

By Paul McGinn



## Endophthalmitis guidelines represent strong defence against lawsuits

*The new ESCRS guidelines for post-operative endophthalmitis represent an impressive shield against malpractice claims for European ophthalmic surgeons.*

The new "ESCRS Guidelines on Prevention, Investigation, and Management of Post-Operative Endophthalmitis," released at the XXIII Annual ESCRS Congress in Lisbon, draw on almost 200 studies, meta-analyses of studies, and book chapters about eye surgery and ocular infection. Four leading experts in endophthalmitis from Ireland, Germany, and the UK – Peter Barry, Wolfgang Behrens-Baumann, Uwe Pleyer, and David Seal – edited the guidelines with contributions from clinical ophthalmologists and researchers in nine more countries.

The legal importance of these first-ever European-wide standards for post-operative endophthalmitis prevention and treatment cannot be underestimated. For the first time, ophthalmologists who face lawsuits or complaints anywhere in Europe can measure their practice against written guidelines that specify, in a step-by-step fashion, the standard of care for preventing, investigating, and treating endophthalmitis.

Throughout its five chapters, the new guidelines go to great lengths to prevent confusion between poor practice and bad outcomes – for ophthalmologists, patients, lawyers, and judges alike.

For instance, the guidelines' introductory chapter not only defines and describes endophthalmitis but also – and very importantly for lawyers – includes the various incidence rates and risk factors for contracting endophthalmitis.

Given that the incidence of endophthalmitis varies significantly between countries and has been recorded as high as 0.5% in some countries, the guidelines underscore the fact that endophthalmitis is a real and expected – albeit unfortunate – complication of cataract surgery.

Against such statistics, a patient who develops endophthalmitis must prove not only that he was unfortunate but also that the treating ophthalmologist caused or contributed to that bad outcome. Endophthalmitis incidence rates are particularly important for cataract surgery because they remind lawyers and judges that even the world's most often practised surgical procedure is not risk-free even in the best hands.

### Guidelines help clarify best practice

Just how an ophthalmologist may cause or contribute to that bad outcome is often a

root allegation in a malpractice lawsuit. The guidelines go to great lengths to specify what practices are known to constitute risks and which practices are not known – at least for now – to constitute such risks for endophthalmitis. Such a discussion of risk factors may seem far removed from a malpractice suit, but in many cases, lawyers for patients often will allege that a patient would not have contracted endophthalmitis if the ophthalmologist had approached the cataract surgery differently.

One immediate issue that may come to the mind of a lawyer is whether the ophthalmologist sacrificed standards to meet health service costs. For instance, with health services increasingly putting pressure on ophthalmologists to perform more outpatient surgery, lawyers for patients who develop endophthalmitis may question whether the patient would have ever contracted the infection if he or she had been treated as an inpatient. On this point, the guidelines are very clear – and honest. "There are only a few data on the incidence of endophthalmitis between inpatient and out-patient surgery," the guidelines read. "Various studies give no evidence of any difference."

The introductory section of the guidelines also should alert ophthalmologists – and remind lawyers – that the standard for preventing endophthalmitis – like the standard for every segment of ophthalmology is always changing. And because the standard is changing, no court can apply an absolute standard against an ophthalmologist if the evidence for such a standard is inconclusive.

Of course, the guidelines note that standards can become conclusive with proper clinical research, such as the ongoing Prophylaxis for Endophthalmitis study directed by the ESCRS.

### Common sense caveats

Even before research discovers new ways to reduce further the rate of endophthalmitis, ophthalmologist must use the knowledge they have now to reduce that infection risk, according to the guidelines. Sometimes, that means just applying common sense. As the guidelines point out, infection can often be traced to the failure to wash – much less sterilise – instruments properly. "Care is required with both washing and autoclaving them as

the latter is never an absolute or an exact science!" the guidelines warn. "Both matters should be investigated if there is an ongoing 'epidemic' of post-operative endophthalmitis with different types of skin bacteria viz. coagulase-negative staphylococci within a surgical unit or for no obvious reason."

Other common sense standards of the guidelines include caveats that tubing should not be re-used and that bottles of balanced salt solution should never be kept or used for more than one operating session. Think of what a patient's lawyer would do if he or she found out that the operating ophthalmologist had re-used tubing from a previous patient or balanced salt solution from a previous day.

Of course, the guidelines highlight the role of antiseptics and antibacterials in preventing endophthalmitis in the first place. In particular, the guidelines note that povidone-iodine solution is the preoperative treatment of choice and recommends the solution should be allowed to act for a minimum of three minutes before commencing surgery to ensure that the solution penetrates the skin's sebaceous glands. The guidelines also note that chlorhexidine is an appropriate substitute if the patient is allergic to povidone-iodine.

### Diagnosis and treatment

The guidelines do not stop with standards for preventing endophthalmitis. That should be reassuring for ophthalmologist who may be sued because most endophthalmitis lawsuits not only focus on the failure to prevent the infection. Many lawsuits also focus on the ophthalmologist's failure to recognise and treat the endophthalmitis quickly enough to reduce the effect of the infection.

In particular, the guidelines note that the initial diagnosis of acute endophthalmitis may begin within the first 24 hours of surgery or even as late as a fortnight after the surgery, with such symptoms as ocular pain, reduced vision, hypopyon, red eye and even eyelid swelling.

The guidelines also leave no room for doubt after the diagnosis of acute bacterial endophthalmitis. "The diagnosis of acute bacterial endophthalmitis is a medical emergency requiring an immediate vitreal tap and installation of intra-vitreous antibiotics and corticosteroid," the guidelines state. There is no doubt about



what "immediate" means in such cases, according to the guidelines. Immediate means within one hour of diagnosis.

