

Revisions to Policy 3.1.14 (PHS Guideline) to Require Use of Only the 2013 PHS Guideline for Medical-Social Evaluation

*Ad Hoc Disease Transmission
Advisory Committee*

*Dr. Michael Green, MD, MPH, Chair
November 11-12, 2013
Atlanta, GA*

Executive Committee Actions

Aug 27, 2013

- Defined “PHS Guideline” in OPTN Policy 3.1.14
- Housekeeping to change all references to PHS Guideline in current policy to this common term
- Approved temporary use of either the 1994 or 2013 Guideline for donor evaluation
 - Allows OPOs and living donor recovery centers time to train staff and update internal policies and processes.

Executive Committee Decision to Defer August 27, 2013

- Deferred an additional resolution to finalize a date to sunset option of using either guideline for donor evaluation, favoring full BOD discussion.
 - Immediate policy concerns that were causing confusion in the OPO and living donor community were addressed quickly
 - This decision left for broader BOD discussion during its standing November meeting

Proposed Modifications

- Eliminate the option to use either the 1994 or 2013 PHS Guideline for medical-social evaluation of deceased and living donors based upon increased risk behavior criteria
- Proposed effective date: February 1, 2014

Related Programming

- **Project Size = Demand Request**

- Does not require BOD prioritization (very small)
- Work already underway to update DonorNet[®] and donor forms to remove “high risk” label in favor of language provided below:

“According to the OPTN policy in effect on the date of referral, does the donor have risk factors for blood-borne disease transmission?”

Expected Benefits

New behavioral criteria in 2013 Guideline:

- Include Hepatitis B and C in addition to HIV
- Are more clearly defined for interviewing potential living donors or deceased donor family members
- Cover a time period more in line with window period infection

Overall, these modifications will allow for enhanced patient safety!

Comparing the Evaluation Criteria Questions

1994 Guidelines	2013 Guideline
<p><i>Behavior/History Exclusionary Criteria</i></p> <p><i>Specific Exclusionary Criteria for Ped Donors #1- (Children meeting any of the exclusionary criteria listed below for adults should not be accepted as donors)</i></p>	<p><i>Donors who meet one or more of the following 11 criteria should be identified as being at increased risk for recent HIV, HBV, and HCV infections. Each factor listed reflects increased risk of all 3 pathogens as an aggregate, as there is overlap of associated risk, even though each factor does not convey risk from all pathogens equally. The first six factors address sexual contact; the definition of "had sex" refers to any method of sexual contact, including vaginal, anal and oral contact:</i></p>
#5- Persons who have had sex in the preceding 12 months with any person described in items 1-4 or with a person known or suspected to have HIV infection	People who have had sex with a person known or suspected to have HIV, HBV, or HCV infections in the preceding 12 months
#1- Men who have had sex with another man in the preceding 5 years	MSM in the preceding 12 months
#5- Persons who have had sex in the preceding 12 months with any person described in items 1-4 or with a person known or suspected to have HIV infection	Women who have had sex with a man with a history of MSM behavior in the preceding 12 months
#4- Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years	People who have had sex in exchange for money or drugs in the preceding 12 months
#5- Persons who have had sex in the preceding 12 months with any person	sex with a person who had money or drugs in the

A full side-by-side comparison on these questions is available on Transplant Pro.

Resolution 7 (page 25)

**** RESOLVED, that modifications to Policy 3.1.14 (PHS Guideline), as set forth in Exhibit B, are hereby approved, effective February 1, 2014.**

Policy Language

3.1.14 PHS Guideline. For requirements that reference the “PHS Guideline,” members must use ~~either the United States Public Health Service (PHS) *Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissues and Organs (1994)* or the PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation (2013)~~. For the purposes of the PHS Guideline, ~~“increased risk of disease transmission” is used interchangeably with “high risk.”~~ For each organ donor, ~~OPOs must document in the donor highlights section of DonorNet which set of guidelines it used to evaluate that particular donor.~~

Questions?

Thank you.