

At-a-Glance

- **Proposal to Require Transplant Centers to Inform Potential Recipients about Known High Risk Donor Behavior.** (Proposed Revisions to Policy 4.0 - Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Recipient Diseases Or Medical Conditions, Including Malignancies, of Donor Origin)
- **Sponsoring Committee:** OPTN/UNOS Executive Committee
- Following the transmission of HIV from an organ donor to four transplant recipients, HRSA tasked UNOS staff with reviewing current policy to determine if there are any opportunities to further protect transplant recipients from transmission of HIV.
- **Affected groups**
All transplant professionals including OPO and transplant center personnel, as well as the general public, transplant recipients, transplant candidates, and donor family members .

Proposal to Require Transplant Centers to Inform Potential Recipients about Known High Risk Donor Behavior. (Proposed Revisions to Policy 4.0 - Acquired Immune Deficiency Syndrome (AIDS), Human Pituitary Derived Growth Hormone (HPDGH), and Reporting of Potential Recipient Diseases Or Medical Conditions, Including Malignancies, of Donor Origin)

Sponsoring Committee: OPTN/UNOS Executive Committee

Summary and Goals of the Proposal:

In December 2007, the Executive Committee approved policy language to require that transplant centers inform potential organ recipients about any known high risk behavior (as defined by CDC Guidelines) by the donor. This policy was approved prior to public comment to address potential patient safety issues. While this policy is currently in effect, the Executive Committee is seeking comment and will reconsider policy language during its June 2008 Board of Directors meeting. The intent of this policy is to clarify the criteria for high risk behavior that requires transplant professionals to notify potential organ recipients prior to implantation.

Background and Significance of Proposal:

In response to a recent disease transmission event, current policy was reviewed to determine if there were opportunities to further protect transplant recipients. Current policy requires communication between the Host OPO and transplant centers regarding any high risk behavior as defined by the CDC Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. Current policy, however, does not require that this information be communicated to potential organ recipients. Additionally, while the policy specifically cites the CDC guidelines, there is considerable variation in the level of knowledge and practice of the specific criteria by organ placement personnel.

The proposed policy modifications are intended to *clearly* identify the criteria for high risk that the Host OPO must communicate to transplant centers receiving organ offers. The modifications are also intended to close the communication gap by requiring transplant centers, when they are notified by the Host OPO that the donor meets one or more of the criteria, to share this information with any potential recipient prior to implantation. Decisions about whether to accept organs from donors who meet one or more of the CDC high risk criteria must continue to be made by transplant professionals and potential recipients through a shared decision-making process on a case by case basis. This policy only intends to:

- require an informed consent process when an organ donor meets high risk criteria as defined by the CDC;
- clarify what information must be communicated during the informed consent process; and
- require documentation of the informed consent process.

The proposed modifications to Policy 4.0 were discussed and approved by the OPTN/UNOS Executive Committee during its December 18, 2007 meeting. Committee members agreed that the modifications would strengthen the current requirements for the informed consent for transplant candidates regarding high risk donors. The Executive Committee approved the proposed Policy modifications which were made effective pending notice to OPTN members. The Executive Committee also

determined at that time to circulate these policy modifications for public comment. The modifications will be reconsidered by the OPTN/UNOS Board of Directors in June 2008.

Supporting Evidence and/or Modeling:

While the CDC guidelines were written in 1994, they remain the only evidence-based guidelines that address preventing transmission of HIV through organ donation. To eliminate confusion among organ placement personnel regarding what constitutes “high risk” and for the purpose of OPTN member convenience, UNOS Staff recommend that the specific criteria be placed directly into Policy 4.0. Some minor adjustments to the criteria were necessary including:

- Removing the reference to autopsy records in (Laboratory and Other Medical Exclusionary Criteria #3).
- Removing all references to “exclusionary” and “should not donate”. This policy is not intended to say that these donors should not be donate. Rather, this policy is saying that potential recipients must be informed if the donor meets any of the CDC’s criteria.

The CDC high risk organ donor guidelines and supporting evidence document can be found at the following link: <http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm>.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The proposed policy modifications support the following OPTN requirements as set forth in the Final Rule regarding HIV and communicable disease communication and prevention:

- Sec. 121.6 Organ procurement.

The suitability of organs donated for transplantation shall be determined as follows:

- (a) Tests. An OPTN member procuring an organ shall assure that laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN.
- (b) HIV. The OPTN shall adopt and use standards for preventing the acquisition of organs from individuals known to be infected with human immunodeficiency virus.

- Sec. 121.4 OPTN policies: Secretarial review and appeals.

- (a) The OPTN Board of Directors shall be responsible for developing, with the advice of the OPTN membership and other interested parties, policies within the mission of the OPTN as set forth in section 372 of the Act and the Secretary's contract for the operation of the OPTN, including:

- (1) Policies for the equitable allocation of cadaveric organs in accordance with Sec. 121.8;
- (2) Policies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases;

Plan for Evaluating the Proposal:

UNOS staff will request documentation from OPOs and Transplant Centers for donors who meet the criteria defined by the Centers for Disease Control and Prevention as “high risk” and included in OPTN Policy 4.1.1. UNOS staff will review the documentation to ensure:

- the OPO communicated the donor’s history to all transplant centers that received organs from that donor; and
- the transplant center obtained informed consent from the recipient, legal next of kin, designated healthcare representative, or appropriate surrogate prior to implantation of the organ.

UNOS staff will forward any potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee for review and potential action.

Expected Implementation Plan:

This policy change does not require programming in UNetsm.

