

Multisociety OICS Task Force issues recommendations on reducing topical drug waste in ophthalmic surgery

by David F. Chang, MD

References

1. Chang DF, Mamalis N, Ophthalmic Instrument Cleaning and Sterilization Task Force. Guidelines for the cleaning and sterilization of intraocular surgical instruments. *J Cataract Refract Surg.* 2018;44:765-773.
2. Chang DF, Thiel CL, Ophthalmic Instrument Cleaning and Sterilization Task Force. Survey of cataract surgeons' and nurses' attitudes toward operating room waste. *J Cataract Refract Surg.* 2020;46:933-940.
3. Theil CL, et al. Differences in reuse of cataract surgical supplies and pharmaceuticals based on type of surgical facility. *J Cataract Refract Surg.* 2022. Online ahead of print.
4. Tauber J, et al. Quantification of the cost and potential environmental effects of unused pharmaceutical products in cataract surgery. *JAMA Ophthalmol.* 2019;137:1156-1163.
5. Chambers WA. Waste no more. *Ophthalmology.* 2021;128:1667-1668.
6. American Society of Ophthalmic Registered Nurses. Recommended practice for registered nurses: use of multi-dose medications. Accessed March 11, 2022. asorn.org/professional-resources/policies-and-recommendations/asorn-recommended-practice-use-of-multi-dose-medications/.

The Ophthalmic Instrument Cleaning & Sterilization (OICS) Task Force is comprised of representatives from the American Society of Cataract and Refractive Surgery (ASCRS), the American Academy of Ophthalmology (AAO), the American Glaucoma Society (AGS), and the Outpatient Ophthalmic Surgery Society (OOSS), and previously developed ophthalmology-specific guidelines for surgical instrument processing and sterilization.¹ Co-chaired by Cathleen McCabe, MD, and myself, the Task Force is also focused on reducing operating room waste, which significantly increases the cost and carbon footprint of ophthalmic surgery.

In a 2020 survey by the OICS Task Force, 93% of ophthalmologists thought that operating room waste was excessive.² Almost all (98%) were using or were willing to consider using multidose bottles of topical medication for multiple cataract patients. However, less than half were using multidose bottles for topical anesthetic (43%), mydriatics (48%), NSAIDs (38%), and antibiotics (45%). In a subsequent sub-analysis, those using multidose bottles on multiple patients were much more likely to be operating in ambulatory surgery centers (ASCs) than in hospital outpatient departments (52% vs. 19% using multidose mydriatic drops).³ A separate survey of OOSS member ASCs was conducted by the OICS Task Force in 2021. Most ASCs were using multidose bottles on multiple patients, but only 12% said they continued utilizing them until the labeled expiration date; others were discarding the bottles at the end of the day (9%), the week (3%), or the month (72%).

These two surveys revealed wide variation in whether multidose bottles are reused on multiple surgical patients, and if so, for how long. This is important because surgical drugs account for a significant proportion of cataract surgery's cost and carbon footprint. A 2019 study analyzed the economic and environmental impact of medication waste at four cataract surgical facilities.⁴ Based on their analysis, the researchers

Documenting the policies of multiple regulatory and accreditation agencies, this evidence-based paper clarifies that multidose bottles can be used on multiple patients and need not be arbitrarily discarded at the end of the day, the week, or the month.

projected that drug waste costs approximately \$150 per case and generated 23,000 to 105,000 metric tons of unnecessary CO₂ equivalent emissions annually in the U.S.

An OICS subcommittee led by David Palmer, MD, and Alan Robin, MD, researched the regulations regarding multidose bottles by contacting multiple agencies, including The Joint Commission, the Accreditation Association for Ambulatory Health Care, the American Association for Accreditation of Ambulatory Surgery Facilities, the Centers for Disease Control and Prevention, the U.S. Food and Drug Administration (FDA), and the Centers for Medicaid & Medicare Services (CMS). Following discussions with the Task Force, Wiley Chambers, MD, director of the FDA Office of Specialty Medicine, Division of Ophthalmology, wrote a supportive editorial on reducing drug waste.⁵ These agencies were consistent in permitting surgical facilities to use topical drugs in multidose containers on multiple patients until the manufacturer's labeled date of expiration, assuming that proper guidelines are followed. The OICS Task Force specifically asked CMS to

Contact

Chang: dceye@earthlink.net

continued on page 34 ➔

Mitosol® (mitomycin for solution) 0.2 mg/vial Kit for Ophthalmic Use\ Rx only

BRIEF SUMMARY: Please consult package insert for full prescribing information

INDICATIONS AND USAGE: Mitosol® is an antimetabolite indicated for use as an adjunct to ab externo glaucoma surgery.

CONTRAINDICATIONS: Hypersensitivity: Mitosol® is contraindicated in patients that have demonstrated a hypersensitivity to mitomycin in the past.

WARNINGS AND PRECAUTIONS: Cell Death: Mitomycin is cytotoxic. Use of mitomycin in concentrations higher than 0.2 mg/mL or use for longer than 2 minutes may lead to unintended corneal and/or scleral damage including thinning or perforation. Direct contact with the corneal endothelium will result in cell death. **Hypotony:** The use of mitomycin has been associated with an increased incidence of post-operative hypotony. **Cataract Formation:** Use in phakic patients has been correlated to a higher incidence of lenticular change and cataract formation.

