

Hot Topics in Tissue Safety

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PHS Final Guideline

- *“PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation” (June 2013)*
 - For organ donation, supersedes *“Guidelines for Preventing Transmission of Human Immunodeficiency Virus through Transplantation of Human Tissue and Organs (May 1994)”*
 - No longer uses “high risk,” and expanded from ‘only HIV’
 - Includes 34 recommendations covering:
 - Risk assessment (**screening**) of living and deceased donors
 - Testing of living and deceased donors
 - Informed consent discussion with transplant candidates
 - Testing of recipients pre- and post-transplant
 - Collection and/or storage of donor and recipient specimens;
 - Tracking and reporting of HIV, HBV, and HCV

PHS Final Guideline

(Donor screening only – vs 1994 Guidelines)

- **Exhaustive**, systematic review of evidence to determine behaviors posing “increased risk” for recent infection with HIV, HBV, or HCV (GRADE, Evidence Report). Based on evidence, there are 11 criteria:
 - Removes two risks from 1994 guideline
 - Receipt of HDCFCs, and sex with someone who has
 - Adds one, specifically for HCV risk
 - On hemodialysis in the preceding 12 months
 - Updates one
 - Regarding “inmates of correctional systems”:
“People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the preceding 12 months” (matches terms used in *AATB Standards*)

PHS Final Guideline

(Donor screening only – vs 1994 Guidelines)

- Clarifies one (see slide 15)
 - People who have been newly diagnosed with, or have been treated for, syphilis, gonorrhea, *Chlamydia*, or genital ulcers in the preceding 12 months
- Uses “in the preceding 12 months” as a standard risk period.
 - These used to be “in the preceding 5 years” for MSM, IDU, sex for \$\$ or drugs, ~~receipt of HDCFCs~~
- Now defines “had sex” as “any method of sexual contact, including vaginal, anal, and oral contact”
 - This is the same language used in a preamble to questioning about sex on the “DRAI for a donor > 12 years old”; it’s also testing just fine (comprehension and otherwise)

PHS Final Guideline

(Donor screening only – vs 1994 Guidelines)

– Child donors

- Adds HBV & HCV risks to HIV risk for a child who is ≤ 18 months of age and born to a mother known to be infected or who is at an increased risk of infection

- Also, previously used < 18 months

- Risk related to breastfeeding remains only if born to a mother with or at risk for HIV infection, and if it occurred within the preceding 12 months

- addressed in AATB Standard **F1.100 Donor Suitability Review** this way:

“In the case of pediatric donors who have been breastfed within the past 12 months and/or are 18 months of age or less, the birth mother’s risk for transmissible disease shall be evaluated for HIV, HBV, HCV and other infectious agents when indicated. See Appendix II.”

(Appendix II describes if birth mother has or is at risk for any of these, the pediatric donor is excluded)

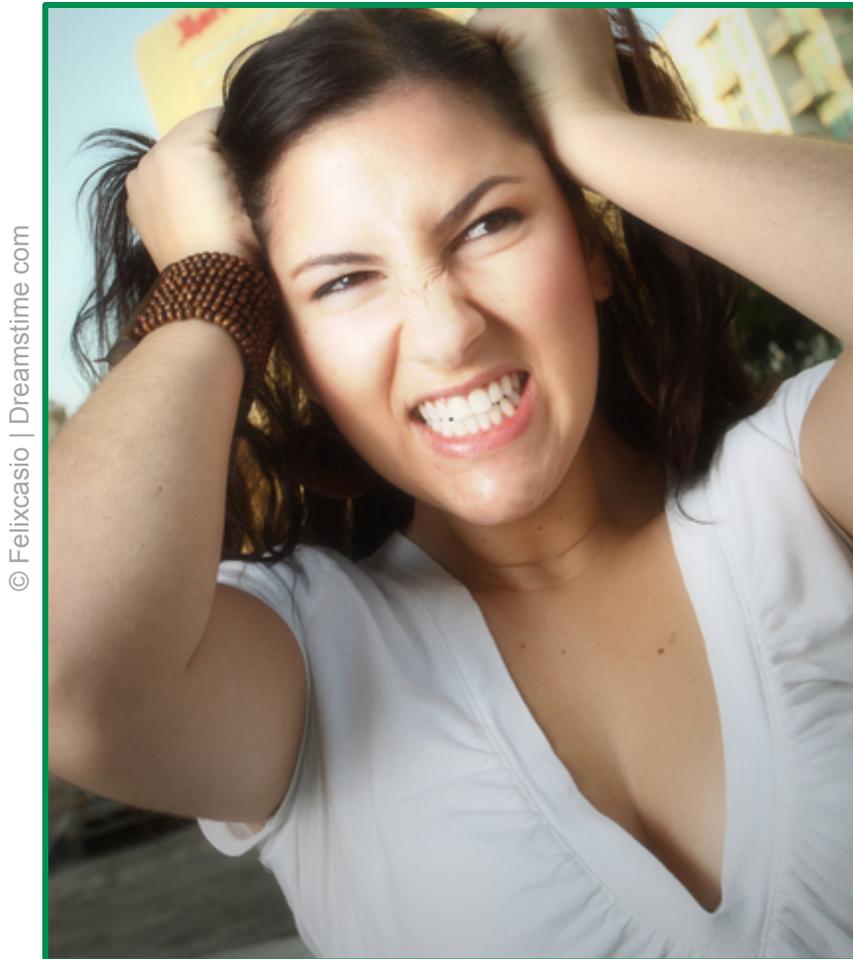
PHS Final Guideline

(Not used from 1994 Guidelines)

“Laboratory and Other Medical Exclusionary Criteria

3. Persons whose history, physical examination, medical records, or autopsy reports reveal other evidence of HIV infection or high-risk behavior, such as a diagnosis of AIDS, unexplained weight loss, night sweats, blue or purple spots on the skin or mucous membranes typical of Kaposi’s sarcoma, unexplained lymphadenopathy lasting >1 month, unexplained temperature >100.5 F (38.6 C) for >10 days, unexplained persistent cough and shortness of breath, opportunistic infections, unexplained persistent diarrhea, male-to-male sexual contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.”

