Tackling the challenge of needless surgical waste in ophthalmology



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In a survey of North American cataract surgeons conducted by the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force and published in 2020, 93% felt that operating room (OR) waste was excessive and should be reduced.¹ In this issue, a new ESCRS survey shows a similar consensus within Europe (Chang et al., page 341).² This begs the question: if more than 1500 ophthalmic surgeons from 2 major continents are nearly unanimous in this opinion, why do we continue to waste so much and how can we surmount this problem? Can a root cause analysis of this complex predicament suggest strategies to pursue?

A Need for Education

Changing long-established behavior and practices requires us to understand the importance and urgency of doing so. In these 2 surveys of ophthalmologists' attitudes toward OR waste, 43% of North American and 32% of European cataract surgeons said that they were completely unaware of the environmental impact of the healthcare system and of surgical waste.^{1,2} A 2019 report from Health Care Without Harm estimated that the healthcare sector is responsible for 4.4% of all global greenhouse gas emissions; 71% of these emissions come from the manufacture, use, and disposal of healthcare supplies.³ If the global healthcare sector was a country, it would be the fifth largest emitter in the world.⁴ The healthcare system accounts for nearly 10% of greenhouse gas emissions in the United States, where it is the second largest contributor to landfills after the food industry.^{5,6} ORs account for a major share of the total emissions and waste from the healthcare sector.

Amid the pandemic of the century, the World Health Organization declared in 2021 that climate change is the single biggest health threat facing humanity.⁸ Poorer countries and communities will disproportionately bear the burden of poor air quality and food and water shortages.⁹ Climate change also compromises eye health.¹⁰ According to the International Agency for the Prevention of Blindness (IAPB), the climate crisis will disrupt eyecare delivery and inequitably increase many eye diseases, such as blinding infections, in the most vulnerable populations.¹¹ Although ophthalmologists are specialists, we are also physicians who should be concerned and alarmed by these forecasts. In 2021, the National Academy of Medicine launched the Action Collaborative on Decarbonizing the U.S. Health Care Sector.¹² That same year, IAPB declared a climate emergency and called on our profession to take action.¹¹ Because our specialty has the highest procedural volumes, ophthalmology has a compelling opportunity and obligation to lead efforts within medicine to make our essential services more sustainable.¹³ Simple and immediate steps to reduce waste, such as eliminating infrequently used custom-pack items or recycling paper and plastic packaging, might be implemented if more ophthalmologists and nurses understood the detrimental impact of healthcare's contribution to greenhouse gas emissions.^{7,14}

Infection Control Guidelines: Recommendations or Requirements?

Organizations that accredit and license surgical facilities are charged with safeguarding patients from healthcareassociated complications and infections. Universal OR infection control recommendations are typically developed by guidelines committees within organizations such as the Centers for Disease Control and Prevention (CDC) or the Association of Perioperative Registered Nurses (AORN) in the United States. Many scientifically proven recommendations should be mandatory requirements. Others, based on the opinions of experts without peer-reviewed studies, might better serve as guidance or suggestions. Regulatory and licensing bodies, however, may decide to mandate and enforce these recommendations that are more eminence than evidence based. In 2015, AORN recommended wearing bouffant head covers and long-sleeved surgical jackets in the OR, and The Joint Commission subsequently began enforcing these AORN recommendations as compulsory requirements. However, a study of more than 34000 inpatient surgeries at the University of Alabama found that these regulations, which cost more than \$300,000 annually to comply with, did not lower the rate of surgical site infection.¹⁵ Expert opinions are subject to bias, and in this

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case, the assumption of greater safety was contradicted by the evidence.

Another issue is that universal infection control guidelines are applied to all surgeries by default. However, it stands to reason that some measures (eg, many environmental infection control guidelines) required for orthopedic or thoracic surgery would be unnecessary for ophthalmic procedures, which are relatively clean. In the United States, compulsory guidelines to prevent airborne microbial cross-contamination include disinfecting the OR countertops between cataract surgeries and discarding multi-dose vials of injectable drugs after a single use in the OR. However, multiple studies prompted by the COVID-19 pandemic concluded that the risk for crosscontamination from aerosolized pathogens during phacoemulsification is exceedingly remote.¹⁶⁻²¹ This underscores the need for more research to ascertain which universal infection control policies do or do not lower the endophthalmitis risk.

