2013 Public Health and Safety Guidelines for reducing HIV, HBV and HCV Transmission Though Organ Transplantation: Implications for Counseling and Disclosure

Dianne LaPointe Rudow DNP, ANP-BC, CCTC
Director of The Zweig Family Center for Living Donation
Associate Professor of Health Evidence and Policy
Recanati Miller Transplantation Institute
Mount Sinai Medical Center
New York, New York
Dianne.LaPointeRudow@mountsinai.org
Objectives

• Discuss what the new Public Health and Safety Guidelines for reducing HIV, HBV and HCV Transmission Though Organ Transplantation mean for the donor evaluation
• Describe the elements of PHS screening
• Identify what and when testing needs to be disclosed
• Describe best strategies for donor counseling on PHS guidelines
Current Infectious Disease Screening for the Live Organ Donor

- CMV (Cytomegalovirus) Antibody
- EBV (Epstein Barr Virus) Antibody
- HIV 1,2 (Human Immunodeficiency Virus) antibody testing
- HepBsAg (Hepatitis B surface antigen)
- HepBcAB (Hepatitis B core antibody)
- HepBsAB (Hepatitis B surface antibody) recommend removal
- HCV (Hepatitis C Virus) antibody testing
- Syphilis testing
- TB screening
- Testing for diseases prevalent in endemic areas (Chagas, Strongyloides, West Nile)

- Infectious disease risk assessment
- Should be at least as comprehensive as screening of a deceased donor
- Utilize FDA approved tests when available
- NAT testing considered
What are the PHS Guidelines?

- On June 19, 2013 the PHS Guidelines for reducing HIV, HBV and HCV through organ transplantation was released by HRSA, CDC.
- It supersedes the 1994 PHS Guideline for preventing HIV transmission through transplant (Old CDC High risk criteria).
- Expands old guidelines to include HBV and HCV.
- Uses updated factors known to be associated with increased likelihood of transmitting infection.
- Limits focus to organs and blood vessel conduits recovered for transplant not human cell and tissue products.
- Related to adult and pediatric donors, living and deceased as well as transplant candidates and recipients.
- Does NOT assess infection beyond HIV, HBV, and HCV.
- Goal: to provide Guidance to OPO personnel, transplant centers (MDs, RNs, administrators, lab personnel,) and those developing and implementing infection control programs.
- Input was sought from Public and private health professionals over a few years.
Methodology and Reporting

- PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation

- [http://www.publichealthreports.org/issueopen.cfm?articleID=2975](http://www.publichealthreports.org/issueopen.cfm?articleID=2975)
Areas of Questions for Systematic Review

<table>
<thead>
<tr>
<th>Major topic area of the guideline</th>
<th>Question for systematic review</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Probability of transmission of HIV, HBV, or HCV through organ transplantation</td>
<td>1. What are the prevalence and incidence rates of HIV, HBV, and HCV among potential organ donors?</td>
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<tr>
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<td>2. What are the rates of transmission to recipients from donors infected with HIV, HBV, or HCV? Do the rates vary by the organ transplanted or when the donor was infected?</td>
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<td></td>
<td>3. What behavioral risk factors are associated with an increased probability of infection with HIV, HBV, or HCV? What is the prevalence of these characteristics among potential organ donors?</td>
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<tr>
<td></td>
<td>4. What nonbehavioral factors are associated with an increased probability of infection with HIV, HBV, or HCV? What is the prevalence of these factors among potential organ donors?</td>
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<td></td>
<td>5. What are the test characteristics of the screening methods available to detect HIV, HBV, and HCV in potential organ donors? Do test characteristics differ in particular populations and with donor clinical status (i.e., donation after brain death vs. donation after cardiac death OR adult vs. pediatric donors)?</td>
</tr>
<tr>
<td>II. Methodology to better estimate donor infection with HIV, HBV, or HCV</td>
<td>6. Which donor interventions reduce the probability of pathogen transmission from an organ donor infected with HIV, HBV, or HCV to a previously uninfected recipient?</td>
</tr>
<tr>
<td>III. Donor interventions to decrease transmission of HIV, HBV, or HCV from infected donors</td>
<td>7. How do the clinical outcomes of recipients of organs from donors infected with HIV, HBV, or HCV compare with those who remain on the transplant list?</td>
</tr>
<tr>
<td>IV. Potential risks and benefits of transplanting, or not transplanting, organs from donors positive for HIV, HBV, or HCV</td>
<td>8. How do the clinical outcomes of transplant recipients who receive organs from donors with behavioral or nonbehavioral risk factors compare with those who remain on the transplant list?</td>
</tr>
<tr>
<td>V. Potential risks and benefits of transplanting, or not transplanting, organs from donors with risk factors for HIV, HBV, or HCV</td>
<td>9. What is the impact of excluding potential organ donors with behavioral or nonbehavioral risk factors on the organ donor pool?</td>
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<tr>
<td></td>
<td>10. What is the impact of false-positive tests on the organ donor pool?</td>
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</table>
Areas of focus for the Guidelines

