Maine Medical Center
Maine Transplant Program
Policies and Procedures
Identification and Management of Transmissible Diseases Post Transplantation

Purpose:
To outline a consistent Policy and Procedure for the identification, management, and informed consent for transmissible diseases that are identified pre or post-transplant.

Policy: In accordance with UNOS Policy 15, the Maine Transplant Program will follow identified procedures in the screening of candidates, informed consent of recipients, management of post-transplant recipients who have received PHS-IRD organs, and communication of post-transplant or donation discovery of disease or malignancy.

Procedure:
1. The surgeon on call will act as the identified UNOS Patient Safety Contact and will be available to receive or address information needs regarding potential disease transmission. S/he will communicate any information received regarding potential disease transmission to the Medical Director as soon as possible but within 24 hours of receipt of information.

2. A Patient Safety Contact will be available 24/7 per the surgeon on call schedule.

3. All transplant candidates will be screened for HIV, hepatitis B and hepatitis C as part of their transplant evaluation. Candidates who test positive will be offered counseling and medical care as deemed appropriate by the transplant physician.

4. As part of the transplant evaluation process and prior to listing for transplant, all candidates will be educated regarding the risks and benefits of considering a PHS-IRD organ. A PHS-IRD organ will be defined as one that meets any of the criteria for increased risk of transmitting HIV, hepatitis B, and hepatitis C as specified in the U.S. Public Health Services (PHS) Guideline.

5. Prior to transplantation, the transplant surgeon will obtain specific informed consent any time: that the donor has a known medical condition that in his/her judgement may be transmissible to the recipient, including HIV; the donor meets any of the criteria identified in the U.S. PHS Guideline; or when a hemodiluted specimen is used for donor HIV, hepatitis B, or hepatitis C screening.

6. The informed consent will be obtained using the KIDNEY TRANSPLANT SURGERY CONSENT. The consent will be used to identify the specific category of potential transmissible disease presenting increased risk to the recipient, and will include information regarding follow up post transplantation to assess the presence of any transmissible disease and assessment by a transplant Infectious Disease Specialist if needed.

7. The informed consent will also contain information regarding the general risks of potential transmission of malignancies and disease from organ donors including: requirements for evaluation and screening (UNOS Policy 2.3); evaluation and screening of living donors (UNOS Policy 14.4); that there is no comprehensive way to screen deceased and living donors for all transmissible diseases; and that transmissible diseases and malignancies may be identified after transplant.

8. The surgeon will explain risks and obtain informed consent before transplant and the KIDNEY TRANSPLANT SURGERY CONSENT will be scanned into the patient record.

9. If additional donor disease or risk of malignancy transmission risk is identified pre transplant, the surgeon must obtain and document informed consent prior to transplant.
10. In accordance with UNOS Policy 15.5.A, the Program will follow steps outlined in the Policy if testing of the donor by the Program indicates disease or malignancy. These steps include notification of the host OPO, living donor recovery hospital, or recipient if under care of the transplant program.

11. In accordance with UNOS Policy 15.5.B, the Program will follow the steps outlined in the Policy if the organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease infection or malignancy and there is substantial concern that it could be from the transplanted organ. These steps include notification of the OPO or living donor recovery hospital, and reporting through the OPTN Patient Safety Portal.

12. In accordance with UNOS Policy 15.5.C, the Program will submit information as required if a Maine Transplant Program recipient is involved in an OPTN Patient Safety Portal report.

13. In accordance with UNOS Policy 15.6.A, if the Program learns new information about a living donor during the two year follow up period that indicates risk of potential disease or malignancy, the Program will disclose to the living donor that this information will be communicated to the receiving program (if applicable) and the OPTN Patient Safety Portal. Both of these steps will be taken by the Program following disclosure.

14. In accordance with UNOS Policy 15.6.B, if a report is made for a living donor through the OPTN Patient Safety Portal, the Program will take all steps outlined in the Policy including the provision of information for follow up review.

15. Recipients receiving PHS IRD organs are identified via the Organ Record in Epic and will be tracked and actively monitored by the Post-transplant team. The Quality Business Analyst will maintain a report of patients and due dates for follow up testing. HIV, Hepatitis B, and Hepatitis C NAT testing will occur immediately prior to surgery, and 1 month, 3 months, and 12 months post-transplant. Any positive test results will be reported to UNOS Disease Transmission Advisory Council and the patient will be referred to the transplant Infectious Disease Specialist for ongoing management.

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