

Risk Management Hotline



Sterilization Breakdowns in Endophthalmitis/TASS

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The malpractice case featured in this issue's lead article stemmed from a series of breakdowns in the facility's sterilization process. When notified of the problem, the physician consulted with the ASC's medical director and together they decided not to alarm the patient until they knew the facts. By not warning the patient of the symptoms to watch for, they arguably missed an opportunity to diagnose the problem earlier.

Q Should I tell my patient of potential problems with sterilization?

A Yes for several reasons. Patients have a need and a right to know about their own condition and can help monitor the development of symptoms. Such disclosure of adverse events is best understood as a continuation of the informed consent process begun before the surgery. Moreover, communicating with the patient sympathetically and non-defensively within the shortest appropriate time period may help dispel much of the anger, confusion, and distrust that complications may engender, while preventing allegations of fraudulent concealment that could extend the statute of limitations or allow for punitive damages. Stick to the currently known facts, avoiding speculation or blame. As more information becomes available, share it with the patient and document it in the medical record.

Q How should I proceed if I suspect a cluster of endophthalmitis or TASS cases?

A You will need to coordinate with the facility, your staff, and your patients in order to respond effectively. All patients operated on that day need to be notified of the events, screened for symptoms, and educated about when and why to contact you. The facility needs to sequester all involved materials, interview staff, and evaluate equipment, devices, solutions, medications, and the sterilization process. The investigation will help locate the responsible organism or toxic agent, ascertain liability, and determine what steps to take to remedy any identified problems.

Q What specific information do I need to collect for the investigation?

A Nick Mamalis, MD, of the Intermountain Ocular Research Center at the University of Utah has developed an Excel-based protocol that can be used for individual or clustered cases of infectious or sterile endophthalmitis. Detailed information about each patient's pre- and postoperative course, the facility, equipment, supplies, medication preparation, and sterilization technique are compiled, entered into the spreadsheet, and sent to the center for review. Research fellows are available for on-site evaluations, and charge only airfare and nominal expenses. In response to more than 80 TASS cases nationwide, the AAO and ASCRS announced in May 2006 that an ad hoc committee chaired by Dr. Mamalis had been established to help determine the causes. Ophthalmologists with TASS cases are urged to complete two short questionnaires about the products involved during cataract surgery and the actual process of cleaning and preparing instruments and patients for surgery and forward them to Dr. Mamalis. The protocols and questionnaires are available on the OMIC web site, via email at nick.mamalis@hsc.utah.edu, or by calling (801) 581-6586.

Q What measures can I and the ASC take to prevent TASS?

A While it can be very difficult to pinpoint the cause of TASS, pH, preservatives, and cleaning solutions are often implicated. Dr. Mamalis suggests a whole team approach to the ordering, cleaning, sterilizing, and preparation of all instruments, viscoelastic, medications, and irrigation solutions to ensure proper pH, osmolality, and non-toxicity. Avoid re-use, especially of cannulas and damaged instruments. Rinse I/A tips and phaco hand pieces at the conclusion of each cleaning step with sterile, deionized water through both ports. Replace ultrasound water baths daily. Change the steam autoclave sterilizer at least weekly. Take care with wound construction and avoid ophthalmic ointment and patches with clear corneal incisions.¹

Q Does the OMIC endophthalmitis claims study identify specific ways that physicians can minimize their liability?

A Yes. Treat preexisting blepharitis. Screen for and stabilize medical conditions, such as immunosuppression or uncontrolled diabetes, that could adversely impact the patient's healing process. Use povidone iodine to prepare the eyelid, carefully construct the wound, and check for leakage. Base your choice of antibiotic prophylaxis on current peer-reviewed recommendations. Provide written discharge instructions on wound care, signs and symptoms to report, and contact information. Carefully screen complaints from postoperative patients and evaluate the need to personally examine the patient. Following possible breaks in sterilization or clusters, consider examining or talking to the patient daily until infection/TASS has been ruled out or effectively treated.

1. Mamalis, Nick et al. "Review/Update: Toxic Anterior Segment Syndrome." *J Cataract Refract Surg* Vol 32, February 2006:324-333.