- Risk factors for recent infection
- Risk assessment (screening) of live (LD) and deceased donors (DD)
- Testing of LD and DD
- Informed consent discussions with transplant candidates
- Testing of recipients pre and post transplant
- Collection and storage of donor and recipient specimens
- Tracking and Reporting of HIV, HBV, HCV transmissions
- Recommendations for further study
Behavioral and non behavioral risk factors

varying degree of risk

<table>
<thead>
<tr>
<th>Type of infection</th>
<th>Behavioral characteristics</th>
</tr>
</thead>
</table>
| HIV               | • MSM
                  • IDU
                  • Non-injection illicit drug use
                  • Multiple sex partners
                  • Sex with partner known to be HIV-infected
                  • Age ≤18 years at first sexual intercourse |
| HBV               | • MSM
                  • IDU
                  • Multiple sex partners |
| HCV               | • IDU
                  • Non-injection illicit drug use
                  • Multiple sex partners
                  • Sex worker
                  • Inmates
                  • Age ≤18 years at first sexual intercourse
                  • Sex with partner known to be HCV-infected
                  • Sex with an injection drug user
                  • Tattooing performed by nonprofessional |

<table>
<thead>
<tr>
<th>Type of infection</th>
<th>Nonbehavioral characteristics</th>
</tr>
</thead>
</table>
| HIV               | • STD
                  • Marital status |
| HBV               | • Hemodialysis
                  • STD
                  • Marital status |
| HCV               | • Hemodialysis
                  • Receipt of blood transfusion
                  • Signs and symptoms (i.e., jaundice, elevated ALT)
                  • STD
                  • Marital status |
## Screening Guidelines

<table>
<thead>
<tr>
<th>Behavior/History Exclusionary Criteria</th>
<th>1994 Guidelines</th>
<th>2013 Guideline</th>
</tr>
</thead>
<tbody>
<tr>
<td>People 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</td>
<td>People who have had sex with a person described in items 1-4 or with a person known or suspected to have HIV infection</td>
<td>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:</td>
</tr>
<tr>
<td>Men who have had sex with another man in the preceding 5 years</td>
<td>MSM in the preceding 12 months</td>
<td></td>
</tr>
<tr>
<td>People 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</td>
<td>Women who have had sex with a person with a history of MSM behavior in the preceding 12 months</td>
<td></td>
</tr>
<tr>
<td>Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years</td>
<td>People who have had sex in exchange for money or drugs in the preceding 12 months</td>
<td></td>
</tr>
<tr>
<td>People 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</td>
<td>People who have had sex with a person who has sex in exchange for money or drugs in the preceding 12 months</td>
<td></td>
</tr>
<tr>
<td>People who have had sex in the preceding 12 months with a person that has injected drugs by IV, IM, or subQ route for nonmedical reasons in the preceding 12 months</td>
<td>A child who is &lt;18 months of age and born to a mother known to be infected with, or at increased risk for HIV, HBV, or HCV infections</td>
<td></td>
</tr>
</tbody>
</table>

**Specific Exclusionary Criteria for Ped Donors #2-** Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory exclusionary criteria for adult donors (regardless of HIV status) should not be accepted as donors unless HIV infection can be definitely excluded in the child as follows:

Children >18 months of age who are born to mothers with or at risk for HIV infection, who have not been breastfed within the last 12 months, and whose HIV Ab tests, physical exam, and review of medical records don’t indicate evidence of HIV infection can be accepted as donors.
**Screening Guidelines**

