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Concise Communication

CDC consultations related to ophthalmic practices and settings, January 2016–December 2023

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Abstract

Consultations with the Centers for Disease Control and Prevention's Division of Healthcare Quality Promotion revealed patient harms associated with ophthalmic care. Adherence to core infection prevention and control principles, tailored guidance for ophthalmic settings, and compliance with manufacturing and compounding standards could decrease adverse events and patient exposures to contaminated products.

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Introduction

Healthcare activities that include instrumentation or manipulation of mucosal tissue or normally sterile sites can place patients at risk of infectious and other complications. Within the orbit of the eye, the globe and supporting structures are relatively vulnerable to external environmental conditions and exposures. The use of ophthalmic devices, drops, ointments, and other medical products for diagnosis or treatment and the manipulation of tissue can increase the likelihood of eye infection and other adverse events.

Outbreaks of infectious organisms and clusters of adverse events have been noted in the ophthalmic setting. For example, there have been outbreaks of epidemic keratoconjunctivitis associated with contamination of the ophthalmic clinical environment with adenovirus.[1,2] Additionally, eye infections involving a variety of microorganisms from the use of contaminated medical products, such as eye drops, have been reported.[3,4] Postsurgical adverse events can also be seen with common ophthalmologic procedures such as cataract surgery.[5,6] Reusable medical equipment has been implicated in adverse events in eye care settings,[2] and the most common infection control citations from surveyors in outpatient settings, including ambulatory surgical centers (ASC) performing ophthalmologic procedures, are related to lapses in proper reprocessing of reusable medical equipment.[7]

We reviewed queries to the Centers for Disease Control and Prevention's (CDC) Division of Healthcare Quality Promotion (DHQP) that were focused on ophthalmologic procedures and settings to identify opportunities to improve infection prevention and control (IPC) practices in these settings.

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Methods

CDC/DHQP assists health departments and healthcare facilities with investigations of infection control breaches and outbreaks involving the provision of health care. Internal CDC consultation records received from January 1, 2016, through December 31, 2023, were reviewed to identify those involving ophthalmologic procedures or settings. All queries involving eye care and ophthalmologic and optometric practices and procedures were included. Consultations were reviewed to determine the setting type (eg, inpatient vs outpatient), number of patients affected, organisms identified, nature of IPC breaches, and whether medical products were implicated. Consultations were grouped into categories based on common themes and IPC breaches identified, and respective frequencies were calculated.

This activity was reviewed by the CDC/DHQP Science Office (0900feb822f57ca); data were collected as part of public health investigations, and the project was deemed a non-research activity not requiring Institutional Review Board (IRB) approval. Work was conducted consistent with applicable federal law and Centers for Disease Control and Prevention policy (eg, 45 C.F.R. part 46.102(l) (2), 21 C.F.R. part 56; 42 U.S.C. §241(d); 5 U.S.C. §552a; 44 U.S.C. §3501 et seq.).

Results

We identified 26 consultations among 25 US health jurisdictions, with 2 consultations involving more than 1 jurisdiction. Most consultations (n = 21, 81%) involved outpatient settings, of which 10 (48%) were ASC. Five of the remaining outpatient clinics performed cataract surgery and other procedures but did not have specific ASC designation, while 6 were traditional ophthalmologic and optometric eye clinics not performing invasive procedures. Consultations included the following non-mutually exclusive categories (Table 1) with some investigations involving multiple categories of events: postsurgical adverse events (n = 19, 73%), toxic anterior segment syndrome following cataract surgery (n = 5, 19%),

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Table 1. Categories and examples of CDC consultations (n = 26) for investigations involving ophthalmic settings or procedures, United States, 2016–2023

