The Focal Point: Advocacy and Legislative Update
May 8, 2018

FDA Releases Updated Zika Donor Screening Guidance

The Food and Drug Administration (FDA) released updated guidance for establishments that make donor eligibility determinations for those donating human cells, tissues, and cellular and tissue-based products (HCT/Ps), with recommendations for screening donors for infection with Zika virus.

This guidance updates information in the March 2016 guidance by:

1. providing findings from more recent epidemiological studies including impact on public health;
2. reporting new data that informs the potential for transmission of ZIKV [Zika virus];
3. discussing the current status of availability of ZIKV tests;
4. updating sexual contact risk factors;
5. updating when an area is considered to have an increased risk for ZIKV transmission; and
6. providing additional scientific references. This update supports the continuation of recommendations to screen living donors of HCT/Ps for risks of infection with ZIKV based on geographic areas with risk.

FDA's recommendations for living and deceased HCT/P donors remain unchanged from the previous guidance. Non-heart beating (cadaveric) donors with a medical diagnosis of ZIKV infection in the past 6 months should be considered ineligible. FDA still recommends that establishments implement the recommendations in this guidance as soon as feasible, but not later than 4 weeks after its issue date.

FDA Posts HCT/P Inspection Information for FY 2017

The Food and Drug Administration (FDA) published their compliance summary for HCT/P inspections performed in fiscal years 2013 through 2017. Of the 621 inspections completed in FY 2017, 561 inspections were classified as NAI – no action indicated; 57 were VAI – voluntary action indicated; and 8 were classified as OAI – official action indicated.

FDA Withdraws Final Rule to Cut Biologics Inspections

The Food and Drug Administration (FDA) withdrew a direct final rule to amend the general biologics regulations on inspection time requirements and to remove inspectors' duties.

In January, FDA called the biennial inspection schedule "outdated and unnecessary" because since July 2012, when the Food and Drug Administration Safety and Innovation Act (FDASIA) was signed into law, the biennial requirement was replaced with a requirement that FDA inspect establishments in accordance with a risk-based schedule.

The FDA published their direct final rule on January 26, 2018, but it is withdrawn effective May 7, 2018 because the Agency received significant adverse comment.

Joint Statement on Ear and Hair Covering

The American College of Surgeons (ACS), the American Society of Anesthesiologists (ASA), the Association of peri-Operative Registered Nurses (AORN), the Association for Professionals in Infection Control and Epidemiology (APIC), the Association of Surgical Technologists (AST), the Council on Surgical and Perioperative Safety (CSPS); and The Joint Commission (TJC) met on February 27, 2018, to review and discuss the literature related to recommendations for operating room (OR) attire, specifically ear and hair covering.

Over the past couple of years, the interpretation and compliance with CDC and AORN recommendations have created controversy as it relates to the type of head coverings that should be used, the extent of hair on the neck that can be exposed, and whether ears must be covered. It became increasingly apparent that in practice, covering the ears is not practical for surgeons and anesthesiologists and in many cases counterproductive to their ability to perform optimally in the OR.

In reassessing the strength of the evidence for this narrowly defined recommendation, the group concluded the following:

- Evidence-based recommendations on surgical attire developed for perioperative policies and procedures are best created collaboratively, with a multi-disciplinary team representing surgery, anesthesia, nursing, and infection prevention.
- The requirement for ear coverage is not supported by sufficient evidence.
- At present, available scientific evidence does not demonstrate any association between the type of hat or extent of hair coverage and SSI rates. One recent study[1] on head coverings (disposable bouffant or skullcap, cloth cap), identified that the commonly available disposable bouffant hat is the least effective barrier to transmission of particles.
- Other issues regarding areas of surgical attire need further evaluation.

Ocular Melanoma Cluster Baffles Experts

An unusually high number of ocular melanoma cases have been reported in two states, baffling researchers and epidemiologists.

The cancer, which normally occurs in about six in every 1 million individuals, has been identified in more than 50 individuals around two locations: Huntersville, North Carolina, and Auburn, Alabama. At least 38 of these individuals attended Auburn University between 1983 and 2001.

