

Public Comment Proposal

Align OPTN Policy with U.S. Public Health Service Guideline, 2020

OPTN Ad Hoc Disease Transmission Advisory Committee

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Align OPTN Policy with U.S. Public Health Service Guideline, 2020

Affected Policies:

1.2: Definitions
 2.2: OPO Responsibilities
 2.4: Deceased Donor Medical and Behavioral History
 2.5: Hemodilution Assessment
 2.7: HIV Screening of Potential Donors
 2.9: Required Deceased Donor Infectious Disease Testing
 13.11: Receiving and Accepting KPD Match Offers
 14.1.A: Living Donor Psychosocial Evaluation Requirements
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 15.2: Potential Candidate Screening Requirements
 15.3.B: Donors with Risk Identified Pre-Transplant
 15.3.C: Recipients of Organs from Donors with Increased Risk of Disease Transmission
 16.3.D Internal Labeling of Extra Vessels
Ad Hoc Disease Transmission Advisory
 August 4, 2020 – October 1, 2020

Sponsoring Committee:

Public Comment Period:

Executive Summary

This proposal revises OPTN policies to be in alignment with the most up to date Public Health Service (PHS) recommendations for mitigating the risk of acquiring human immunodeficiency virus (HIV), hepatitis B (HBV) and hepatitis C (HCV) through organ transplantation. The OPTN Final Rule requires the OPTN to develop 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."¹

This proposal seeks to modify existing OPTN policy to reflect recommendations outlined in the updated PHS publication.² The major categories of proposed policy modifications include:

- Risk assessment of living and deceased donors
- Living and deceased solid organ donor testing
- Transplant candidate informed consent
- Recipient testing and reporting
- Collection and storage of donor and recipient specimens

The revisions published by the PHS are in response to concerns by the OPTN and the greater transplant community that more donors were being classified as increased risk than appropriate and it was leading

¹ 42 C.F.R. §121.4(a)(2)

² JM Jones, I Kracalik, ME Levi, et al, "Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020," *Morbidity and Mortality Weekly Report*, 69, (No. RR-4), June 26, 2020, 1-16, <http://dx.doi.org/10.15585/mmwr.rr6904a1>.

to unnecessary discard or turndowns of these organs. Organ transplant candidates who are on the waiting list are at high risk for death, and those who decline organs designated as increased risk have higher rates of death and graft failure than patients who accept increased risk organs.^{3,4,5} The 2020 revisions to criteria are overall less restrictive than the current ones, with the additional safeguards of more testing on donors and recipients to identify potential disease transmission.

The intent of revising OPTN policy is to maintain transplant recipient safety while more accurately identifying organ donors that have certain risk factors for acute human immunodeficiency virus (HIV), hepatitis B (HBV), and hepatitis C (HCV) infection. The risks of using these organs remains low due to use of sensitive molecular testing and the rising availability of effective treatments should unintended transmission occur.

³ MG Bowring CM Holscher, S Zhou, et al., "Turn down for what? Patient outcomes associated with declining increased infectious risk kidneys," *American Journal of Transplantation*, March 2018; 18: 617–24, <https://doi.org/10.1111/ajt.14577>.

⁴ KP Croome, DD Lee, S Pungpapong, et al., "What are the outcomes of declining a Public Health Service increased risk liver donor for patients on the liver transplant waiting list?" *Liver Transplantation*, (24), April 2018, 497–504, <https://doi.org/10.1002/lt.25009>.

⁵ Organ Procurement and Transplantation Network. National data. Richmond, VA: US Department of Health and Human Services, Health Resources and Services, Organ Procurement and Transplantation Network, <https://optn.transplant.hrsa.gov/data/view-data-reports/national-data/>.

Background

Recommendations to help prevent transmission of infectious disease from organ donors have been developed and subsequently updated by the Centers for Disease Control and Prevention (CDC), part of the U.S. Public Health Service (PHS), for the past 35 years. The first recommendation was developed in 1985 when Acquired Immune Deficiency Syndrome (AIDS) was emerging and the associated scientific knowledge was in its infancy. The recommendation was that organ donors be tested for antibodies to Human T-Lymphotropic Virus III/Lymphadenopathy Associated Virus when feasible and that persons in groups recognized as having an increased risk for AIDS not be used as organ donors regardless of the test results.⁶

The Organ Procurement and Transplantation Network (OPTN) Final Rule, which became effective in 2000, required that the OPTN Board of Directors develop 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”.⁷ This requirement remains today.