**Specific Exclusionary Criteria for Ped Donors #3-**
Children ≤18 months of age who are born to mothers with or at risk for HIV infection or who have been breastfed within the past 12 months should not be accepted as donors regardless of their HIV status

| #2- Persons who report nonmedical IV, IM, or subQ injection of drugs in the preceding 5 years | People who have injected drugs by IV, IM, or subQ route for nonmedical reasons in the preceding 12 months |
| #7- Inmates of correctional systems. (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population.) | People who have been in lockup, jail, prison, or a juvenile correctional facility for more than 72 hours in the preceding 12 months |

**Laboratory and Other Medical Exclusionary Criteria #3-** Persons whose history, physical exam, 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, MSM contact, sexually transmitted diseases, or needle tracks or other signs of parenteral drug abuse.

| #3-People who have been newly diagnosed with or have been treated for syphilis, gonorrhea, Chlamydia, or genital ulcers in the preceding 12 months |
| #6- Person who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane. |

**NEW**

| #3-People who have been newly diagnosed with or have been treated for syphilis, gonorrhea, Chlamydia, or genital ulcers in the preceding 12 months |

**Laboratory and Other Medical Exclusionary Criteria**

| #1- Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g. hemodilution that could result in a false negative test), or any other reasons |

| #2- Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 Ab regardless of the result of supplemental assays. |

| Donors who meet the following criterion should be identified as being at increased risk for recent HCV infection only: People who have been on hemodialysis in the preceding 12 months |
| #6- Person who have been exposed in the preceding 12 months to known or suspected HIV-infected blood through percutaneous inoculation or through contact with an open wound, nonintact skin, or mucous membrane. |

| Not addressed specifically in 2013 med-soc criteria |
| Not addressed specifically in 2013 med-soc criteria |

| Hemodilution specifically addressed in Recommendation 5b |
Assessment of Live Donors

1. Have you had sex with a person known or suspected to have HIV, HBV, or HCV infection in the preceding 12 months? Yes   No
2. Are you a Man who has had sex with men (MSM) in the preceding 12 months? Yes No
3. Are you a woman who has had sex with a man with a history of MSM behavior in the preceding 12 months? Yes No
4. Have you sex in exchange for money or drugs in the preceding 12 months? Yes No
5. Have you sex with a person who had sex in exchange for money or drugs in the preceding 12 months? Yes No
6. Have you sex with a person who injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months? Yes No
7. Have injected drugs by intravenous, intramuscular, or subcutaneous route for nonmedical reasons in the preceding 12 months? Yes No
8. Have you been in lockup, jail, prison, or a juvenile correctional facility for more than 72 consecutive hours in the preceding 12 months? Yes No
9. Have you been newly diagnosed with, or have been treated for, syphilis, gonorrhea, *Chlamydia*, or genital ulcers in the preceding 12 months? Yes No
Individual Programmatic Approach to Assessment

- The donor evaluation is invasive on multiple levels
  - PHS increased risk screening is part of the psychosocial evaluation
  - PHS increased risk screening is part of the medical evaluation
  - Developing a relationship with the donor is critical for a truthful bi-directional interaction

- Documentation in the medical record is required and audited by program surveyors
  - Keeping records confidential is important

- Approach varies
  - Define “SEX”
  - Interview
  - Questionnaires and discussion
  - Signed document attesting to low risk
  - Method to consent to disclose behavior

- Risk assessment determines testing
**Figure 5. Living potential organ donor test recommendations based on risk status for HIV, HBV, and HCV infection**

<table>
<thead>
<tr>
<th>All donors</th>
<th>Additional testing when a risk factor is identified</th>
<th>Timing of test</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibodies to HIV (i.e., anti-HIV 1/2 or HIV Ag/Ab combination assay)</td>
<td>HIV NAT or HIV antigen (e.g., HIV Ag/Ab combination assay)</td>
<td>As close as possible to the date of the donor operation, but at least within the 28-day time period prior to surgery</td>
</tr>
<tr>
<td>Anti-HCV and HCV NAT</td>
<td>No additional testing</td>
<td></td>
</tr>
</tbody>
</table>
Recommended Testing for Recipient of PHS Increased Risk Donor

Figure 6. Pre- and posttransplant recipient test recommendations when a donor is at increased risk for HIV, HBV, or HCV infection; the donor’s risk for HIV, HBV, and HCV infection is unknown; or the donor is infected with HCV or HBV.