Communication/Education Plan:

If additional modifications to this policy are made following public comment and approved by the Board of Directors, the transplant community will receive this information through a Policy Notice.

Monitoring and Evaluation:

In order to comply with these modifications OPOs are expected to:

- Obtain a donor history for each potential donor
- Evaluate each donor’s history to determine if the donor is high risk according to the criteria identified by the Centers for Disease Control and Prevention (CDC) and included in OPTN Policy 4.1.1
- Inform each transplant center that the donor is high risk according to the CDC criteria when the donor’s history includes any of the criteria outlined in OPTN Policy 4.1.1
- Indicate that the donor meets the CDC definition of high risk in DonorNet[®]
- Maintain documentation that the donor’s history has been communicated to the transplant center

In order to comply with these modifications transplant centers are expected to:

- Be familiar with the criteria defined by the CDC, and included in OPTN Policy 4.1.1, that places a donor in a high risk group for transmitting HIV through transplantation
- Inform the potential recipient, legal next of kin, designated healthcare representative, or appropriate surrogate that the donor is in a high risk group, as defined by the CDC, prior to implantation of an organ

- Obtain and document informed consent from the potential recipient, legal next of kin, designated healthcare representative, or appropriate surrogate prior to implantation when the organ is from a donor who meets the CDC definition of high risk
- Maintain all documentation pertaining to communication of donor history and informed consent, and make this documentation available upon request

Policy Proposal:

4.0 ACQUIRED IMMUNE DEFICIENCY SYNDROME (AIDS), HUMAN PITUITARY DERIVED GROWTH HORMONE (HPDGH), AND REPORTING OF POTENTIAL RECIPIENT DISEASES OR MEDICAL CONDITIONS, INCLUDING MALIGNANCIES, OF DONOR ORIGIN

4.1 SCREENING POTENTIAL ORGAN DONORS FOR HIV. All potential donors are to be tested by use of a screening test licensed by the U.S. Food and Drug Administration (FDA) for Human Immune Deficiency Virus (HIV). If the potential donor's pre-transfusion test for HIV is negative and blood for subsequent transfusions has been tested and found to be negative for HIV, retesting the potential donor for HIV is not necessary. If no pre-transfusion sample of the potential donor's blood is available, the Host OPO (as defined in Policy 2.1) must provide, to the recipient transplant center the screening test results and a complete history of all transfusions received by the donor during the ten (10) day period immediately prior to removal of the organ. Organs from donors with a positive screening test are not suitable for transplantation unless subsequent confirmation testing indicates that the original tests' results were falsely positive for HIV. If additional tests related to HIV are performed, the results of all tests must be communicated immediately to the Organ Center and all institutions receiving organs from the donor. Exceptions for cases in which the testing cannot be completed prior to transplant are provided in paragraph 4.1.3 below.

4.1.1 Communication of Donor History. The Host OPO will obtain a history on each potential donor in an attempt to determine whether the potential donor is in a "high risk" group, as defined by the Centers for Disease Control and Prevention (CDC). If the donor meets the criteria below,¹ the Host OPO must communicate this information regarding donor history to all institutions receiving organs from the donor.

Behavior/History Criteria

- i) Men who have had sex with another man in the preceding 5 years.
- ii) Persons who report nonmedical intravenous, intramuscular, or subcutaneous injection of drugs in the preceding 5 years.
- iii) Persons with hemophilia or related clotting disorders who have received human derived clotting factor concentrates.

¹ Rogers MF, Simonds RJ, Lawton KE, et al. Guidelines for Preventing Transmission of Human Immunodeficiency Virus Through Transplantation of Human Tissue and Organs. CDC MMWR Recommendations and Reports. 1994;May 20/ 43(RR-8):1-17. <http://www.cdc.gov/mmwr/preview/mmwrhtml/00031670.htm>

- iv) Men and women who have engaged in sex in exchange for money or drugs in the preceding 5 years.
- v) Persons who have had sex in the preceding 12 months with any person described in terms i-iv above or with a person known or suspected to have HIV infection.
- vi) Persons 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.
- vii) Inmates of correctional systems (This exclusion is to address issues such as difficulties with informed consent and increased prevalence of HIV in this population).

Pediatric Donor Criteria

- viii) Children meeting any of the criteria listed above for adults.
- ix) Children born to mothers with HIV infection or mothers who meet the behavioral or laboratory criteria for adult donors (regardless of their HIV status) unless they are greater than 18 months of age, have not been breast fed within the last 12 months and the child's antibody tests, physical examination, and review of medical records do not indicate evidence of HIV infection.
- x) Children less than or equal to 18 months of age who are born to mothers with or at risk for HIV infection or who have been breast fed within the past 12 months.

Laboratory and Other Medical Criteria

- xi) Persons who cannot be tested for HIV infection because of refusal, inadequate blood samples (e.g., hemodilution that could result in false-negative tests), or another other reasons.
- xii) Persons with a repeatedly reactive screening assay for HIV-1 or HIV-2 antibody regardless of the results of supplemental assays.
- xiii) Persons whose history, physical examination, or medical records 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 greater than 1 month, unexplained temperature greater than 100.5 F (38.6 C) for greater than 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.

If the transplant center receives information from the Host OPO that the donor meets any of the above criteria, the transplant center must inform the potential recipient prior to implantation. The transplant center shall maintain documentation of the potential

recipient's informed consent to receive an organ from the donor who meets any of the above criteria. In the event that the potential recipient is not able to provide informed consent, the legal next of kin, designated healthcare representative, or appropriate surrogate may provide consent on this matter.