Background: 2013 PHS Guideline

The *PHS Guideline* is intended to reduce the risk of unintended transmission of disease through organ transplantation. The 2013 *Guideline*, originally released for public comment by the CDC in 2011, added measures to assess and mitigate HBV and HCV risk.⁸ After reviewing significant feedback from the OPTN that included input from the Ad Hoc Disease Transmission Advisory Committee (DTAC) and other OPTN Committees, the CDC finalized the “*PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation*” in 2013.⁹ In addition to outlining fourteen criteria to assess donor risk for HIV, HBV, and HCV, the updated *Guideline* also provided 34 specific recommendations (and sub-recommendations) regarding living and deceased donor testing, pre- and post-transplant recipient testing, and extra vessels usage.

The 2013 *Guideline* was the most expansive to date and the subsequent result was a significant number of organs being placed under the newly termed “increased risk designation (IRD)” category. Changes were made to the living donor medical/social evaluation, informed consent was required for IRD donors, and HCV nucleic acid testing (NAT) was required for all donors. Increased risk donors were required to have either HIV NAT or antibody/antigen (Ab/Ag) testing. Due to the extensive nature of the 2013 revisions, a joint workgroup, including the DTAC, other OPTN committee members, and representatives from the major professional transplant societies studied the revisions and developed proposals to align

⁶ CDC, “Provisional Public Health Service inter-agency recommendations for screening donated blood and plasma for antibody to the virus causing acquired immunodeficiency syndrome,” *Morbidity and Mortality Weekly Report*, May 24, 1985;34:15, <https://www.cdc.gov/mmwr/preview/mmwrhtml/00000547.htm>.

⁷ 42 C.F.R. §1 21.4(a)(2).

⁸ CDC, Proposed Guideline, “Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV) Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation,” September 21, 2011, <https://www.regulations.gov/docket?D=CDC-2011-0011>.

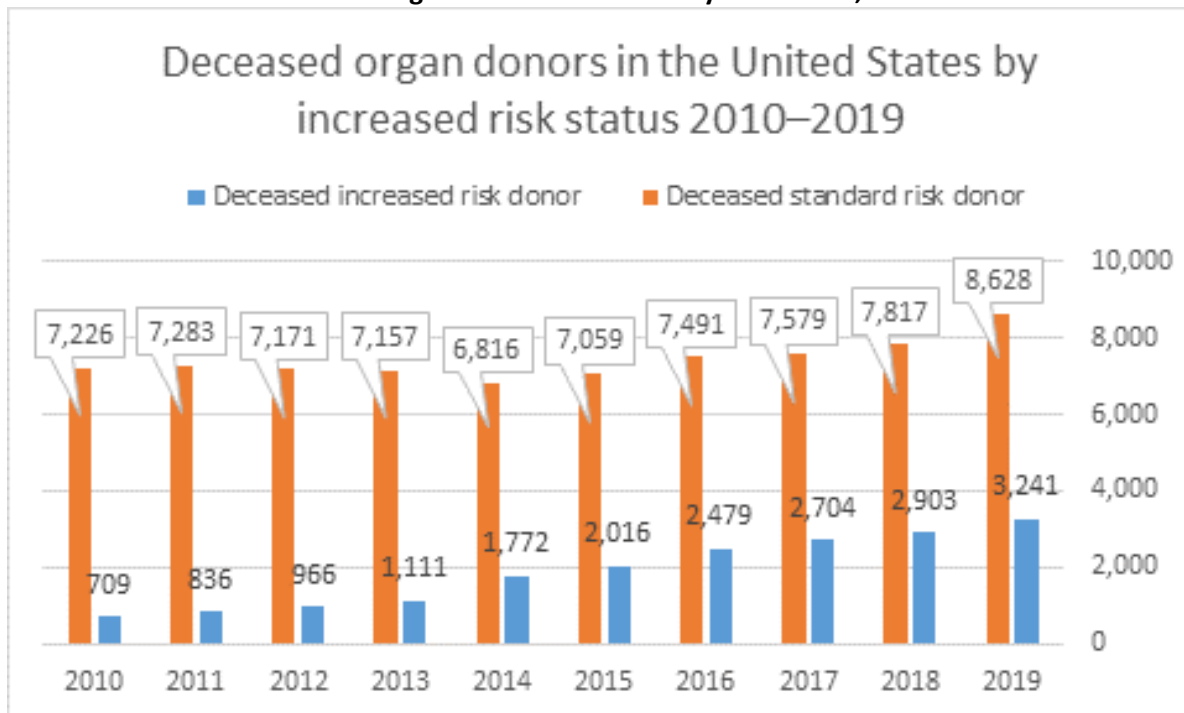
⁹ DL Seem, I Lee, C Umscheid, et al, “ Public Health Service Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV) Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation”, *Public Health Reports*, 128 (4), July 2013, 247-343, <https://doi.org/10.1177/003335491312800403>.

