SPECIAL REPORT

Reducing ophthalmic surgical waste through electronic instructions for use: a multisociety position paper

Emily M. Schehlein, MD, John Hovanesian, MD, Aakriti Garg Shukla, MD, Audrey Talley Rostov, MD, Oliver Findl, MD, MBA, FEBO, David F. Chang, MD

Every ophthalmic surgical supply, including intraocular lenses (IOLs), IOL cartridges, and ophthalmic viscosurgical device syringes, is packaged with instructions for use (IFU). These pamphlets are printed in multiple languages and, in the case of an IOL, significantly increase the size and weight of the packaging. To eliminate this significant and unnecessary source of waste, we recommend that manufacturers move to Quick Response codes that link to online electronic IFU (e-IFU) as a sensible alternative. In addition to reducing carbon emissions and manufacturing costs, e-IFU can be updated more easily and accessed by surgeons in the clinic, where IOL models and powers are selected. Varying and inconsistent IFU requirements between different countries are a barrier to wider adoption of e-IFU by the ophthalmic surgical industry. Regulatory agencies in every country should allow and encourage e-IFU. This position paper has been endorsed by the 3 major societies that sponsor EyeSustain, a consortium of global societies dedicated to advancing sustainability in ophthalmology.

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In 2021, the World Health Organization stated that climate change is the leading threat to global health and will disproportionately harm the poorest and most vulnerable communities.[1] The global healthcare system is a major contributor to waste and accounts for 4.4% of global greenhouse gases.[2] The National Academy of Medicine recently launched its Action Collaborative on Decarbonizing the U.S. Health Sector to "activate all parts of the health sector for sustainable change" focusing on the healthcare supply chain and infrastructure.[3] Ophthalmic procedures represent some of the most common in medicine; almost 30 million cataract surgeries are performed globally each year.[4,5] Aging populations in most countries will lead to steady increases in ophthalmic procedural volumes over time.[6,7] This gives ophthalmology a unique opportunity to reduce unnecessary waste and carbon emissions.

Regulatory agencies, such as the European Union (EU) Medical Device Regulation (MDR) and the U.S. Food and Drug Administration (FDA), require manufacturers to provide detailed instructions for use (IFU) to guide proper and safe use of surgical devices and products. The IFU describe how to use the product and may include information about applications, component parts, indications and contraindications, precautions, warnings, study results, and adverse events. In ophthalmic surgery, paper IFU accompany most devices and supplies used, such as intraocular lenses (IOLs), IOL insertion cartridges, ophthalmic viscosurgical device (OVD) syringes, dropper bottles of saline, irrigating solution, and phacoemulsification tips and sleeves. Although some IFU may be printed on the package exterior, most are separately supplied as a printed booklet or folded handout within the product package. As an alternative to paper IFU, electronic instructions for use (e-IFU) can be accessed through websites linked through Quick Response (QR) codes on the package. Both MDR and FDA regulations permit e-IFU, although for MDR, this is limited to certain products. If a downloadable PDF version were available, surgical facilities could print 1 copy of each IFU for each product used in the surgery without the waste of including a printed copy with every unit.

EyeSustain, a coalition sponsored by ASCRS, ESCRS, and AAO, collaborated with the Medical Device Manufacturers Association in the United States to develop a survey that was emailed to 227 American instrument and supply manufacturers across multiple surgical specialties about e-IFU. Of the 32 responding companies, 95% believed that

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From the Brighton Vision Center, Brighton, Michigan (Schehlein); Harvard Eye Associates, Laguna Hills, California (Hovanesian); Columbia University Medical Center, New York, New York (Shukla); Himalayan Cataract Project (HCP) Cureblindness, Waterbury, Vermont (Rostov); Vienna Institute for Research in Ocular Surgery (VIROS), Hanusch Hospital, Vienna, Austria (Findl); Altos Eye Physicians, Los Altos, California (Chang).