The widely accepted use of short-cycle instrument sterilizers for cataract surgery is another example of why we need infection control guidelines that are specific to ophthalmology. In 2014, the Centers for Medicare and Medicaid Services (CMS) ruled that immediate use steam sterilization, the replacement term for flash sterilization, was not acceptable for routine surgical instrument sterilization.²² In response, the OICS task force, comprised of representatives from ASCRS, the American Academy of Ophthalmology (AAO), and the Outpatient Ophthalmic Surgery Society (OOSS), was established to develop specialty-specific guidelines for the cleaning and sterilization of ophthalmic surgical instruments.²³ A study conducted by the task force determined that shortcycle instrument sterilization and unwrapped settings were appropriate for sequential same-day ophthalmic cases when performed in compliance with U.S. Food and Drug (FDA)-approved sterilizers.²⁴ As a result of discussions with the OICS task force, the CMS continues to allow short-cycle sterilization for ophthalmic instruments.²⁵ Because tissue contamination of cataract surgical instruments is usually insignificant, the guidelines also discouraged routine use of enzymatic cleaners because of the unique risk for toxic anterior segment syndrome posed by introducing microscopic detergent residue into the anterior chamber.²³

Surgical Manufacturing Industry

Most ophthalmologists want manufacturers to offer more reusable options for surgical supplies, drugs, devices, and instruments.^{1,2} Most are also willing to reuse single-use ophthalmic devices reprocessed by third parties, although this is rarely an option at present. Survey respondents most frequently cited profit motive and liability protection as factors driving the surgical manufacturing industry toward single-use products. Another commonly cited problem was the lack of environmental considerations in product design and packaging. The largest surgical manufacturers in ophthalmology have heeded these concerns and committed

to reducing product emissions and waste. Some are targeting carbon neutrality across their global operations. Governmental directives, such as the European Union (EU) taxonomy regulations, are accelerating corporate prioritization of environmental goals. On the other hand, onerous and costly regulatory approval processes often impede the ability of manufacturers to mitigate carbon emissions through improved surgical product design and packaging. For example, simply reducing the amount of plastic packaging may require a manufacturer to revalidate the safety and efficacy of the medical device following this change. Meanwhile, the new EU Medical Device Regulation (MDR) policy has introduced stricter requirements and is forcing manufacturers to recertify many previously approved devices. Increasingly stringent certification requirements may hamper or imperil responsible corporate efforts to decrease surgical waste and emissions.

Regulatory Enforcement of Device Manufacturers' Instructions for Use

Regulatory agencies, such as the EU MDR and the FDA, require manufacturers of medical instruments and devices to provide detailed instructions on how to clean, disinfect, and/or sterilize these items. These instructions for use (IFU) also specify whether an item can be reprocessed and reused. These recommendations are not always based on scientific evidence. Because manufacturers may be required to revalidate the safety and efficacy of a product that has been reprocessed, it is generally much easier to obtain commercial approval for a single-use indication. Specifying single use may also reduce product liability. As an example, some companies label their titanium phacoemulsification tips single use, whereas others allow multiple uses. In a study performed at the Moran Eye Center (Salt Lake City, Utah), we could not identify any significant ultrastructural differences between brand new tips and single-use tips that were used multiple times in a testing model.²⁶ This is consistent with the absence of any clinical evidence that reusing phacoemulsification tips is unsafe.

The 2009 U.S. Recovery Act funded increased ambulatory surgery center (ASC) oversight and inspections by the CMS. That same year, the CMS issued a new set of ASC Conditions for Coverage, including many compulsory infection control measures.²⁷ CMS surveyors were instructed to "Determine whether the ASC re-uses devices marketed for single use, and if so, does it send them to an FDA-approved vendor for reprocessing?" The new guidelines specified that only devices approved by the FDA for reprocessing could be reused and that this must be done by an FDA-approved reprocessor. These changes effectively eliminated any physician or facility discretion to reuse any products labeled single use.

Most cataract surgeons want device and supply manufacturers to allow more discretion to reuse products in their IFU.^{1,2} Without specifying single use, manufacturers could limit their liability with a disclaimer that the safety of reprocessing and reusing the product has not been established. Regulatory agencies should not require or mandate



Figure 1. Manufacturers' Instructions for Use pamphlets printed in multiple languages are an example of waste. On right, the instructions for a monofocal IOL; on left, instructions for the IOL cartridge.

single use unless deemed necessary by the manufacturer. By strictly enforcing every single-use label, the CMS puts the onus on manufacturers to validate reprocessing through the FDA and precludes physicians from using their judgment while considering other scientific evidence, such as the phacoemulsification tip study. Affording surgical facilities greater discretion regarding device reuse within their instrument processing policies and procedures would significantly reduce unnecessary waste.