“Organ” vs “Tissue” donor criteria differences promote confusion and mistakes. Especially the time periods attributed to risk behaviors...



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Questions are rolling in from tissue banking professionals at OPOs...

PHS Final Guideline

(vs FDA's HCT/P Donor Eligibility Guidance – Aug 2007)

Both identify these as “increased risk” for HIV, HBV, or HCV

FDA Tissue Donor

- 5 yrs
 - MSM
 - IDU
 - Sex for \$\$ or drugs
 - Receipt of HDCFCs (or once w/in 12 mos)
- 12 months
 - Sex with persons above (all 4)
 - Sex with any person who has HIV infection, including a positive or reactive test for HIV, hepatitis B infection, or clinically active (symptomatic) hepatitis C infection

PHS Organ Donor

- No 5-yr periods used
 - MSM (w/in 12 mos)
 - IDU (w/in 12 mos)
 - Sex for \$\$ or drugs (w/in 12 mos)
 - Receipt of HDCFC not increased risk
- 12 months
 - Sex with persons above (1st 3)
 - Sex with a person known or suspected to have HIV, HBV, or HCV infection

PHS Final Guideline

(vs FDA's HCT/P Donor Eligibility Guidance – Aug 2007)

Both identify these as “increased risk” for HIV, HBV, or HCV

FDA Tissue Donor

- 12 months
 - been in **juvenile detention**, lock up, jail or prison for more than 72 consecutive hour
 - been treated for or had syphilis within the preceding 12 months
 - (dialysis is not addressed)

PHS Organ Donor

- 12 months
 - been in lockup, jail, prison, or a **juvenile correctional facility** for more than 72 consecutive hours
 - Note: Matches AATB's Standards
 - been newly diagnosed with, or have been treated for, syphilis, **gonorrhea, Chlamydia, or genital ulcers**
 - Note: AATB's Standards cover syphilis and gonorrhea
 - been on hemodialysis

PHS Final Guideline

(vs FDA's HCT/P Donor Eligibility Guidance – Aug 2007)

Both identify these as “increased risk” for HIV, HBV, or HCV

FDA Tissue Donor

- 12 months
 - been exposed in the preceding 12 months to known or suspected HIV, HBV, and/or HCV-infected blood through percutaneous inoculation (e.g., needle stick) or through contact with an open wound, non-intact skin, or mucous membrane
 - lived with (resided in the same dwelling) another person who has hepatitis B or clinically active (symptomatic) hepatitis C infection

PHS Organ Donor

- 12 months
 - (these are not identified as increased risks)
 - (this is not identified as increased risk)

PHS Final Guideline

(vs FDA's HCT/P Donor Eligibility Guidance – Aug 2007)

Both identify these as “increased risk” for HIV, HBV, or HCV

FDA Tissue Donor

- 12 months
 - have undergone tattooing, ear piercing or body piercing in the preceding 12 months, in which sterile procedures were not used, e.g., contaminated instruments and/or ink were used, or shared instruments that had not been sterilized between uses were used

PHS Organ Donor

- 12 months
 - (these are not identified as increased risks)

PHS Final Guideline

(vs FDA's HCT/P Donor Eligibility Guidance – Aug 2007)

Both identify these as “increased risk” for HIV, HBV, or HCV

FDA Tissue Donor

- Persons who have had a past diagnosis of clinical, symptomatic viral hepatitis after their 11th birthday (Refs. 70 and 71), unless evidence from the time of illness documents that the hepatitis was identified as being caused by hepatitis A virus, Epstein-Barr Virus (EBV), or cytomegalovirus (CMV).

PHS Organ Donor

- (this is not identified as increased risk)

PHS Final Guideline

(vs FDA's HCT/P Donor Eligibility Guidance – Aug 2007)

Both identify these as “increased risk” for HIV, HBV, or HCV

FDA Tissue Donor

- HIV-1 Group O risk
 - Persons or their sexual partners who were born or lived in certain countries in Africa (Cameroon, Central African Republic, Chad, Congo, Equatorial Guinea, Gabon, Niger, or Nigeria) after 1977
 - Persons who have received a blood transfusion or any medical treatment that involved blood in the countries listed in criterion 27, after 1977
 - No need to screen if using donor screening test (Ab) with HIV-1 Grp O indication

PHS Organ Donor

- (these are not identified as increased risks)

PHS Final Guideline

(vs FDA's HCT/P Donor Eligibility Guidance – Aug 2007)

Both identify these as “increased risk” for HIV, HBV, or HCV

FDA Tissue Donor

- Children born to mothers (only refers to HIV risk)
 - If 18 months of age or younger, or
 - If breast-fed within the preceding 12 months

PHS Organ Donor

- A child born to a mother known to be infected with, or at increased risk for, HIV, HBV, or HCV infection
 - who is ≤ 18 months of age
 - AATB Standards agree (+)
- A child who has been breastfed within the preceding 12 months and the mother is known to be infected with, or at increased risk for, HIV infection
 - AATB Standards agree (+)