

**Maine Medical Center
Maine Transplant Program
Policies and Procedures
Identification and Management of Transmissible Diseases Pre and 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 pre transplant testing and screening of candidates, informed consent of recipients, post-transplant infectious disease testing, 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. For asymptomatic, vaccinated patients who are positive for COVID by NAT (nucleic acid test by PCR) during pre-transplant pre-op, the following timeline will apply prior to being approved for surgery:
 - Initial repeat nasal swab PCR at four weeks from positive result
 - If negative, repeat again a week apart and if negative proceed to schedule OR
 - Two negative NAT from > 30 days from initial diagnosis
4. 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. The candidate's HBV vaccination status will be reported to OPTN via UNet. If HBV vaccination has not or will not be completed, the reasons will be documented in the medical record.
5. Per UNOS Policy 15.2, the following testing will be completed for all transplant recipients during the hospital admission for transplant but prior to anastomosis: HIV full reflex (HIVCR), Hepatitis B surface antigen; Hepatitis B core antibody; Hepatitis B surface antibody; Hepatitis C antibody, and Hepatitis C RNA NAT. Candidates who test positive for HIV, Hep B or Hep C will be offered referral and counseling if not previously identified and referred by the Transplant team to an Infectious Disease specialist.
6. **Prior to transplantation**, the transplant surgeon will obtain specific informed consent any time the donor tests positive for any of the following: HBsAG, Hep B NAT, or Hep C NAT.
7. 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.

8. 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.
9. If the donor has any risk criteria for acute HIV, HBV or HCV infection according to the US Public Health Service Guideline, the surgeon will inform the recipient after the organ offer but before transplant that risk criteria are present in the donor. This notification will be documented in the patient medical record.
10. If additional donor disease or risk or malignancy transmission risk is identified pre transplant, the surgeon must obtain and document informed consent prior to transplant.
11. 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.
12. 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.
13. 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.
14. 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.
15. 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.
16. All transplant recipients will be tested post-transplant for HIV (NAT); HBV (NAT), and HCV (NAT) at least 28 days but no later than 56 days post-transplant. If the recipient is known to be infected with HIV, HBV, or HCV, testing is not required but other tests required according to the Policy will be performed.
17. If a recipient has received a kidney from a donor who has tested positive for Hepatitis B surface antigen, Hepatitis B NAT, or Hepatitis C NAT, s/he will be monitored post-transplant with NAT testing at 1 month, 3 months, and 12 months post-transplant.
18. The Transplant Program will offer recipients treatment for HIV, HBV and HCV when indicated.

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