Category[a]	Number (%)	Example consultations and IPC concerns	Investigation trigger	Implicated organism(s)	Outcomes
Postsurgical adverse events	19 (73%)	• Nontuberculous mycobacterial infections after laser surgery; facility routinely used flash sterilization for reprocessing	• Three patients with mycobacterial infections after LASIK procedures performed on the same day	• *M. chelonae* and *M. abscessus*	• At least 1 patient with permanent loss of vision
		• Fungal endophthalmitis postcataract surgery; no obvious lapses noted in IPC practices	• Two patients with endophthalmitis following surgery at the same center	• *A. fumigatus* and *P. lilacinum*	• Patient outcomes unknown
		• Bacterial infection after LASIK surgery; multiple failures in instrument reprocessing and lack of appropriate sterilizer maintenance	• Five patients with corneal infections at single ambulatory surgical center (ASC) over several months	• *S. pneumoniae*, *S. mitis*, and *S. aureus*; suspicion of fungal infection but no recovery	• Patient outcomes unknown
		• Progressive cellulitis at the site of intravenous catheter used during cataract surgery	• Single patient with rapidly progressive cellulitis at ASC	• *S. pyogenes* (group A strep)	• Patient had multiorgan failure
Toxic anterior segment syndrome (TASS) following cataract surgery	5 (19%)	• Two investigations implicated potentially contaminated compounded medications	• Four patients within a 2-month period; 5 patients from 2 facilities using the same compounded product	• No organism identified	• Patient outcomes unknown; specific contaminant not identified
		• Medication preparation and reprocessing concerns related to water exposures and introduction of contaminants	• 16 patients across 3 facilities in the same region; similar operative medications and device reprocessing procedures	• No organism identified	• Patients with mild/moderate symptoms; no permanent sequelae reported
Infections following routine ophthalmologic care in the clinic setting	11 (42%)	• Epidemic keratoconjunctivitis due to adenovirus 8; adenovirus identified from visual acuity test eyepieces, eye cover, and outside of multiuse eye drop bottle[b]	• Two separate investigations precipitated by multiple patients with keratoconjunctivitis	• Adenovirus 8 identified in both investigations	• Patients with mild/moderate symptoms; no permanent sequelae reported
Suspected intrinsic contamination of medication	8 (31%)	• Contamination of ophthalmic medications or solutions manufactured or compounded off-site[c]	• Donor rims for cataract surgery noted to be positive for bacterial growth	• Multiple gram-negative organisms cultured	• Patient outcomes unknown; product recalled
		• Outbreak of multidrug-resistant *P. aeruginosa* due to contaminated artificial tear products manufactured internationally[4]	• Clusters of patient infections with an unusual organism in noncontiguous states among different patient groups	• *P. aeruginosa*	• Dozens of patients affected with symptoms of varying severity; a case-control study identified artificial tears as a common product
Medical device reprocessing concerns	8 (31%)	• Inappropriate high-level disinfection or sterilization processes	• Onsite IPC visit to outpatient clinic noted concerning breaches	• No organism identified	• No known patient harms, but patients not notified about potential risk
		• Ophthalmic laser lenses marketed with a method of disinfection that is not consistent with FDA standard guidance and without complete and detailed instructions for use	• IPC breach noted during a survey by The Joint Commission	• No organism identified	• Review of patient charts revealed no patient infections
		• Use of individual patient glucometer on multiple patients	• Concerning practice noted on visit by state survey and certification staff	• No organism identified	• Review of patient charts revealed no patient infections
Ineffective environmental cleaning and disinfection	8 (31%)	• Persistent contamination of environmental surfaces with adenovirus during outbreak, with recovery of virus from high touch surfaces[b]	• Local ophthalmologist notified the local health jurisdiction of the increased number of infected patients	• Adenovirus 8	• Over 75 patients infected; no permanent sequelae reported
		• EPA-registered disinfectant with activity against adenovirus not utilized for disinfection	• Ophthalmology practice with multiple clinics noted an increase in keratoconjunctivitis	• Adenovirus 8 primarily, but also adenovirus 64	• Over 20 patients infected; no permanent sequelae reported

(*Continued*)

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Table 1. (*Continued*)

Category[a]	Number (%)	Example consultations and IPC concerns	Investigation trigger	Implicated organism(s)	Outcomes
Mishandling of medications	3 (12%)	• Syringe with medication for injection into the eye used on multiple patients and stored in an unmonitored freezer between uses	• Site visit by the state health department noted multiple IPC breaches	• No organism	• No known patient harms, but patients not notified about potential risk
		• Medication preparation in sink splash zones; potential contamination of medications	• Cluster of TASS cases reported to the local health department	• No organism	• Patients with mild/moderate symptoms; no permanent sequelae reported
Contaminated donor tissue	3 (12%)	• Donor corneas with bacterial contamination from 2 noncontiguous states	• State health departments notified of positive cultures	• Two cultures, 1 with *K. oxytoca*, 1 with *E. coli*	• One patient required new cornea
		• Swabs of donor rims grew a variety of gram-negative bacteria; an eye wash recently introduced to the eye bank was found to be contaminated[c]	• State health department notified of multiple donor corneas with bacterial contamination	• Multiple bacteria, including *A. xylosoxidans*, *B. cepacia*, *S. maltophilia*, *E. meningoseptica*	• No known patient harms, but investigation resulted in nationwide product recall

Note: *A. fumigatus*, *Aspergillus fumigatus*; *A. xylosoxidans*, *Achromobacter xylosoxidans*; *B. cepacia*, *Burkholderia cepacia*; CDC, Centers for Disease Control and Prevention; *E. coli*, *Escherichia coli*; *E. meningoseptica*, *Elizabethkingia meningoseptica*; EPA, Environmental Protection Agency; FDA, Food and Drug Administration; IPC, infection prevention and control; *K. oxytoca*, *Klebsiella oxytoca*; LASIK, laser-assisted in situ keratomileusis; *M. abscessus*, *Mycobacterium abscessus*; *M. chelonae*, *Mycobacterium chelonae*; *P. lilacinum*, *Purpureocillium lilacinum*; *P. aeruginosa*, *Pseudomonas aeruginosa*; *S. aureus*, *Staphylococcus aureus*; *S. maltophilia*, *Stenotrophomonas maltophilia*; *S. mitis*, *Streptococcus mitis*; *S. pneumoniae*, *Streptococcus pneumoniae*; *S. pyogenes*, *Streptococcus pyogenes*.

