



## The Focal Point: Advocacy & Legislative Update April 10, 2018

### **ASCRS/AAO/OOSS Release Updated Guidelines for Ophthalmic Instrument Cleaning and Sterilization**

The American Society of Cataract and Refractive Surgery (ASCRS), the American Academy of Ophthalmology (AAO), and the Outpatient Ophthalmic Surgery Society (OOSS) have released new [specialty-specific guidelines for the sterile processing of ophthalmic surgical instruments](#). This document makes evidence-based recommendations regarding issues that may be unique to the cleaning and sterilization of intraocular surgical instrumentation.

These guidelines update the original recommended practices for cleaning and sterilizing intraocular surgical instruments published in 2007. This document outlines minimum standards for intraocular instrument cleaning and sterilization based on a consensus of experts representing the three sponsoring societies forming the Ophthalmic Instrument Cleaning and Sterilization (OICS) Task Force

Most of the recommended practices are derived from existing evidence-based recommendations for cleaning and sterilizing all surgical instruments in general, from published analyses of Toxic Anterior Segment Syndrome (TASS) outbreaks and from manufacturers' instructions for use (IFU) for surgical instruments and equipment.

The new guidelines address the safety and acceptability of short-cycle ophthalmic instrument processing for sequential same-day surgery. An additional issue addressed by the guidelines is the necessity of routinely using enzymatic detergent to clean ophthalmic instruments prior to sterilization, given that minute enzyme residue left on intraocular instruments can cause TASS.

### **Adam Boehler to Lead CMS' Innovation Center**

Secretary of Health and Human Services (HHS) Alex Azar tapped founder and former [Landmark Health CEO Adam Boehler to lead the CMS Innovation Center \(CMMI\)](#). The center was established under the Obama administration to encourage innovation, but the Centers for Medicare and Medicaid Services (CMS) has shifted its focus towards value in an effort to reform the health system.

Boehler is expected to join the department next week. Landmark is a medical care company that uses a technology platform to deliver medical services to complex and chronically ill patients at home.

He is also the founder of Avalon Healthcare Solutions, a laboratory benefit services company. Boehler was formerly an operating partner at global private equity firm Francisco Partners with a healthcare technology and services portfolio.

### **Stay Up to Date with ISBT 128**

Version 7.13.0 of the [ISBT 128 Product Description Code Database](#) is now available to licensed facilities. All database updates are listed in the version control sheet.

[Standard Terminology for Medical Products of Human Origin v7.13](#) has also been released.

ICCBBA has also released version [5.9.0 of the ISBT 128 Standard Technical Specification](#) (ST-001).

### **FDA Releases Draft Guidance on Inclusion of Pregnant Women in Clinical Trials**

The Food and Drug Administration (FDA) announced the availability of a draft guidance for industry entitled “[Pregnant Women: Scientific and Ethical Considerations for Inclusion in Clinical Trials](#).” This draft guidance discusses the ethical and scientific issues when considering the inclusion of pregnant women in clinical trials of drugs and biological products. The guidance is intended to advance scientific research in pregnant women and discusses issues that should be considered within the framework of human subject protection regulations.

### **Study Shows Ebola Survivors Can Safely Have Cataract Surgery**

Survivors of Ebola virus disease (EVD) often suffer long-term vision complications that can now safely be corrected with cataract surgery, according to [new research from Emory Eye Center ophthalmologists published in EBioMedicine](#).

From 13% to 34% of Ebola survivors will have post-infection vision impairment due to uveitis, an eye inflammation caused by cataracts. But because the Ebola virus is known to remain in ocular fluid even after clearing the rest of the body, doctors are hesitant to perform cataract or other ocular surgeries on survivors because of the risk of infection.

The EVICT (Ebola Virus Persistence in Ocular Tissues and Fluids) study tracked 50 survivors (46 with vision impairment) in Sierra Leone after the 2014 - 2016 Ebola outbreak. Researchers tested ocular fluid for the Ebola virus at an average of 19 months after patients' initial diagnosis with Ebola virus disease in the first phase of the study, and at an average of 34 months after diagnosis of Ebola in the second phase of the study. All samples were negative and 34 patients elected to have cataract surgery. All patients who had surgery saw restoration of 20/30 vision.

### **Congressional Briefing on Whole Eye Transplantation**

Eye Bank Association of America (EBAA) staff attended the Alliance for Eye and Vision Research (AEVR) Congressional Briefing, “[Whole Eye Transplantation—From Experimental Model to Clinical Translation](#)” on March 29. Dr. Kia Washington, a reconstructive surgeon from the University of Pittsburgh Medical School discussed her groundbreaking research into whole eye transplantation. Her research has led to the development of the first vascularized eye transplant in a small animal model.

Her research is funded through the Department of Defense Vision Trauma Research Program, with the goal of restoring vision following ocular trauma and ischemic or degenerative damage. Although whole eye transplantation is an audacious goal, Dr. Washington believes that “it will happen within my lifetime.”