OPTN policies with the 2013 *Guideline* that were ultimately adopted by the OPTN Board of Directors.^{10,11,12} In 2015, the final policy alignment, NAT testing, was implemented.

The CDC Responds the Community's Requests for Revisions

Since the implementation of the 2013 *PHS Guideline*, the OPTN, CDC, and greater transplant community received community feedback and began to identify unintended consequences associated with the related OPTN policy changes. Donors classified under the PHS increased risk criteria grew from 13% in 2013 to 27% in 2019. **Chart 1** below illustrates the significant increase from 2014-2019 in those deceased donors classified under the IRD designation.¹³ There was concern in the transplant community that more donors were being classified as IRD risk than appropriate and it was leading to unnecessary discard or turndowns of these organs. There is indication of significant differences in use of organs based on PHS increased risk criteria.¹⁴ Based on transplant community feedback and its own subject matter expertise, the DTAC requested that the CDC revisit the *Guideline* to address these concerns. DTAC cited the need to adequately balance the risk of not using IRD organs and waitlist mortality along with the growing availability of effective detection and treatment for HIV, HBV, and HCV.

Chart 1: Deceased Organ Donors in the U.S. by Risk Status, 2010-2019¹⁵



¹⁰ Policy Clarifications Resulting from June 19, 2013, Release of the PHS Guideline for Reducing HIV, HBV, and HCV through Organ Transplantation, available at: https://optn.transplant.hrsa.gov/media/1562/policynote_20130801.pdf.

¹¹ Proposal to Modify Deceased Donor Testing Requirements, OPTN Policy Notice, July 23, 2014, available at: https://optn.transplant.hrsa.gov/media/1280/policynote_20140724.pdf.

¹² Aligning OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of HIV, HBV, and HCV through Solid Organ Transplantation, OPTN Policy Notice, February 1, 2014, Available at: https://optn.transplant.hrsa.gov/media/1140/policy_notice_12-2014.pdf.

¹³ OPTN data as of July 3, 2020.

¹⁴ WE Abara, MG Collier, A Moorman, et al., "Trends in Deceased Solid Organ Donor Characteristics and Hepatitis B, C, and HIV Screening Results—United States, 2010–2017," *Morbidity and Mortality Weekly Report*, 68(3), January 25, 2019, 61-66, <http://dx.doi.org/10.15585/mmwr.mm6803a2>.

¹⁵ OPTN data as of July 3, 2020.

In response to this feedback and request, the CDC conducted and published more recent research specific to solid organ transplantation to inform next steps to revise the 2013 *PHS Guideline*.^{16,17,18,19} CDC research suggests that donors, when tested with NAT, have less than a 1/1,000,000 risk of undetected infection within 14 days of potential increased risk behaviors for HIV and HCV and within 30 days for HBV.²⁰

Highlights from the four CDC research publications found:

- IRD donors are more likely to be infected with HCV than non-IRD donors
- Transmissions of HBV and HCV from recently infected IRD to organ recipients continue to occur, but early identification and treatment can improve outcomes
- IRD designation is associated with underutilization of adult lungs and kidneys and pediatric hearts
- Period during which reported donor risk behaviors result in IRD designation can be safely shortened
- Hemodialysis can be removed as IRD criteria while preserving safety

The CDC presented findings at the Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA) in April 2019.²¹ OPTN representatives shared their support and comments at this meeting. Proposed revisions were published subsequently in the Federal Register for public comment in August 2019.²²