Another unnecessary and wasteful practice is the inclusion of printed IFU with every device (Figure 1). Despite standardized usage, virtually every IOL, ophthalmic viscosurgical device, and medication package contains a printed IFU in multiple languages. The size of the intraocular lens (IOL) box is often determined by the size of the paper IFU booklet. What prevents companies from providing this same information digitally, such as with a QR code that could be scanned by any mobile device even during a power outage? Incredibly, there are more than 60 countries that currently do not accept eIFU for medical devices. Many are smaller low- to middle-income countries, but the list also includes South Africa, Russia, and China. For globally marketed products, providing eIFU might therefore require 2 production lines to package a product, both with and without a paper IFU.

Liability

Because endophthalmitis is a potentially blinding complication, medicolegal concerns undoubtedly influence decision-making in ophthalmic ORs. As mentioned, liability also affects whether manufacturers allow reuse in their IFU, even if there is no evidence that reprocessing the device several times is unsafe. It has been estimated that defensive medicine costs approximately \$46 billion annually in the United States.²⁸ To that we must add the incalculable environmental impact of unnecessarily discarding most products after a single use. Although physician surveys are not scientific, they are relevant to considerations of what practices violate community standards. For example, in the 2 OR waste surveys, 48% of Europeans and 32% of North Americans were reusing intraocular antibiotic solutions on multiple patients; another 39% and 63%, respectively, were not but were willing to consider reuse.^{1,2}

What Should We Do?

Ophthalmologists must collectively implore the surgical manufacturing industry to provide us with more reusable products and devices. In the 2 OR waste surveys, 8 to 10 times as many surgeons would prefer a reusable over a disposable instrument of equal cost.^{1,2} Research and development should be directed toward more environmentally friendly product design and packaging. For example, pairing preloaded IOL cartridges with reusable injectors would generate less plastic waste than current single-use, preloaded IOL insertion systems. Professional societies should advocate for reducing regulatory obstacles that either dissuade or impede manufacturers' efforts to reduce the environmental impact of their products. Regulatory agencies such as the EU MDR and the U.S. FDA should both encourage and ease the requirements for validating reprocessing of devices.

An immediate and meaningful reduction in unnecessary medical waste would result if regulatory agencies stopped enforcing every manufacturer's single-use recommendation as a compulsory requirement, unless disallowing reuse was based on well-established evidence. Commensurate with off-label prescribing, surgeons should have reasonable discretion to reuse appropriate products under the auspices of their surgical facility's policies and procedures. It is an irrational regulatory paradox to permit off-label intraocular injection of a topical antibiotic solution and intrascleral haptic fixation of an IOL but prohibit reusing a phacoemulsification tip. Nor should every CDC or AORN infection control recommendation be enforced as a mandatory requirement, especially considering the wide variation in procedure types. Prior to 2009, ASCs in the United States were given much greater latitude to responsibly develop infection control policies that were appropriate for their individual setting and mix of procedures.

As was done with the OICS task force instrument processing guidelines, ophthalmic societies should collaborate to develop evidence-based, specialty-specific infection control guidelines for ophthalmic surgery where appropriate.²³ Without these, universal across-theboard guidelines that are unnecessary or inappropriate for ophthalmic surgery may be enforced by default.²⁵ In

2022, the ASCRS, AAO, OOSS, and the American Glaucoma Society released a multisociety position paper on reducing unnecessary topical drug waste at surgical facilities.²⁹ The OICS task force researched the relevant literature and the policies of multiple regulatory and accreditation agencies in the United States. The resulting position paper recommended that multidose bottles of topical drugs could be used on multiple ophthalmic surgical patients until the expiration date. Furthermore, the OICS Task Force convinced the CMS to clarify for its surveyors that, unlike injectable medications, multidose eyedrop bottles do not need to be discarded after 28 days; if not contaminated, they can be used until the date of expiration.³⁰

In both the North American and European OR waste surveys, most respondents wanted their medical societies to advocate for more sustainable delivery of eyecare.^{1,2} EyeSustain was created to fulfill that aspiration and to centralize resources and information on sustainability for our entire profession. With both a website (www.eyesustain.org) and an app, EyeSustain is a global coalition of ophthalmic societies and their members, who are committed to advancing the sustainability of eyecare through research, education, advocacy, and collaboration with industry and with other medical specialties. EyeSustain has prioritized reducing unnecessary surgical waste because of its considerable economic and environmental impact and the increased risk for supply chain shortages. The AAO has recently joined ASCRS and ESCRS as cosponsors of EyeSustain. Numerous other global organizations have joined EyeSustain as member societies, including the American Society of Retina Specialists and EURETINA (European Society of Retina Specialists), who have agreed to codevelop a section on sustainability in retinal care. Every member society has pledged to incorporate sustainability into its educational programs, to establish a committee on sustainability, and to designate representatives to a global EyeSustain council that will share and disseminate new information, publications, position papers, and innovative ideas across an international network.