<table>
<thead>
<tr>
<th>Pre-transplant test</th>
<th>Timing of pre-transplant test</th>
<th>Posttransplant test</th>
<th>Timing of posttransplant test</th>
</tr>
</thead>
<tbody>
<tr>
<td>No recommendation on type of assay</td>
<td>During hospital admission for the organ transplant, but prior to organ implantation</td>
<td>HIV NAT or HIV Ag/Ab combination assay</td>
<td>1–3 months</td>
</tr>
<tr>
<td></td>
<td></td>
<td>HCV NAT</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>HBV NAT and HBsAg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anti-HBs, anti-HBc, and either HBV NAT or HBsAg</td>
<td>At 12 months</td>
</tr>
</tbody>
</table>
Implication for Policy Changes

- PHS document are guidelines
- The Final Rule notes that the OPTN Board of Directors is responsible for developing policies that are consistent with recommendations of the Centers for Disease Control and Prevention (CDC) to test potential organ donors and following transplant recipients to prevent the spread of infectious disease.
- Currently, policy requirements don’t fully align with the new Guideline’s recommendations
- OPTN Task force (Living Donor Committee, OPO Committee, Operations and Safety Committee, four professional societies and DTAC) developed proposal out for public comment to modify some existing policy language and also create new policies to reflect recommendations outlined in PHS document.
- Goal: to promote transplant patient safety, increase capacity to identify patient safety issues, and ultimately, increase the number of transplants by improving donor screening requirements.
OPTN: policy addresses:

- All potential LDs should be informed of the donor evaluation process, including the review of medical and behavioral history, physical examination, and laboratory tests to identify the presence of infectious agents or medical conditions that could be transmitted by organ transplantation.
- LD should be interviewed in a confidential manner about behaviors that may have increased the potential donor’s probability of having HIV, HBV, or HCV infection.
- LDs with behaviors associated with an increased risk of acquiring HIV, HBV, or HCV identified during evaluation should receive individualized counseling on specific strategies to prevent exposure to these viruses during the time period prior to surgery.
- All living potential donors should be tested for HIV, HBV, and HCV as close as possible to the date of the organ recovery operation, but at least within the 28-day time period prior to surgery.
- When organs from HBV or HCV infected donors will be used, the transplant team care should have an informed consent discussion with the transplant candidate, or medical decision maker, prior to transplantation regarding the risks related to disease transmission. (This includes HBV core positive)
- Post transplant testing of recipients should be conducted when the live donor is identified as being at increased risk for HCV infection.
- When a living LD recovery center receives information before organ recovery that a potential LD is infected with HIV, HBV, or HCV, the living donor recovery center should notify the transplant center intended to receive the organ, public health authorities, the OPTN and the LD.

- LD should be given the option to OPT out prior to disclosure to recipient and OPTN
  - Role for Physicians, Nurse, Psychosocial Personnel and the ILDA
Implications for Donor Education, Testing and Counseling

- Donors need to be assessed for increased risk
  - Difficult to discuss
  - Honesty
  - Interventions to minimize future risk

- Testing
  - Multiple visits
  - False positive results
  - Testing errors

- Disclosure
  - If you can perform NAT testing must you disclose?
  - Does recipient rights take precedence over donor

- Relationship
  - What impact will disclosure have on the donor recipient relationship
  - Is there ever a time when disclosure is more risky that to disclose
  - Options available to preserve relationships
  - Will this result in less donors willing to donate
Case Studies

26 year old male whose father is in need of a kidney transplant. He is medically cleared.

- Social history: Single homosexual male in a monogamous relationship. He has not disclosed to his parents his sexual orientation
- Are you a Man who has had sex with men (MSM) in the preceding 12 months? Yes
- Implications:
  - Testing
  - Counseling
  - Disclosure
  - Abstinence

37 year old female who wants to donate to her sister. Medically cleared for donation

- Social history: married for 12 years has two children works as a secretary
- Spouse is a salesman who travels two weeks out of the month, their relationship has been strained at this time. Team notes spouse to be quite flirtatious.
- PHS Questions 1 -9 No
- Implications:
  - Testing
  - Counseling
  - Disclosure
  - Abstinence
Resource available on OPTN website
Summary

- PHS Guidelines are available to assist transplant programs to determine who is at increased risk for HIV, HBV, HCV.
- Risk assessment and testing of the donor is critical for donor safety and reduction of transmission of disease.
- Live donor teams need to be mindful of the confidentiality and disclosure issues that can affect the donor should they be determine to be at increased risk.