The OPTN submitted a formal public comment response citing support for a new term to replace “increased risk donor,” shortening risk factor criteria from 12 months, universal post-transplant recipient testing, and revision of hemodialysis and hemodilution risk criteria.²³ A request was made to modify the requirement for repeat deceased donor testing was made as only 44 known HIV, HBV, or HCV transmissions occurred from donors between 2008 and 2018, showing the overall low risk of disease transmission from deceased donors did not adequately support the recommendation.²⁴ The OPTN also opposed the recommendation that living donor testing be performed within a 7-day period prior to organ recovery. The OPTN cited that only three known transmissions of HIV, HBV, or HCV from living donors between 2008 and 2018 demonstrating the low risk of disease transmission from living donors under the current 28-day testing requirement.²⁵ The OPTN’s contributing stakeholder

¹⁶ JM Jones, BM Gurbaxani, A Asher, et al, “Quantifying the risk of undetected HIV, Hepatitis B virus, or Hepatitis C virus infection in Public Health Service increased risk donors,” *American Journal of Transplantation*, (9), September 2019, 2583-2593, <https://doi.org/10.1111/ajt.15393>.

¹⁷ MRP Sapiano, JM Jones, J Bowman, et al, “Impact of U.S. Public Health Service increased risk deceased donor designation on organ utilization,” *American Journal of Transplantation*, (9), September 2019, 2560-2569, <https://doi.org/10.1111/ajt.15388>.

¹⁸ D Bixler, P Annambhotla, WE Abara, et al, “Hepatitis B and C virus infections transmitted through organ transplantation investigated by CDC, United States, 2014-2017,” *American Journal of Transplantation*, (9), September 2019, 2570-2582, <https://doi.org/10.1111/ajt.15352>.

¹⁹ WE Abara, MG Collier, A Moorman, et al, “Characteristics of Deceased Solid Organ Donors and Screening Results for Hepatitis B, C, and Human Immunodeficiency Viruses—United States, 2010–2017,” *Morbidity and Mortality Weekly Report*, 68 (3), January 25, 2019, 61-66, <http://dx.doi.org/10.15585/mmwr.mm6803a2>.

²⁰ JM Jones, “Quantifying the risk”.

²¹ ACBTSA April 16, 2019 - Meeting Summary, Office of Infectious Disease and HIV/AIDS Policy, HHS.gov, available at: <https://www.hhs.gov/oidp/advisory-committee/blood-tissue-safety-availability/meeting-summary/2019-04-16/index.html>.

²² “Request for Information-Revisions to the PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation; Extension of Comment Period”, August 27, 2019, available at: <https://www.federalregister.gov/documents/2019/09/20/2019-20419/request-for-information-revisions-to-the-phs-guideline-for-reducing-human-immunodeficiency-virus-hiv>.

²³ OPTN Memorandum, “Comments on Revisions to the PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation,” September 16, 2019.

²⁴ OPTN data as of September 6, 2019.

²⁵ Ibid.

committees (DTAC, Organ Procurement Organization, Operations and Safety, Living Donor, Ethics, Transplant Coordinators, and Transplant Administrators) were overall supportive of the revisions.

The CDC published the revised PHS recommendations, “*Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020*,” on June 26, 2020.²⁶ In response to OPTN concerns, the published *Guideline* left the current 28-day living donor testing timeframe. The repeat testing requirement was modified to require deceased donor specimens be collected within 96 hours before organ procurement with results of these screening tests available at the time of organ procurement. There was no time frame specified for pre-transplant deceased donor testing in the 2013 *Guideline*.

The OPTN Prepares to Align Policy to Updated 2020 PHS Guideline

Prior to release of the 2020 *PHS Guideline*, the DTAC formed a PHS workgroup in February 2020, in anticipation of the changes to be published later in the year. The workgroup included representatives from the following stakeholder groups:

- OPTN Committees: DTAC, Ethics, Living Donor, Operations and Safety, Patient Affairs, Pediatrics, Transplant Administrators, and Transplant Coordinators
- Transplant Societies: American Society of Transplantation (AST), American Society of Transplant Surgeons (ASTS), Association of Organ Procurement Organizations (AOPO), and NATCO
- Federal Government: Human Resources and Services Administration (HRSA) and CDC

Potential Impact to Data Collection

The DTAC submitted a formal memorandum on behalf of the workgroup to the OPTN Data Advisory Committee (DAC) on February 24, 2020, informing the DAC of potential data changes to OPTN data. The memorandum detailed potential changes to data elements in DonorNet®, including removal of terminology using “increased risk”, addition of fields to identify individual risk criteria, and change to functionality of date fields associated with testing and recovery. Data element changes in TIEDI® candidate forms could include addition of vaccination data, and fields to track and report HIV, HBV, and HCV universal testing.