Think of the lawyer who finds out that the treating ophthalmologist may have delayed the vitreal tap for a few hours or even a day.

The guidelines are clear that while surgery is the obvious ultimate treatment, the standard of care expected of the treating ophthalmologist depends on his own expertise. Some ophthalmologists – who are also vitreo-retinal surgeons – will be able to perform the "gold standard of care" and perform a three port pars plana vitrectomy within a few hours of the diagnosis and reduce the risk that the endophthalmitis will ultimately lead to blindness – and potential lawsuit.

The guidelines also note that a more practical "silver" standard of care for treating endophthalmitis – which could be enough to defend an ophthalmologist against a malpractice lawsuit – may rely on the vitreous biopsy and intra-vitreous injection of antibiotics while the cataract surgeon awaits the arrival of a vitreo-retinal surgeon.

The guidelines also include specific – and common sense – recommendations about using antibiotics in treating endophthalmitis. Those recommendations include:

- Never return diluted drugs to the same vial;
- Never dilute at greater than one to ten;
- Do not re-use syringes or bottles;
- Avoid the use of drugs with preservatives;
- Inject antibiotics slowly.

Against such recommendations, think of the patient's expert or lawyer who discovers that the treating ophthalmologist returned diluted drugs to the same vial or who over-diluted the antibiotic. Also, think of the patient's expert or lawyer who learned that the treating ophthalmologist used the same

## Defending bad outcomes difficult without clear, written standards

As ophthalmologists well know, bad cataract surgery outcomes are not usually caused by negligence or even poor practice. However, defending bad outcomes is rarely easy. In such cases, judges see blind patients and can sympathise with their disability.

By contrast, the potentially blameless ophthalmologists who operated on those now-blind patients may often have little tangible evidence to prove that what they did was correct and that the bad outcomes were no one's fault.

Without a written, objective standard to explain the cataract surgeon's method – such as the “ESCRS Guidelines on Prevention, Investigation, and Management of Post-Operative Endophthalmitis” – a judge deciding a malpractice lawsuit is faced with a dilemma. The judge often must decipher complicated evidence about what – and who – caused the endophthalmitis.

In those European courts where both sides have an expert, a judge can often be confused by such conflict. For instance, the patient's expert ophthalmologist will tell the judge that the treating ophthalmologist's care fell below the acceptable standard expected in such an

operation and that such sub-standard care caused or contributed to the endophthalmitis and resulting blindness. By contrast, the ophthalmologist's expert will tell the judge that the endophthalmitis occurred despite the ophthalmologist doing everything possible to prevent it.

Even in those countries where a judge relies on the evidence of its own expert, written guidelines will surely provide assistance to that expert to focus the court's attention on whether the ophthalmologist followed the standard of care – not on whether the patient contracted endophthalmitis.

In addition, the guidelines will help ophthalmologists in countries with no fault compensation systems. In those countries, ophthalmologists may not be sued, but they surely may be blamed by their patients and their families for the endophthalmitis. With such guidelines, the treating ophthalmologist can explain to the patient and family members that the endophthalmitis occurred despite the ophthalmologist doing everything possible not only to prevent the endophthalmitis but also to diagnose and treat it promptly.

syringe and bottle over and over again or who used antibiotics with preservatives or who injected such antibiotics too quickly.

The guidelines also remind cataract surgeons that anti-inflammatory therapy with corticosteroids is crucial because “not only the microbes but also their interplay with the immune mechanisms are important in the outcome of endophthalmitis.”

In all, these guidelines not only will help cataract surgeons make better choices in preventing, diagnosing and treating post-operative endophthalmitis but also help Europe's courts in assessing malpractice claims more accurately – and more fairly – when patients with bad outcomes sue. And for that, Europe's cataract surgeons, lawyers, judges, and patients owe the editors and contributors to these guidelines a debt of gratitude.

*To receive a copy of the guidelines, email [escrs@escrs.org](mailto:escrs@escrs.org)*

## ESCRS endophthalmitis prophylaxis study will update legal standard for endophthalmitis

The ESCRS is hoping to answer some of the leading questions about risk factors for post-operative endophthalmitis following completion of its multi-centre study of antibiotic prophylaxis for endophthalmitis in 2006. In so doing, the society will help inform – and influence – European courts that adjudicate malpractice cases against cataract surgeons.

The randomised controlled trial compares the incidence of endophthalmitis following phacoemulsification and IOL implantation with or without intensive topical levofloxacin and with or without intracameral cefuroxime. As the “ESCRS Guidelines on Prevention, Investigation, and Management of Post-Operative Endophthalmitis” point out, that study hopes to additionally identify a number of potential risk factors for post-cataract endophthalmitis, including:

- Clear cornea incision;
- Type of wound closure;
- Method of inserting the IOL;
- Type of IOL material;
- Whether the patient is a diabetic;
- Whether the patient's immunity is compromised;
- Whether the equipment used is disposable or reusable;
- The quality of the operating theatre air;
- Experience of the surgeon;
- Length of operation;
- Complications from cataract surgery.

As soon as more information is available from the ESCRS study about such potential risk factors, ophthalmologists will be able to modify the way they operate. If they cannot modify their practice to meet such new standards, they will be able to re-write their patient consent forms to reflect the different risks that may be associated with the type of cataract surgery that the ophthalmologist has planned.

Armed with a different approach to surgery and a consent form that warns the patients about what could go wrong despite their best efforts – ophthalmologists will have yet another shield to defend themselves against a bad outcome and possible lawsuit.