REVIEW/UPDATE

# Reducing topical drug waste in ophthalmic surgery: multisociety position paper

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This position article on reducing topical drug waste with ophthalmic surgery was written by the Ophthalmic Instrument Cleaning and Sterilization Task Force, comprising representatives of the ASCRS, American Academy of Ophthalmology, American Glaucoma Society, and Outpatient Ophthalmic Surgery Society. Drug waste significantly increases the costs and carbon footprint of ophthalmic surgery. Surgical facilities should be permitted to use topical drugs in multidose containers on multiple patients until the manufacturer's labeled date of expiration, if proper guidelines are followed. Surgical patients requiring a topical medication not used for other patients should be allowed to bring that partially used medication home for postoperative use. These recommendations are based on published evidence and clarification of policies from multiple regulatory and accrediting agencies with jurisdiction over surgical facilities. Surveys suggest that most ambulatory surgery centers and hospitals performing cataract surgery are wasting topical drugs unnecessarily.

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Unnecessary waste of perioperative topical ophthalmic medications (eyedrops and eye ointments) significantly increases the cost and carbon footprint of ophthalmic surgery and the risk for periodic drug shortages. This document, endorsed by the ASCRS, American Academy of Ophthalmology (AAO), American Glaucoma Society (AGS), and Outpatient Ophthalmic Surgery Society (OOSS), establishes recommendations to reduce costly and unnecessary wastage of topical medications.

## BACKGROUND

Beyond the rising economic burden of our healthcare system, there is increasing awareness of its disproportionately large carbon footprint and environmental effect.[1–4] The healthcare sector generates approximately 9% of total greenhouse gas emissions in the United States and is the second largest source of landfill trash.[3,4] Operating rooms (ORs) contribute up to 30% of a hospital's waste.[4] Cataract surgery is one of the most common surgical procedures in medicine, with a large projected increase in global volume. This gives ophthalmology a unique opportunity, and it is imperative to prioritize the financial and environmental sustainability of quality eyecare delivery.[5]

A British study reported that 1 phacoemulsification (contemporary cataract surgery) in the United Kingdom generated the same carbon emissions (approximately 130 kg $CO_2$eq) as driving a car for 500 km (310 miles).[6] The procurement sector was the major source of $CO_2$ emissions with supply chains for medical equipment and pharmaceuticals accounting for 33% and 18% of this sector, respectively.[6] By comparison, phacoemulsification at the Aravind hospital system in India was found to generate the same carbon emissions (approximately 6 kg $CO_2$eq) as driving a car for 23 km (14 miles).[7,8] The largest difference was attributed to reuse of most surgical supplies and pharmaceuticals at the Aravind hospital system. Despite this, their endophthalmitis rate for phacoemulsification was only 0.01% in more than 335 000 consecutive cases, which is lower than the rate (0.04%) reported by the American Academy of Ophthalmology IRIS Registry (Intelligent Research in Sight).[9,10]

Prescription drugs account for approximately 10% of healthcare costs in the U.S. A 2019 study analyzed the economic and environmental effect of topical, injectable, and systemic medication waste at 4 centers performing cataract surgery.[11] Nearly half of all drugs (and two-thirds of topical drugs) were discarded after a single usage across all 4 sites for up to an estimated $195 000 wasted annually per site on unused medication. Discarded topical eyedrops and ointments from unused or partially used containers accounted for an approximate cost of $150 per case. The authors estimated that this drug wastage generated 23 000 to 105 000

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metric tons of unnecessary $CO_2$eq emissions annually in the U.S. Aside from cost and environmental considerations, needless waste also increases the potential for and effect of periodic drug shortages.

The Ophthalmic Instrument Cleaning and Sterilization (OICS) task force, comprising specialists representing the ASCRS, AAO, AGS, and OOSS, has previously published ophthalmology-specific guidelines for surgical instrument processing and sterilization.[12] One focus of this multisociety task force is the reduction of unnecessary waste in ophthalmic surgery. An OICS task force survey in 2020 of more than 1300 cataract surgeons and nurses found that 93% said they believed OR waste is excessive and should be reduced, 91% were concerned about climate change, and 78% felt that we should seek ways to safely reuse supplies and instruments.[13] There was strong consensus that regulatory policies and manufacturer's printed instructions for use, which prohibit reuse of many potentially multiuse products and medications, are major contributors to excessive waste.

This statement provides 3 recommendations regarding the safe and responsible use of perioperative topical medications. These consensus recommendations are based on a review of published studies and discussions with multiple regulatory and accrediting organizations in the U.S. and have been endorsed by the 4 eyecare specialty societies that this task force represents.