Workgroup Considers Policy Changes

The PHS released its published *Guideline* on June 26, 2020 with the expectation that revised OPTN policies to align with the new recommendations would be sent to the OPTN Board of Directors for consideration at their December 2020 meeting.²⁷

A crosswalk outlining detailed changes between 2013 and 2020 PHS Guidelines and OPTN Policy (current and proposed) is available in **Appendix A**. Highlights of major changes include:

1. Risk assessment of living and deceased donors: Fewer donor risk criteria and risk assessment prior to organ procurement shortened from twelve months to one month and removal of using term “increased risk donor”
2. Living and deceased solid organ donor testing: Requirement for universal testing for HIV, HBV, and HCV on all recipients

²⁶ JM Jones, “Assessing Solid Organ Donors”.

²⁷ Ibid.

3. Transplant candidate informed consent: Replacement of “informed consent” with a risk factor discussion between provider and candidate
4. Recipient testing and reporting: Requirement of universal NAT testing post-transplant and requirement to assess need for HBV vaccination pre-transplant and to report status to OPTN
5. Collection and storage of donor and recipient specimens: Requirement to store living donor blood specimens for at least 10 years

This proposal contains policy changes related to nearly all areas where the *PHS Guideline* has been revised. The OPTN Policy definition for the *PHS Guideline* has been proposed to be updated to reference the 2020 version. All policy requirements that refer to the need to conduct a donor medical/social assessment will then be referring to the 2020 *PHS Guideline* which removes four risk criteria currently used since 2013 and shortens the donor assessment timeframe. This timeframe would be reduced from the donor having any risk criteria present in the past year to the past 30 days of the assessment date.

The *PHS Guideline* recommends that all candidates receive HBV vaccination. The PHS workgroup and DTAC strongly supported proposing OPTN policy requiring Hepatitis B vaccination for candidates. However, the OPTN requirement to be consistent with CDC recommendations is for donor testing and recipient follow up. Proposed policy would require an assessment of the need for HBV vaccination and reporting to the OPTN when vaccination cannot be initiated or completed. The proposed policy requiring data regarding HBV vaccination will enable the OPTN to assess HBV immunity status and prevention of infectious disease. Community feedback on specific data collected is requested.

In addition, the proposal contains slightly expanded timeframes for post-transplant recipient testing. The Committee believes the proposed timeframes are consistent with the CDC recommendations and still meet the Final Rule requirement but that the timeframes needed slight adjustment to accommodate operations and recipient follow up activities without compromising the intent or patient safety.

Purpose

The U.S. PHS "*Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation*" was last revised in 2013, upon which the OPTN aligned its policies to be consistent with the Guideline and educated the transplant community on these changes.²⁸ The 2013 *PHS Guideline* recommendations were not intended to restrict transplantation or exclude specific donors but rather to facilitate appropriate donor laboratory screening, enhance informed decision-making by transplant candidates and families, and ensure prompt recognition and treatment of donor-derived infections.

The CDC, which administers the PHS, evaluated and revised the 2013 *PHS Guideline* on June 26, 2020 at the request of the OPTN and greater transplant community. Several advances in solid organ transplantation, including universal implementation of nucleic acid testing (NAT) of solid organ donors for HIV, HBV, and HCV, improved understanding of risk factors for undetected organ donor infection with these viruses, and the availability of highly effective treatments for infection with these viruses are reasons for the requested and proposed revisions.²⁹ The PHS recommendations pertain to transplantation of solid organs procured from donors without laboratory evidence of HIV, HBV, or HCV infection, for identification of risk criteria for these infections among solid organ donors,

²⁸ DL Seem, "PHS Guideline".

²⁹ JM Jones, "Assessing Solid Organ Donors".

implementation of laboratory screening of solid organ donors, and monitoring of solid organ transplant recipients.

This proposal revises OPTN Policies to be in alignment with the most up to date PHS recommendations, as required by the OPTN Final Rule. The OPTN Final Rule requires that the OPTN develop 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." ³⁰

Overview of Proposal

This proposal would align OPTN Policy to the 2020 *PHS Guideline*. Each Guideline is included in language revisions and is outlined in detail in **Appendix A**. The revisions resulted from the PHS workgroup and DTAC discussions.