[a]Categories are non-mutually exclusive.

[b]MMWR Morb Mortal Wkly Rep 2017;66:811–812, https://doi.org/10.15585/mmwr.mm6630a3.

[c]Recalls, Market Withdrawals, & Safety Alerts > United Exchange Corp Issues Voluntary Nationwide Recall of Family Care Brand Eye Wash Due to Microbial Contamination (archive-it.org), https://wayback.archive-it.org/7993/20180126102114/https://www.fda.gov/Safety/Recalls/ucm519583.htm.

infections following receipt of nonsurgical ophthalmic clinical care (n = 11, 42%), suspected contamination of medications at point of manufacture or during compounding prior to receipt at point of use (n = 8, 31%), medical device reprocessing concerns (n = 8, 31%), improper environmental cleaning and disinfection (n = 8, 33%), mishandling of medications within the clinical setting (n = 3, 12.5%), and events associated with potentially contaminated donor tissue (n = 3, 12.5%). Lapses in general IPC practices, such as poor adherence to hand hygiene recommendations and inconsistent use of standard precautions, spanned across all categories. Overall, half of all consultations (n = 13) identified medical device reprocessing concerns, issues with environmental cleaning and disinfection, or specific breaches in facility-level IPC practices (eg, failed opportunities for hand hygiene, use of single-use medical device for multiple patients). When a consultation included the identification of a pathogen (n = 12, 46%), organisms included bacteria (n = 8, 64%), fungi (n = 3, 25%), and viruses (n = 2, 17%). A total of 243 patients had confirmed ophthalmic infections or adverse events.

Discussion

Preventable observed and potential harms associated with medical device reprocessing deficiencies and improper environmental cleaning and disinfection, among other factors, were noted in this review of CDC consultations involving ophthalmic care and settings. These identified IPC concerns in ophthalmic settings may be addressed by heightened attention to education and training related to environmental cleaning and medical device reprocessing. Increased emphasis on, and awareness of, the critical role of environmental cleaning and disinfection of surfaces may be particularly beneficial given multiple reports of eye-clinic-associated transmission of environmentally hardy organisms such as adenovirus.[1,2] Additionally, more specific training, with refresher training as necessary and performance audits, with monitoring and documentation, is important for those performing medical instrument and device reprocessing and those charged with the preparation and use of medical products and treatments.

The American Academy of Ophthalmology (AAO) has issued a comprehensive document, "Infection Prevention in Eye Care Services and Operating Areas and Operating Rooms—2012," that provides guidance on standard precautions, cleaning, disinfection and sterilization procedures, and other topics relevant to maintaining a robust IPC program.[9] This document relies heavily on guidance and recommendations from the CDC, the Association of Professionals in Infection Control and Epidemiology, the National Institute of Occupational Safety and Health, and others. The update of the AAO document tailored to the unique aspects of ophthalmologic settings and practice and consistent implementation and practice of the AAO recommendations could have a substantial impact in improving IPC practices and reducing adverse outcomes in the ophthalmic setting.

Our review has several limitations. First, consultations with the CDC/DHQP are voluntary, and the findings summarized here may not be generalizable to all investigations involving ophthalmic settings across the country. Each state's decision to request CDC assistance likely depends upon many factors, including the health department's experience with response to similar situations, available personnel and areas of expertise, and competing priorities from other public health needs. Second, the CDC does not always receive complete follow-up information (eg, details regarding onsite observations, including those related to specific reprocessing concerns or breaches in IPC practices) for each investigation for which it is consulted. Third, healthcare investigations do not always include formal epidemiologic studies, and most investigations do not identify a single, definitive IPC failure responsible for transmission. However, onsite observations and environmental sampling are often suggestive

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of potential transmission routes. A formal outbreak reporting system for outpatient settings, including those focused on ophthalmic practices and settings, could clarify the nature and frequency of IPC issues of greatest concern to help inform targets for prevention efforts.

A review of consultations to the CDC/DHQP involving ophthalmic settings and practices found documented and potential patient harms associated with a variety of suboptimal practices. Enhanced education, training, and auditing of healthcare personnel and the use of IPC guidance specific to this setting could improve patient outcomes and decrease the likelihood of adverse events. Additionally, good manufacturing practices and safe handling and adherence to pharmacy standards during compounding will decrease the likelihood of patient contact with contaminated ophthalmic products.[10]

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