Corresponding author: David F. Chang, MD, Altos Eye Physicians, 762 Altos Oaks Drive, Los Altos, CA 94024. Email: dceye@earthlink.net.

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e-IFU were an acceptable alternative to paper IFU. Most believed that e-IFU would reduce product paperwork (84%) and reduce production costs (80%). However, e-IFU were currently used for all products by only 20%, most products by 10%, many (<50%) products by 25%, a few products by 25%, and no products by 20%. Barriers most frequently cited (in decreasing order of frequency) were varying and inconsistent IFU requirements between different countries (100%), manufacturer liability (58%), cost to implement (53%), lack of customer demand (32%), lack of company awareness/consideration (32%), and lower company prioritization (21%).

We recommend that surgical manufacturers replace paper IFU with e-IFU whenever possible for ophthalmic surgical products. Given the large volume of ophthalmic surgeries, transitioning from printed to e-IFU will significantly reduce waste while making the same information readily accessible to surgical teams. To understand the potential benefits and disadvantages of e-IFU for virtually all ophthalmic surgical products, it is helpful to consider the example of IOLs.

e-IFU FOR IOLs

Only a few companies have implemented e-IFU for IOLs in the United States and European Union. The content of each IOL IFU is repeated in multiple languages and includes information on the IOL power calculation (such as the A constant), insertion instructions, warnings/precautions, expected postoperative results, and patient registration information. Because of the extensive information provided in multiple languages, the IFU print size is small, making it more difficult to read than newsprint. Printed paper IFU booklets also contribute to the overall weight and size of the IOL package.

In a 2013 analysis of carbon emissions from cataract surgery in the NHS, Morris et al. found that more than 50% of the carbon emissions arose from medical equipment (32.6%) and pharmaceutical (18%) supply chains.[8] They also noted that the IOL packaging (plastic and paper) weighed 64 grams and included a 70-page IFU booklet translated into 11 languages. By comparison, the IOL weighed less than 1 gram. A 2023 study of packaging of IOLs commonly used in the United States showed a range of package weight from 29 to 79.5 grams (A. Keyser, unpublished data, September 2023). Eliminating the IFU booklet would net a 60-fold reduction in the paper waste from the IOL packaging. A 2017 analysis performed at the Aravind Eye Care System found that each cataract surgery produced only 250 grams of waste because of the routine reuse of most surgical and pharmaceutical supplies. The IFU and IOL packaging accounted for 25% of this waste.[9]

Assuming that 40 g of the 61 g total weight of an IOL package is from the paper IFU, we estimate that the production and shipping of 30 million IOLs per year produce more than 5 million kilograms of carbon dioxide equivalent ($kgCO_2e$) per year. Transitioning to e-IFU could reduce greenhouse gases from IOL packaging to less than 2 million (1 736 860 $kgCO_2e$) for a 67% reduction (Thiel, Cassandra, personal communication, email, January 3, 2023). This would save approximately 3500 metric tons of CO_2 emissions annually, equivalent to the annual greenhouse gas emissions from 753 passenger cars or the energy use of 425 U.S. homes. In addition, a 2023 European study by Stern et al. estimated that transitioning from paper to e-IFU could lead to an 84% reduction in paper and the preservation of more than 2000 trees or more than 50 000 reams of copier paper each year.[10] Eliminating the excess weight of IOL packaging might reduce costs for waste treatment and product shipment.

The ramifications of implementing e-IFU for IOLs can also be considered from the standpoint of 4 different parties and stakeholders. These considerations can be generalized to most surgical products.

Surgical Facility Considerations

Reliable internet connectivity is an important consideration for reliance on e-IFU. In most countries, wireless internet or cellular data are widely available and global internet access is rapidly expanding. In the unlikely event that a surgeon urgently needed to refer to the IFU in the operating room, e-IFU would expedite searching for the required information through the "find" option, as opposed to reading the multiple pages and small print of a paper IFU pamphlet. Viewing e-IFU on a computer, tablet, or mobile device would allow the user to enlarge the font and adjust brightness. With a QR code linked to the e-IFU, any mobile device could display the information without the need for a desktop or laptop computer in the OR. As a backup to e-IFU, such as when internet or LTE access is unreliable, facilities should print and file 1 copy from a downloadable PDF on the company's website or request a printed copy from the company for each product used in surgery.