CDC Reports Rising Number of Vector-Borne Illnesses

A Centers for Disease Control and Prevention (CDC) Vital Signs report found that the incidence of illnesses in the U.S. caused by diseases that ticks and mosquitoes transmit has more than tripled from 2004 to 2016. The findings are based on an analysis of 16 vector-borne diseases reported in the U.S. National Notifiable Diseases Surveillance System. A total of 642,602 cases of 16 diseases caused by bacteria, viruses, or parasites transmitted through the bites of mosquitoes, ticks, or fleas were reported during this period, although these cases were substantially underreported.

Tickborne diseases more than doubled in 13 years and were 77% of all vector-borne disease reports. Lyme disease accounted for 82% of all tickborne cases, but spotted fever rickettsioses, babesiosis, and anaplasmosis/ehrlichiosis cases also increased.

The most common mosquito-borne viruses in 2016 were West Nile, dengue and Zika. Dengue, chikungunya, and Zika viruses were almost exclusively transmitted in Puerto Rico, American Samoa, and the U.S. Virgin Islands, where they were periodically epidemic. West Nile virus, also occasionally epidemic, was widely distributed in the continental United States, where it is the major mosquito-borne disease.

Nine new pathogens spread by mosquitoes and ticks have been discovered or introduced since 2004. This will be a continuing threat to the United States and U.S. territories

To view the full report, click here.

Afghanistan War Veteran Undergoes First Full Penis and Scrotum Transplant

A U.S. serviceman who was severely injured by an IED blast in Afghanistan has received the world's first total penis, scrotum and partial abdominal wall transplant at the Johns Hopkins University School of Medicine.

The man, whose identity was not released, is recovering well and expected to regain both urinary and sexual function. The medical team did not transplant the donor's testes, due to ethical concerns about the patient being able to father the late donor's children.

The donor was not identified, nor was his cause of death, although his family released a statement through New England Donor Services. "We are so thankful to say that our loved one would be proud and honored to know he provided such a special gift to you," said the statement, read by Alexandra Glazier, president and CEO of New England Donor Services. "We hope you can return to better health very soon and we continue to wish you a speedy recovery."

Louisiana Bill Threatens Certification

The Occupational Licensing Review Act (Louisiana House Bill 748), passed the Louisiana House of Representatives, by a vote of 87-7 and appears to be on its way to passage in the Senate. If passed, the risks to certification programs could eventually expand far beyond the state of Louisiana.

The legislation bans the use of the term "certification" issued from professional credentialing bodies unless such certification is used in conjunction with licensure in that state. This pending legislation if enacted would effectively place Louisiana off-limits to most certification organizations and, for the few certifications recognized by Louisiana's licensing laws, would lay the groundwork for eliminating those certification requirements.

Facing outcry from professional credentialing organizations, the Louisiana Senate Commerce Committee has briefly delayed consideration of Louisiana House Bill 748 but is scheduled to take up the bill on May 9.

FDA Approves BLA for Procleix Ultrio Elite Assay

The Food and Drug Administration (FDA) approved the Biologics License Application (BLA) for the Procleix® Ultrio Elite Assay on the Panther System on May 3, 2018. This assay is a qualitative in vitro nucleic acid amplification test to screen for human immunodeficiency virus type 1 (HIV1), hepatitis C virus (HCV) RNA, and/or hepatitis B virus (HBV) DNA and to detect human immunodeficiency virus type 2 (HIV-2) RNA, in plasma and serum specimens from individual human donors, including donors of whole blood, blood components, and source plasma, and from other living donors. It is also intended for use in testing plasma and serum specimens to screen organ and tissue donors when specimens are obtained while the donor's

heart is still beating, and in testing blood specimens from cadaveric (non-heart beating) donors. This assay is not intended for use on cord blood specimens.

Cadaveric (non-heartbeating) donors must be tested using the individual donor testing method only. This assay is intended to be used in conjunction with licensed tests for detecting antibodies to HIV-1, HIV-2, HCV, and hepatitis B core antigen, and with licensed tests for hepatitis B surface antigen (HBsAg).