What can ophthalmologists and surgical facilities do right now? The EyeSustain website offers several recommendations, which individual surgical facilities can formally pledge to pursue. In addition to using multidose bottles for topical drugs, centers should consider eliminating the whole-body drape and not changing patients into hospital gowns for ophthalmic surgery. Regularly reviewing custom surgical packs may identify infrequently used items to eliminate. Reusable instrument or device options, such as diamond blade keratomes, should be considered. Recycling strategies should be implemented where feasible.¹⁴ In one large ophthalmic center, switching from water-based to alcohol-based hand scrub for surgical prep was calculated to save more than 61 000 L of water and more than \$280,000 annually per operating room.³¹ Finally, staff education and appointing a nurse and/or physician sustainability officer can motivate a team approach to safely reducing unnecessary waste.⁷ Small initial steps can make an immediate impact and spur greater progress in the future.

Evidence and Opportunity

A reason for optimism is that we already have a compelling waste reduction blueprint to guide our research and advocacy efforts. In a special issue on planetary health published by the Royal College of Surgeons of England, we wrote about frugal innovation for global surgery.³² The premise was that low- to middle-income countries can teach us about more efficient and sustainable use of resources. Without the luxury of allowing needless waste, low-resource healthcare settings, such as India's Aravind Eye Care System (AECS), have long optimized valuebased care out of necessity.

To provide 60% of its services and surgery to an indigent population, every AECS hospital routinely reuses surgical gowns, gloves, irrigation bottles, phaco cassettes and irrigation-aspiration tubing, cannulas, metal blades, and both topical and intraocular drugs.³³ They do not change patients into hospital gowns and simultaneously prepare and operate on multiple patients within the same OR. As a result, the carbon emissions generated by one phacoemulsification at AECS is approximately 1/20 of that generated by one phacoemulsification in the United Kingdom.³⁴ Because each of these practices (other than topical drug reuse) is a forbidden infection control violation in the United States, one would expect their postoperative endophthalmitis (POE) rate to be much higher than ours. In fact, it is not. Using their electronic data registry, we reported that the POE rate in 2 million consecutive cataract surgeries at AECS from 2011 to 2018 was 0.04%.³⁵ Half of this population did not receive intracameral (IC) antibiotics. The AAO Intelligent Research in Sight (IRIS) registry reported an identical 0.04% POE rate in 8.5 million consecutive cataract surgeries during an overlapping period from 2013 to 2017.³⁶ Approximately half of American surgeons would have been using IC antibiotics in 2014.37 Routine IC moxifloxacin prophylaxis further lowered the POE rate at AECS to 0.01% in 335000 consecutive phacoemulsification procedures.³⁵

Big data analytics allow us to compare the rate of rare complications associated with different policies and practices. In a subsequent study, we found no improvement in the POE rate at AECS after they temporarily adopted new infection control measures on resuming surgery following the national COVID-19 moratorium on elective eye surgery in 2020.³⁸ The new measures enacted to prevent viral cross-contamination were changing patients into hospital gowns, operating on one patient at a time in the OR, changing gloves after every case, and cleaning OR counters and floors between patients. This and the other studies of potential COVID-19 transmission during phacoemulsi-fication provide persuasive evidence that cataract surgery is a relatively clean procedure with a low risk for microbial cross-contamination.^{16–21} This would explain why strict

enforcement of compulsory bans on reusing most ophthalmic surgical supplies and devices failed to produce a measurable benefit, while generating massive amounts of waste.^{35,36} These registry studies do not scientifically establish that reusing ophthalmic surgical products is always safe and should be routinely adopted. However, these data challenge and contradict the extremely costly assumption that rigorously enforcing single-use mandates and proscribing physician discretion is making ophthalmic surgery safer.

The U.S. Department of Health and Human Services, the federal agency that oversees the CMS, recently proclaimed its commitment to protecting those most vulnerable to illness caused by climate change.³⁹ This noble mission should prompt a willingness by the CMS to reconsider numerous mandated infection control policies that, without proven benefit, unnecessarily increase carbon emissions. With finite resources, global policy-makers must prioritize value-based medicine to maximally enhance public health. Instead, excessive and onerous regulations continue to escalate needless resource waste to unsustainable and detrimental levels worldwide. Due to their staggering economic and environmental impact, overzealous and unproven infection control practices and regulations in ophthalmic surgery will ultimately do more harm than good to the overall health of our society.

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