Surgeon Considerations

Surveys have demonstrated that ophthalmic surgeons overwhelmingly support efforts to decrease cataract surgery's carbon footprint; 1 recent survey reported that 93% believed that OR waste is excessive and should be reduced.[11] In this 2020 survey of more than 1000 ophthalmologist respondents, 71% of surgeons believed that single-use item packaging leads to unnecessary waste. Moreover, 76% of surgeons and 72% of nurses strongly agreed with the statement: "Device and supply manufacturers should consider the environment/carbon footprint in their product design."

For cataract surgery, the IOL model and power are selected preoperatively. Because printed IFU are only accessible after the sterile IOL package is opened, digital IFU would be much easier for surgeons to review preoperatively in the clinic when the IOL model and parameters are selected. From a practical standpoint, surgeons rarely need to reference the IFU, and the fact that a surgeon repetitively uses the same IOL models make inclusion of paper IFU booklets within every IOL box exceedingly wasteful.

Manufacturer Considerations

The global IOL market was valued at almost $4 billion U.S. dollars in 2021 with projections for continued growth.[12]

More than 10 companies produce the most IOLs for cataract surgery worldwide.

One manufacturer was able to reduce their IOL packing weight by 53% by removing the paper IFU where this was allowed.[13] Decreasing packaging size and weight should reduce shipping costs, making this an economical and an ecological choice. Manufacturers can update e-IFU much faster than paper IFU, and updated e-IFU would immediately become available for units that are already in the manufacturer's or the surgical facility's inventory.

Regulatory Agency Considerations

A major obstacle to e-IFU adoption is that several countries still require a printed IFU (Table 1). Many are low- to middle-income countries, but this list also includes several larger markets as well. For companies that sell IOLs in these global markets, it may be impractical and expensive to have 2 different packaging lines—one that includes a paper IFU in the package and another that does not. We believe that requiring paper IFU is outdated and environmentally detrimental. There is no evidence that e-IFU pose a danger to patient care. On the contrary, safety information can be updated much faster and more effectively with e-IFU. This is particularly important for IOLs, given the common practice where IOLs are stored under consignment in surgical facilities. Some infrequently used IOL powers may sit on OR shelves for long periods of time, allowing the enclosed paper IFU to become outdated.

In the United States, the Federal Food, Drug, and Cosmetic Act ensures that IFU for devices used in healthcare settings "… may be made available solely by electronic means, provided that the labeling complies with all applicable requirements of law, and that the manufacturer affords such users the opportunity to request the labeling in paper form, and after such request, promptly provides the requested information without additional cost."[14] In Europe, the MDR provides a set of regulations that all companies in the EU market must abide by for production and distribution of medical devices. Currently, e-IFU for implants such as IOLs are accepted by the MDR across EU member states. However, e-IFU are not accepted by MDR for other products used in cataract surgery, such as instruments and phacoemulsification tubing and machines, because they are not implants or permanently installed systems. MedTech Europe, a trade association for medical technology and devices, published a position paper calling for the use of e-IFU for all medical devices. The association conducted a survey of healthcare professionals, hospital administrators, and pharmacists in multiple languages regarding e-IFU with more than 882 responses from 23 countries. More than 88% of healthcare professionals and more than 90% of hospital pharmacists and administrators stated that they preferred e-IFU because of their easier access and waste reduction. Notably, greater than 99% of respondents had internet access, negating any safety concern about accessing e-IFU.[15] We encourage MDR to resolve this inconsistent logic by permitting e-IFU for all ophthalmic surgical products.