EMBRYO FETAL TOXICITY: Can cause fetal harm. Advise of potential risk to a fetus. Verify pregnancy status in females of reproductive potential prior to use.

ADVERSE REACTIONS: Ophthalmic Adverse Reactions: Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice. The most frequent adverse reactions to Mitosol® occur locally, as an extension of the pharmacological activity of the drug. These reactions include: **Blebitis:** bleb ulceration, chronic bleb leak, encapsulated/cystic bleb, bleb-related infection, wound dehiscence, conjunctival necrosis, thin-walled bleb; **Cornea:** corneal endothelial damage, epithelial defect, anterior synechiae, superficial punctuate keratitis, Descemet's detachment, induced astigmatism; Endophthalmitis; **Hypotony:** choroidal reactions (choroidal detachment, choroidal effusion, serous choroidal detachment, suprachoroidal hemorrhage, hypotony maculopathy, presence of suprachoroidal fluid, hypochogenic suprachoroidal effusion); **Inflammation:** iritis, fibrin reaction; Lens: cataract development, cataract progression, capsular opacification, capsular constriction and/or capsulotomy rupture, posterior synechiae; Retina: retinal pigment epithelial tear, retinal detachment (serous and rhegmatogenous); **Scleritis:** wound dehiscence; **Vascular:** hyphema, central retinal vein occlusion, hemiretinal vein occlusion, retinal hemorrhage, vitreal hemorrhage and blood clot, subconjunctival hemorrhage, disk hemorrhage; **Additional Reactions:** macular edema, sclera thinning or ulceration, intraocular lens capture, disk swelling, malignant glaucoma, lacrimal drainage system obstruction, ciliary block, corneal vascularization, visual acuity decrease, cystic conjunctival degeneration, upper eyelid retraction, dislocated implants, severe loss of vision.

USE IN SPECIFIC POPULATIONS: Pregnancy: Risk Summary: Based on findings in animals and mechanism of action, Mitosol® can cause fetal harm when administered to a pregnant woman. There are no available data on Mitosol® use in pregnant women to inform the drug-associated risk. In animal reproduction studies, parenteral administration of mitomycin resulted in teratogenicity. Advise pregnant women of the potential risk to a fetus. The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% - 4% and 15% - 20%, respectively. Data: Animal Data-Parenteral administration of mitomycin in animal reproduction studies produced fetal malformations and embryofetal lethality. **Lactation:** Risk Summary: There are no data on the presence of mitomycin in human milk, the effects on the breastfed child, or the effects on milk production. Because of the potential for serious adverse reactions in a breastfed child, advise women not to breastfeed during and for 1 week following administration of Mitosol®.

FEMALES AND MALES OF REPRODUCTIVE POTENTIAL:

Mitosol® can cause fetal harm when administered to pregnant women. **Pregnancy Testing:** Verify pregnancy status in females of reproductive potential prior to using Mitosol®. **Pediatric Use:** Safety and effectiveness in pediatric patients have not been established. **Geriatric Use:** No overall differences in safety and effectiveness have been observed between elderly and younger patients.

More detailed information is available upon request.

For information about Mitosol® contact:
1-877-EYE-MITO (1-877-393-6486)



Please also see full Prescribing Information at [Mitosol.com](https://www.mobius-therapeutics.com)

MANUFACTURED FOR:
Mobius Therapeutics, LLC
1000 Executive Parkway
Suite 224, St. Louis MO 63141 USA
(314) 615-6930

Mitosol® is a registered trademark of Mobius Therapeutics, LLC

continued from page 32

clarify to its surveyors that multidose eye drop bottles are not subject to the 28-day expiration policy that applies to injectable solutions. As part of their collaboration with our Task Force, the American Society of Ophthalmic Registered Nurses (ASORN) published an updated multidose eye drop application protocol on its website.⁶

Dr. Palmer previously led efforts to enact legislation in Illinois to enable surgical patients to bring partially used topical medication home for postoperative use, when appropriate. In 2021, the American Medical Association House of Delegates unanimously adopted a modification of the Illinois resolution titled “Permitting the Dispensing of Stock Medications for Post-Discharge Use and the Safe Use of Multidose Eyedrops on Multiple patients,” which had been endorsed by multiple specialty societies, including AAO, ASCRS, AGS, and ASORN.

The OICS Task Force distilled its research into a position statement with three recommendations to reduce unnecessary drug waste with ophthalmic surgery (see box). Endorsed by ASCRS, AAO, AGS, and OOSS, this document was released on April 6, and was posted on each society’s website and on EyeSustain.org. Documenting the policies of multiple regulatory and accreditation agencies, this evidence-based paper clarifies that multidose bottles can be used on multiple patients and need not be arbitrarily discarded at the end of the day, the week, or the month. The paper also stated the Task Force consensus that surgical patients requiring a topical medication not used for other patients should be allowed to bring that partially used medication home for postoperative use. 📍

Recommendations endorsed by ASCRS, AAO, AGS, and OOSS

1. Topical drugs in multidose containers can be used on multiple patients in surgical facilities if proper guidelines are followed.
2. Topical drugs in multidose containers can be used until the manufacturer’s labeled date of expiration if proper guidelines are followed.
3. When applicable, patients should be able to bring their partially used medication home for postoperative use.