## RECOMMENDATION 1

### Topical Drugs in Multidose Containers Can be Used on Multiple Patients in Surgical Facilities if Proper Guidelines are Followed

In 1964, the U.S. Food and Drug Administration (FDA) finalized regulations allowing topical drugs to be packaged in multidose containers containing antimicrobial preservatives and labeled with an expiration date.[14] Two large studies performed at the University of Utah established that proper reuse of eye medication bottles on multiple patients did not contribute to increased rates of endophthalmitis.[15,16] In 2015, the ASCRS released a position statement supporting the established practice of utilizing multidose eyedrops on multiple patients, when proper protocols are followed. A 2021 study evaluated bottle tip contamination when multiuse ophthalmic solutions were instilled in more than 1800 patients prior to eye surgery.[17] When proper guidelines were followed, there was no bottle tip or solution contamination detected by videographic and microbiological analyses.

Ninety-eight percentage of ophthalmologist respondents to the OICS task force OR waste survey said they were willing to consider or were already using eyedrops from multidose bottles on multiple perioperative patients.[13] Nearly half of all respondents were already using topical mydriatics (48%), antibiotics (45%), nonsteroidal anti-inflammatory drugs (38%), anesthetics (43%), and intraocular pressure-lowering medications (42%) on multiple patients from multidose containers. These surgeons reusing multidose bottles were more likely to be operating at ambulatory surgery centers (ASCs) than at hospital outpatient departments ($P < .0001$).[18] In 2021, the OOSS surveyed its member ASCs regarding their use of perioperative topical medications (unpublished): 98% were using multidose bottles of topical medications on multiple perioperative patients. When directly queried, none of the 119 responding facilities reported ever having a case of endophthalmitis attributed to this practice. Taken together, these 2 surveys suggest that many surgeons who are not reusing multidose bottles are practicing at hospital outpatient departments.

However, some surgical facilities require (or have been directed by regulatory agencies to require) that multiuse bottles of eyedrops be discarded after use on a single patient. For example, the Utah Valley Regional Medical Center (Provo, UT) and the Surgical Eye Center of Morgantown (Morgantown, WV) were initially directed during their accreditation processes by The Joint Commission (TJC) auditors to not reuse multiuse bottles of topical medication after instillation on a single patient. Following appeals, both organizations received approval from TJC and/or the West Virginia Office of Health Facility and Licensure Certification[19] to resume reusing multidose topical bottles according to safe handling and administration guidelines established by the AAO.[19,20]

This task force contacted the Ambulatory Association for Ambulatory Health Care accreditation organization in 2021 regarding this recommendation. The Ambulatory Association for Ambulatory Health Care, through its public relations firm (L.C. Williams and Associates, Chicago, IL), wrote that its standards allow multidose eyedrops, provided that the medication is labeled, handled per CDC guidelines, and administered and stored according to policies, manufacturer instructions, and best practice recommendations. Staff must understand safe practice and apply infection control techniques.

## RECOMMENDATION 2

### Topical Drugs in Multidose Containers Can be Used Until The Manufacturer's Labeled Date of Expiration if Proper Guidelines are Followed

In the 2021 OOSS survey regarding ASC policies, multidose topical eyedrop bottles that were not empty were discarded either at the end of the day (9%), the week (3%), or the month (72%) by most responding ASCs (unpublished). Only 12% continued using the bottle until the medication's labeled date of expiration. Multidose topical medication bottles contain antimicrobial preservatives that ensure sterility with proper use up until the stated expiration date as per the manufacturer's package insert. This task force contacted the FDA, TJC, the CDC, and the American Association for Accreditation of Ambulatory Surgery Facilities for clarification regarding the duration that multidose topical formulations could be used at surgical facilities.

In a 2021 editorial, Wiley Chambers, MD, director of the FDA Office of Specialty Medicine, Division of Ophthalmology, wrote as follows: "Products not labeled as single-dose or single-use ophthalmic products are not intended to be limited in use to a single patient. When stored as labeled, products can be expected to be used safely after opening until the expiration date included on the bottle. The location of the use of an ophthalmic drug

product does not influence the expiration date except where the location may alter the storage temperature of the bottle. Neither TJC nor the USP (United States Pharmacopeia) has requirements to use ophthalmic drug products within 28 days. Each historically has discussed 28-day limitations for systemically injected products, but neither has ever included, nor has meant to include ophthalmic products in those discussions. Direct communication with TJC has confirmed that no 28-day limitation for ophthalmic products by TJC exists."[21]

In a 2021 communication with our task force, TJC's Robert Campbell, PharmD, BCSCP, clinical director for the Standards Interpretation Group and Director of Medication Management, wrote that the 28-day expiration dating used for multidose injectable medications does not apply to topical agents such as ophthalmic drops/ointments. The manufacturer's package insert provides expiration dates for the particular product. Ilana Wolf, RN, of The American Association for Accreditation of Ambulatory Surgery Facilities replied by email, "When using multi-dose eyedrops in a surgical facility, it is acceptable for expiration dates to follow the manufacturer's recommendations if multi-dose eyedrops are labeled, handled per CDC guidelines, and administered and stored according to policies, manufacturer instructions, and best practice recommendations. These facilities must monitor and perform surveillance of the administration of multi-dose eyedrops as part of their infection control program. Facility staff must be trained and have ongoing competencies documented specific to multi-dose eyedrops." Subsequent communication with the CDC confirmed that its guidelines are similar.[22]