Global regulatory agencies should honor the increasing trend toward environmentally responsible legislation worldwide. An Extended Producer Responsibility (EPR) strategy is an environmental policy that requires companies

Table 1. Current state of e-IFU by country

e-IFU accepted (*with restrictions*)	e-IFU not accepted	e-IFU acceptance unclear
Australia, Angola, Anguilla, Antigua and Barbuda, Argentina, Aruba, Austria, Bahamas, Bangladesh, Barbados, Belgium, Belize, Bolivia, Brazil, Bulgaria, Canada, Cayman Islands, Chile, Columbia, Costa Rica, Croatia, Curacao, Cyprus, Czech Republic, Denmark, Dominica, Ecuador, El Salvador, Eritrea, Estonia, Finland, France, Germany, Greece, Grenada, Guatemala, Guyana, Honduras, Hungary, Iceland, India, Indonesia, Ireland, Israel, Italy, Jamaica, Japan, Latvia, Liberia, Lichtenstein, Lithuania, Luxembourg, Maldives, Malta, Mauritius, Nepal, Netherlands, New Zealand, Nicaragua, Norway, Poland, Portugal, Puerto Rico, Romania, San Marino, Saudi Arabia, Singapore, Slovakia, Slovenia, South Korea, Spain, St. Lucia, St. Maarten, St. Vincent and The Grenadines, Suriname, Sweden, Switzerland, Tanzania, Thailand, Trinidad and Tobago, Turkey, Turks and Caicos, Uganda, United Kingdom, United States, Venezuela, Zambia, Zimbabwe	Afghanistan, Algeria, Albania, Armenia, Azerbaijan, Bahrain, Belarus, Benin, Bhutan, Brunei, Cambodia, Cameroon, Central Africa, Chad, China, Comoros, Democratic Republic of the Congo, Djibouti, Egypt, Iran, Iraq, Jordan, Kazakhstan, Kosovo, Kuwait, Lebanon, Libya, Malaysia, Mali, Mexico, Moldova, Montenegro, Morocco, Niger, Oman, Pakistan, Peru, Qatar, Russia, Serbia, Sri Lanka, Sudan, Syria, Tunisia, Ukraine, United Arab Emirates, Uruguay, Uzbekistan, Vietnam	Bosnia and Herzegovina, Botswana, Burundi, Dominican Republic, Ethiopia, Georgia, Ghana, Guinea, Kenya, Kyrgyzstan, Lesotho, Madagascar, Malawi, Mongolia, Namibia, Panama, Paraguay, Philippines, Republic of Macedonia, South Africa, Taiwan, Yemen

e-IFU = electronic instructions for use
Source: Personal communication with industry representatives, email January 26, 2023, and September 5, 2023

to assume responsibility for their products past the consumer stage. EPR laws and programs have been implemented in Belgium, South Korea, Spain, India, Japan, the Netherlands, the United Kingdom, British Columbia, and several states in the United States. One such EPR policy increased the recycling rate in Belgium from 10% to 89.8%.[16] Preventing surgical product manufacturers from responsibly reducing unnecessary paper waste and CO_2 emissions by implementing e-IFU is particularly puzzling in this context.

CONCLUSION

Paper IFU contribute significantly to unnecessary waste and adverse environmental impact from ophthalmic surgery. Compared with e-IFU, disadvantages of printed IFU include smaller print, inability to immediately update IFU of IOLs stored in ORs on consignment, and difficulty accessing the information in the clinic when the IOL model and power are selected. Because of the extremely high volume of ophthalmic devices used in procedures such as cataract surgery, implementing e-IFU is a straightforward way for manufacturers to reduce unnecessary waste and carbon emissions. We recommend that the ophthalmic surgical manufacturing industry moves exclusively to e-IFU, initially prioritizing those products routinely used in high volume, such as IOLs, IOL cartridges, and OVD. We request that every global government and regulatory agency facilitate these efforts.

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First author:
Emily M. Schehlein, MD

Brighton Vision Center, Brighton, Michigan