HHS Issues Guidelines For Organ Donor Screening

The Public Health Service has released a new guideline entitled: *PHS Guideline for Reducing HIV, HBV and HCV Transmission through Organ Transplantation*. This guideline supersedes the 1994 *PHS Guidelines for Preventing Transmission of Human Immunodeficiency Virus through Transplantation of Human Tissue and Organs*.

The major changes from the previous PHS guideline are:

- Expanding the guideline to include donor screening for both HBV and HCV, in addition to HIV.
- Recommendation for the use of new, more sensitive laboratory testing, including nucleic acid testing for living and deceased organ donors.
- Inclusion of a revised set of risk factors for HIV, HBV or HCV infection. Updated information about risk factors for these diseases can give clinicians a clearer picture about possible risks associated with donated organs to improve recipient informed consent, and in certain circumstances, to trigger more sensitive laboratory testing of the donor and recipients.
- Limiting the focus to organs and blood vessel conduits recovered for organ transplantation because the Food and Drug Administration (FDA) implemented more comprehensive regulations for human cell and tissue products.
- Recommendation for a robust informed consent discussion between the transplant candidate (or medical decision maker) and the clinician. With the availability of more sensitive tests, doctors and patients can have a more thorough discussion about potential risks and benefits associated with accepting and rejecting individual organs.

The updated guideline can be found at:

[http://www.publichealthreports.org/issueopen.cfm?articleID=2975](http://www.publichealthreports.org/issueopen.cfm?articleID=2975)
FDA Updates Listing of Licensed Donor Screening Tests

FDA recently updated their webpage entitled, *Testing HCT/P Donors for Relevant Communicable Disease Agents and Diseases*.  

AMA Calls for Reconsideration of MSM Blood Donor Deferral Policy

The American Medical Association voted to oppose the FDA’s lifetime deferral policy for blood donations by men who have sex with men, which is “discriminatory and not based on sound science,” AMA board member Dr. William Kobler said in a statement. “This new policy urges a federal policy change to ensure blood donation bans or deferrals are applied to donors according to their individual level of risk and are not based on sexual orientation alone.”

The FDA ban originated in 1983 in response to the AIDS outbreak, when little was known about the virus and gay men were more likely to have contracted the virus. HIV testing has become standard practice in blood donations to minimize risk to recipients. Currently, less than 38 percent of the U.S. population is eligible to give blood.

In 2010 the U.S. Department of Health and Human Services (HHS) created an advisory committee to discuss the policy. The Red Cross, America’s Blood Centers and AABB, released a joint statement advocating changing the policy to allow men, who have had sex with men, to donate blood as long as a certain amount of time has passed since their last sexual encounter. HHS submitted a request for information from additional studies on the potential outcomes of changing the blood donation criteria in 2012 and they are still evaluating the comments they received.

HIV Organ Policy Equity (HOPE) Act Approved by Senate

On June 17, the HIV Organ Policy Equity (HOPE) Act (S. 330), co-authored by Rep. Lois Capps, Rep. Andy Harris, Sen. Barbara Boxer and Sen. Tom Coburn, MD, passed the U.S. Senate by unanimous consent. This legislation will allow research on possible risks for people with HIV receiving organs transplants from donors who have HIV. The bill also guides the Secretary of Health and Human Services (HHS) to establish guidelines for the conduct of research relating to transplantation of organs from HIV-infected donors. This bill does not have any effect on cornea
donation but is definitely of interest in the organ donation community. The bill now heads to the House, where Rep. Lois Capps (D-Calif.) introduced a companion measure, H.R. 698.

To read more about this bill, visit: http://thehill.com/blogs/floor-action/senate/306087-senate-passes-bill-to-allow-research-on-organ-transplants-for-hiv-patients

**New Legislation Seeks to Narrow Gap Between ASCs and HOPDs**

The Ambulatory Surgical Center Quality and Access Act of 2013 was introduced in the US Senate by Ron Wyden (D-Oregon) and Mike Crapo (R-Idaho) on June 11 and is expected to be introduced into the House of Representatives next week.

