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

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Lipo-Dissolve No Longer Covered

In February 2008, the FDA issued the following (excerpted) statement regarding Lipo-Dissolve:

“The FDA is aware of the practice of using Lipo-Dissolve. Lipo-Dissolve is not FDA approved for any use... there are no FDA-approved drugs with an indication to dissolve fat. FDA cannot assure the safety and efficacy of these types of drugs. These are unapproved drugs for unapproved uses and FDA cannot guarantee consumers’ safety... The use of compounded drugs is not considered “off-label” use... FDA approval of a drug includes approved labeling for use, and means that the FDA has evaluated the safety and efficacy of a drug for a specific use and population. Once approved, a drug may be prescribed by a licensed physician for a use that, based on

the physician’s professional opinion, is appropriate...but it is expected that the physician is well-informed about the product and that the “off-label” use is based on sound scientific rationale and adequate medical advice...”

Numerous medical associations, including the American Society of Ophthalmic Plastic and Reconstructive Surgery, have issued warnings regarding injection lipolysis and cautioned their membership against performing such treatments. In addition, several states seek to ban or regulate Lipo-Dissolve procedures.

As a result of these developments, the Board of Directors has determined that OMIC will no longer extend coverage for any Lipo-Dissolve, mesotherapy, or similar procedure unless performed as part of an investigational drug trial under an American IRB-approved protocol.

Message from the Chairman

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reported to OMIC. Only about 220, or 5%, have been related to “wrong” events. Since 1997, the percentage of insureds who have reported a wrong site or wrong IOL matter to OMIC has stayed relatively constant at a median annual average of about 0.5%.

However infrequent, these types of errors have drawn the attention of the public and state and federal policymakers, resulting in fines and licensing sanctions against physicians and non-payment of services by Medicare and other payors. The AAO, OMIC, and other ophthalmic societies are taking a two-prong approach to the problem—education and prevention—via the Academy Practice Improvement Task Force and a three-year Academy Campaign to Eliminate Wrong Site/Wrong IOL Surgery.

The first charge of the Practice Improvement Task Force, a group of seven ophthalmologists representing the AAO, ABO, AUPO, and OMIC, is to develop an online CME activity that will allow ophthalmologists to compare their own practice to those that follow evidence-based performance measures and protocols proven to reduce errors. Simple-to-use checklists will help participants adopt the protocols in their own office.

Anonymous data collection of pre- and post-education practice activities will enable the task force to evaluate the effectiveness of the practice improvement activity on care outcomes.

The campaign to eradicate “Wrong Site Surgery and Wrong IOL Implantation” in the U.S. within three years is another cooperative group effort of ophthalmologists and is led by Gary S. Schwartz, MD. The group will review suggestions drawn from evidence-based medicine to help surgical teams evaluate and improve their own safety systems to eliminate all sources of wrong site or wrong IOL errors, whether operating in an office, hospital, or ambulatory surgery center.

At the state level, the Florida Society of Ophthalmology is working with OMIC and the Academy to educate FSO members on wrong site/wrong IOL surgery prevention. Florida is “ground zero” when it comes to the regulatory impact of system errors, and ophthalmologists in particular have borne the brunt of fines and licensure sanctions. The reason lies principally with the reporting requirements of ASCs and hospitals to the Florida medical board when a wrong site or wrong IOL error occurs in the operating room. The FSO is partnering with the Florida Board of Medicine to develop a statewide regulatory/disciplinary process to handle and correct the systems that produce such violations.

With the leadership and participation of so many prominent ophthalmic organizations, we hope to make the persistent problem of wrong site/wrong IOL a “never” event.

Joe R. McFarlane Jr., MD, JD
OMIC Chairman of the Board