Alignment of OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV Through Solid Organ Transplantation

February 3, 2015
2:00-3:00 PM EST

Audio Information
Dial-in Number: (866) 901-6455
Access Code: 429-899-465
Audio PIN: Shown after joining the training

Reminders
Technical Difficulties
Citrix Global Support (800) 263-6317

Objectives
• By the end of today’s webinar, you will be able to:
  • Explain policy changes associated with risk assessment and screening of deceased and living donors
  • Describe new policy requirements for informed consent in recipients of increased risk donor organs
  • State new data collection and reporting requirements for tracking potential disease transmissions
  • Illustrate member actions that ensure compliance with the policy changes
Q & A Panel

Enter your questions here.

OPTN

Speakers

Daniel Kaul, MD
Lisa Stocks, RN, MSN, FNP
Cameron Wolfe, MD

Leslee Garland, RN, BS
Dianne LaPointe Rudow, APRN, BC, DNP, CCTC
Diana Marsh, RN, MSN

OPTN

Background

• OPTN
  • http://optn.transplant.hrsa.gov/learn/professional-education/other-topics/

• Transplant Pro
  • http://transplantpro.org/education/webinars/
OPTN Final Rule

• OPTN Final Rule §121.4 indicates the OPTN Board of Directors is responsible for developing policies that are consistent with recommendations of the Centers for Disease Control and Prevention to test potential organ donors and follow transplant recipients to prevent the spread of infectious disease.

Policy Changes

• Policy changes will:
  • Enhance patient safety
  • Improve recognition of increased risk of disease transmission
  • Impact living and deceased donors and all organ recipients
PHS Guideline Impact on Policy

- 31 PHS recommendations reviewed:
  - Covered by Final Rule?
  - Policy already in place?
  - Policy changes needed?
- Many recommendations already in policy or common practice

Focus of Policy Changes

- Risk assessment/screening of deceased and living donors
- Informed consent
- Pre- and post-transplant recipient testing
- Collection and storage of donor and recipient specimens
- Tracking and reporting of HIV, HBV and HCV

Policy Implementation

- Policies implemented February 1, 2015 with the exception of NAT testing
- NAT testing requirements will be implemented with programming later in 2015
- Labs, OPOs and Transplant Hospitals should work together ensure required testing is available at implementation
OPO Responsibilities

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Deceased Donor Procurement

• Policy 2.2: Collect and maintain donor blood specimens appropriate for serologic and nucleic testing (NAT) of HIV, HBV and HCV, as available
• Collection and storage of two blood specimens may be needed

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Ideas for Preparation

• CASD archives 2ml of plasma and serum, if both available
• Lab uses plasma first to balance the residual serum available for archive

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**Medical and Behavioral History**

- **Policy 2.4**: Donor is considered at increased risk for HIV, HBV and HCV infection when a deceased donor’s medical/behavioral history cannot be obtained or risk factors cannot be determined.

**Informing Personnel**

- **Policy 2.7B**: OPO must inform personnel of the positive HIV results when caring for such a donor only when necessary for making medical decisions.

**Infectious Disease Testing**

- **Policy 2.9**
  - Clarification of required donor screening for HBV
  - Requirement for testing by HCV NAT
  - Donor identified as increased risk - additional HIV testing is required
Compliance Monitoring

Policy 2.9: Infectious Disease

<table>
<thead>
<tr>
<th>Completion of the following tests:</th>
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<tbody>
<tr>
<td>HIV Ab donor screening or HIV Ag/Ab combination</td>
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<tr>
<td>HBcAb screening</td>
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<tr>
<td>HBsAg screening</td>
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<tr>
<td>HCV Ab screening</td>
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<tr>
<td>HCV RNA by NAT screening or diagnostic</td>
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<tr>
<td>CMV Ab screening or diagnostic</td>
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<tr>
<td>EBV Ab screening or diagnostic</td>
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<tr>
<td>Syphilis screening or diagnostic</td>
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<table>
<thead>
<tr>
<th>Completion of additional HIV test for increased risk donors:</th>
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</thead>
<tbody>
<tr>
<td>NEW HIV RNA by NAT screening</td>
</tr>
<tr>
<td>HIV RNA by NAT diagnostic</td>
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<tr>
<td>HIV Ag/Ab combination test</td>
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Transmissible Disease Screening Requirements for Living Donors
Policy 14.4B: Testing performed at CLIA-certified lab or a lab meeting equivalent using FDA-licensed, approved or cleared tests