The Act is intended to preserve patient access to care provided in ASCs and fix the disparity in current laws which allows CMS to use different measures of inflation for ASCs and hospital outpatient departments when setting rates. At this time, ASCs receive about 58% of the reimbursement afforded HOPDs. According to the Ambulatory Surgery Center Association who supports the Act, this will prevent procedures from migrating into more expensive HOPDs from ASCs. Specifically, the legislation does the following:

- Changes the current ASC update factor based on the Consumer Price Index – Urban (CPI-U) to the Hospital Market Basket Index;
- Establishes a Value-Based Purchasing Program that rewards ASCs that meet certain quality standards;
- Directs CMS to add a representative of the ASC community to be appointed to the Advisory Panel on Hospital Outpatient Payment (ASC payments are based on HOPD rates); and
- Creates transparency within the Medicare procedure approval process by requiring CMS to disclose which of six criteria triggers the exclusion of a procedure from the ASC approved list.

http://www.ascassociation.org/AboutUs/PressRoom/LegislationtoPromoteCostSavingsPatientAccesstoOutpatientSurgicalCareBackedbyASCA/
FDA Updates Their eHCTERS Instructions

FDA recently updated their webpage entitled, *Instructions for Completing the Electronic Human Cell and Tissue Establishment Registration Form*. Please note that the annual registration period begins November 15th and you must complete your annual registration by December 31st.


Economic Burden of Vision Loss

Prevent Blindness America (PBA) released their report "Cost of Vision Problems: The Economic Burden of Vision Loss and Eye Disorders in the United States." The PBA report ranks vision-related diseases as the fourth most common group of chronic diseases and estimates this group costs the United States **$139 billion** each year.

This landmark study updates their prior estimate in 2007, which found the economic burden of eye problems among Americans aged 40 and older to be approximately $51.4 billion in 2004. PBA expanded the analysis to include all disorders related to the eyes and ocular adnexa and children and adults younger than age 40. This report captures the costs of routine eye examinations and costs paid out of pocket or by vision insurance plans. National Opinion Research Center (NORC) estimates direct medical costs at $68.8 B (48%) and indirect costs (primarily productivity loss and long-term care) at $72.2 B (52%), emphasizes that the financial burden will continue to grow due to increasing healthcare costs and an aging population.

Access the report at:  [http://costofvision.preventblindness.org/](http://costofvision.preventblindness.org/)

Let Your Voice Be Heard in the Rulemaking Process

The U.S. Department of Health & Human Services has released the HHS Regulations Toolkit with tips on how you can participate in the rulemaking process. You can help shape regulations by commenting on the Department’s proposed rules published in the Federal Register. HHS has provided helpful tips for submitting effective public comments that clearly communicate and support your position.

Learn more at:  [http://www.hhs.gov/regulations/rulemaking-tool-kit.html](http://www.hhs.gov/regulations/rulemaking-tool-kit.html)
EHR Transition Ahead of Schedule

HHS announced that more than 50% of eligible professionals and more than 80% of eligible hospitals have adopted electronic health record (HER) systems as of the end of last month, compared with 17% of providers and 9% of hospitals in 2008.

Medicare and Medicaid give providers incentive payments for adopting EHRs and these figures were derived from the number of doctors and hospitals receiving these rewards by year. The data mean HHS has hit benchmarks originally set for the end of this year.

CDC Releases Patient Notification Toolkit

The Centers for Disease Control and Prevention (CDC) released a new toolkit to assist health departments and healthcare facilities with notifying patients after an infection control lapse or potential disease transmission during medical care. The toolkit includes the key strategies for patient notification letters and describes how to work with the media and stakeholders/partners.

Although the first section of the toolkit provides sample notification letters for unsafe injection practices, the risk communications principles and media relations sections would be applicable to eye banks performing recalls of corneal tissue.

Click here to access the toolkit: http://www.cdc.gov/injectionsafety/pntoolkit/index.html

FDA Solicits Comments on Biologics License Applications

The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of information relating to general licensing provisions for biologics license applications (BLAs), changes to an approved application, labeling, revocation and suspension, post-marketing studies status reports, and Forms FDA 356h and 2567.

FDA MedWatch Celebrates 20 Years

FDA commemorates the 20th anniversary of MedWatch, the Agency’s premier safety reporting system that helps consumers and health care providers report medical product problems to FDA and allows them receive new safety information from FDA. Additionally, FDA is pleased to announce the availability of two new tools:

- **MedWatchLearn** is a web-based learning tool designed to educate students, health professionals and consumers on reporting in a way that provides the best information for reviewers to further investigate medical product problems.
- **Form FDA 3500B** is a new consumer-friendly voluntary reporting form which contains less technical language than the existing 3500 form.

Please note that eye banks are considered HCT/P manufacturers and should complete the mandatory reporting form, not the voluntary reporting form designed for consumers.

FDA Urges Increased Vigilance Over Cyberthreats

The FDA has issued a safety alert recommending that medical device manufacturers and health care facilities take steps to assure that appropriate safeguards are in place to reduce the risk of failure due to cyber attack, which could be initiated by the introduction of malware into the medical equipment or unauthorized access to configuration settings in medical devices and hospital networks.


Benjamin To Resign As U.S. Surgeon General

U.S. Surgeon General Regina Benjamin said she will depart in July after four years in the position. She said she intends to volunteer at the rural health clinic she helped begin in Alabama.