Confusion over policies established by the Centers for Medicare & Medicaid Services (CMS) may contribute to inconsistent practices and regulatory rulings on this issue. The 2015 CMS Center for Clinical Standards and Quality/Survey and Certification Group State Operations Provider Certification Manual and Surveyor Infection Control Worksheet specifically references a maximum 28-day expiration date for infusible and injectable medications.[23] The absence of specific regulations for when multidose eyedrop bottles must be discarded seems to have caused some surveyors to apply the 28-day expiration policy for injectables to topical eye medications. Our direct communication with the CMS Survey and Certification Group has confirmed (see above) that the policy for injectable medications does not apply to multidose eyedrop bottles.

Microbial contamination of the bottle tip could result from contact with the nurse's fingers or the patient's ocular surface or adnexa. Facility staff must be trained in proper eyedrop installation technique. Multidose bottles whose tips become contaminated should be immediately discarded. After discussions with our task force, the American Society of Ophthalmic Registered Nurses has published a multidose eyedrop application protocol on its website.[24] This protocol adheres to the CDC infection control guidelines and indicates that eyedrops may be used until the manufacturer expiration date or facility end use date with proper storage and administration technique.

## RECOMMENDATION 3

### When Applicable, Patients Should be Able to Bring Their Partially Used Medication Home for Postoperative Use

Some surgical patients require specific topical medications not used for other patients. If that drug needs to be continued postoperatively, it is wasteful and unnecessarily burdensome to discard the newly opened multiuse bottle and instead require the patient to purchase the same medication through an outpatient pharmacy. This approach may be facility specific or the result of state-specific pharmacy dispensing regulations. These state rules may require surgical facilities to label topical medication bottles with instructions and provide medication counseling for patients to take a bottle home for continued care.

In the 2020 OICS task force OR waste survey, 26% of ophthalmologists currently send topical pharmaceuticals administered in the OR to home with patients; 67% would be willing to consider this and only 4% were unwilling to do this.[13] In a 2019 Illinois Society of Eye Physicians and Surgeons survey, only 40% of responding ophthalmologists indicated that medications ordered at the surgical facility could be taken home by the patient postoperatively.[25] Reasons preventing this practice included facility regulations (49%), state regulations (23%), medications being discarded (38%), and pharmacy constraints. The latter included inability to print labels (28%), insufficient pharmacy staffing (23%), and logistical obstacles to patient counseling by pharmacists (36%). Patient barriers to repurchasing these same drugs from an outpatient pharmacy included transportation and support issues (69%) and financial barriers (90%). Forty-two percentage of surgeons felt that the inability to provide medications directly from the facility would adversely affect quality of care, including an increased risk for infection or intraocular inflammation.

Because there is a wide regional variation in pharmaceutical dispensing regulations, obstacles to this recommendation may need to be addressed at the state level. What has been accomplished in Illinois may guide and serve as an example to others. The Chicago and Illinois State Medical Societies introduced a resolution to the Illinois General Assembly in 2020, entitled "Topical Operating Room or Emergency Room Medications for Post discharge Patient Use." Illinois SB579 was signed into a law in 2021 as PA 102-0155, with support from other surgical subspecialty societies including the Illinois Society of Plastic Surgeons, The Chicago Laryngological and Otological Society, the Illinois Dermatological Society, and the Illinois College of Emergency Room Physicians.[26–28] This legislation stipulates that topical medications ordered at least 24 hours preoperatively and used in the OR must be properly labeled before the unused portion can be given to patients for postdischarge care. Physicians provide medication counseling after surgery.[27] 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 the AAO, ASCRS, AGS, and American Society of Ophthalmic Registered Nurses.[29]

We recommend reducing regulatory obstacles to the safe and well-accepted practice of allowing patients to take a multidose bottle of topical medication home for continued use after it was opened and administered to them at the surgical facility. The AAO has established a Topical Medical Waste Reduction Act link to a legislative template based on the Illinois law to assist ophthalmologists and other interested individuals to develop legislative efforts in their states.[30]

## CONCLUSION

These 3 recommendations address ways to reduce topical drug waste while keeping patient safety paramount. There is consensus within ophthalmology that excessive surgical drug waste unnecessarily increases the cost and carbon footprint of eye surgery, particularly given the high volume of procedures such as cataract surgery. With increases in surgical volume anticipated, waste is neither economically nor environmentally sustainable and could make periodic drug shortages more likely and the effect more severe.

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As of June 6, 2022, the position paper has been formally endorsed by each of the 50 American state ophthalmology societies.

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