Requirements:
- HIV Ag/Ab combination test or HIV Ab test
- Addition of HCV RNA by NAT
- Change to syphilis testing where RPR no longer the only option for syphilis testing
- All HIV, HBV, HCV testing completed as close to and within 28 days before organ recovery

Policy 14.4B: If a living donor is at increased risk for HIV, HBV and HCV transmission:
- HIV RNA by NAT (screening or diagnostic) or
- HIV Ag/Ab combination test

Policy 14.4B: If tuberculosis risk is suspected, testing must include screening for latent infection using:
- Intradermal PPD or
- Interferon Gamma Release Assay (IGRA)
**Compliance Monitoring**

**Policy 14.4.B: Medical Evaluation**

Completion of the following tests:
- HIV Ab or HIV Ag/Ab combination*  
- HBsAg*  
- HBeAb*  
- HCV RNA by NAT*  
- HCV Ab*  
- Syphilis  
- EBV Ab  

Additional HIV test for increased risk donors:
- HIV RNA by NAT  
- HIV Ag/Ab combination test

* As close as possible but within 28 days prior to organ recovery

**Q & A Session**

Enter your questions here.
Panelists

Daniel Kaul, MD  Lisa Stocke, RN, MSN, FNP  Leslee Garland, RN, BS  Cameron Wolfe, MD

Dianne LaPointe Rudow, APN-BC, DNP, CCTC  Diana Marsh, RN, MSN  Shandie Covington  Leah Slife

Informed Consent of Transmissible Disease Risk

Poll
Informed consent of transmissible disease risk
Now applies to all deceased and living donors

Living Donor: Informed Consent

Living donor infectious disease risk
Donor may opt out at any time
Disclose to recipient transplant hospital

Transmissible Disease Risk

Informed consent must be obtained before transplant when any of the following occurs:
- Donor has a known medical condition that may be transmissible to the recipient
- Known HIV transmission risk
- Donor meets any of the criteria for increased risk of transmitting HIV, HBV, or HCV
- Hemodiluted specimen is used for donor HIV, HBV, or HCV screening
**Additional Risks – Pre-transplant**

- **Policy 15.3.A:** transplant program must discuss with the recipient additional donor disease risks
  - Explain risks and obtain informed consent
  - Document consent in the recipient’s medical record
  - Follow the recipient for development of potential donor-derived disease after transplant

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**Additional Risks – Post-transplant**

- **Policy 15.3B:** develop and implement a written protocol for post-transplant testing of recipients of increased risk donor organs
  - HIV, HBV and HCV

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**Policy 16.7B: Vessel Storage**

- Extra vessels **may not** be stored from donors who are:
  - HCV Ab positive
  - HBsAg positive
  - HCV NAT positive
  - HBV NAT positive

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Compliance Monitoring

Policies 15.3 and 16.7.B

15.3: Informed Consent
- Sample of recipient records for documentation
- Donor meets any of the PHS criteria for increased risk of HIV, HBV or HCV

16.7.B: Vessel Storage
- Review of internal policies, protocols or procedures or interview key personnel to address:
  - HCV Ab or HCV NAT positive vessels are not stored
  - HBsAG or HBV NAT positive vessels are not stored

Data Collection Changes
- Three new fields added for HIV, HCV and HBV NAT results in:
  - DonorNet®
  - Tiedi®
Q & A Session

Enter your questions here.

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Resources

- 2013 PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation
- A reference handout of articles pertaining to discussion of the 2013 PHS Guideline recommendations
- Frequently Asked Questions: 2013 PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through Organ Transplantation

http://optn.transplant.hrsa.gov/  
http://transplantpro.org/
Resources

- Applying the 2013 PHS Guideline for Reducing HIV, HBV, and HCV Transmission through Organ Transplantation to Donor Evaluations recording
- Guidance for Reporting Potential Donor-Derived Disease Transmission Events
- Guidance for Identifying Risk Factors for Mycobacterium tuberculosis (MTB) During Evaluation of Potential Living Kidney Donors
- OPTN Policy and Evaluation Plan

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http://transplantpro.org/

Contacts

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Instructional Innovations (educational questions) education@unos.org

Evaluation and Assessment

- Take the credit assessment to qualify for one CEPTC point:
- The assessment will close: August 3, 2015.