Below is a summary of proposed changes to OPTN Policies to align to the 2020 *PHS Guideline*:

1. Risk assessment of living and deceased donors

- Change definition of *US PHS Guideline* to refer to the 2020 version which results in:
 - Shorten risk criteria inclusionary timeframe from twelve months to one month
 - Remove four risk criteria including hemodialysis and hemodilution
- Remove specific label of “increased risk designation” (IRD) to describe donors with risk factors for acute HIV, HBV, and HCV infection

PHS Workgroup and DTAC Rationale: Both the PHS workgroup (WG) and the DTAC expressed universal support for changes to risk criteria and shortening of the timeframe due to the evidence from the CDC studies and the new testing requirements that will decrease chances of missing unintended transmission.

Recent DTAC policy evaluation and CDC research have not found that hemodiluted specimens result in undetected transmissions of HIV, HBV, or HCV. Hemodilution was removed from the risk criteria for 2020. OPTN policy is proposed to be modified to remove hemodilution as a PHS risk criteria. Some members have expressed that policy requiring a hemodilution calculation needs to remain for other reasons such as impact on interpreting results for common infections such as cytomegalovirus (CMV) and Epstein-Barr virus (EBV), blood type (ABO) testing or tissue requirements. Other members do not believe that hemodilution assessment needs to remain in OPTN policy given the HIV, HBV, and HCV findings. DTAC plans to assess public comment regarding the need to keep hemodilution calculation in OPTN policy. The current proposal removes hemodilution as a PHS risk criteria but keeps the overall requirement to perform the assessment. The DTAC may propose removing hemodilution calculation requirements based on public comment.

The WG and DTAC support the removal of the term “increased risk designation” or “increased risk donor,” due to the perceived and potentially over-magnified concerns the term elicits and subsequent underutilization of organs. Several studies, cited by the CDC, have reported underuse of organs from donors designated as high risk or increased risk.^{31,32} These groups did note that it may be difficult

³⁰ 42 C.F.R. §121.4(a)(2).

³¹ ML Volk, AR Wilk, C Wolfe, DR Kaul, “The ‘PHS increased risk’ Label Is Associated With Nonutilization of Hundreds of Organs per Year,” *Transplantation*, 101 (7), 2017, 1666–9, <https://doi.org/10.1097/tp.0000000000001673>.

³² TL Pruet, MA Clark, SE Taranto, “Deceased organ donors and PHS risk identification: impact on organ usage and outcomes,” *Transplantation*, 101 (7), 2017, 1670–8, <https://doi.org/10.1097/tp.0000000000001716>.

without a specific term but that the discussions with candidates should be done contextually along with other organ offer risks. Proposed policy language removes all references to this term in an effort to decrease underuse of organs. The replacement language refers to “risk criteria” for “acute HIV, HBV, or HCV infection” which is the same language used in the revised Guideline.

2. Living and deceased solid organ donor testing

- Add new required testing for all potential living and deceased organ donors:
 - HIV: NAT
 - HBV: NAT
- Require deceased donor specimen collected within 96 hours before organ procurement

PHS Workgroup and DTAC Rationale:

The WG and DTAC support these changes. OPTN data analysis showed that of 10,286 deceased donors in 2017, nearly all had NAT testing performed (10,284 had HBV NAT and 10,285 had both HCV and HIV NAT). Among living donors, 6,161 out of 6,188 (99.6%) had HBV and HCV NAT testing in 2017.³³ HIV NAT testing could not be determined because the OPTN reporting field is for serostatus and is not test specific. NAT testing is already an accepted practice among the transplant community.

The collection time period adjustment to 96 hours sufficiently addresses the OPTN public comment made regarding the timeframe for deceased donor sample collection. None of the WG or DTAC members expressed concern over this requirement.

3. Transplant candidate informed consent

- Remove requirement to obtain “informed consent”
- Add requirement that transplant hospitals inform intended recipients when the donor has any risk criteria

PHS Workgroup and DTAC Rationale: The revised Guideline removes separate and specified informed consent for use of IRD organs, and instead requests that a discussion about identified donor risk criteria occur between the intended recipient and the provider. During discussions, the CDC ex-officio DTAC member emphasized that risks of disease transmission from donors with identified HIV, HBV, and HCV risk criteria who test negative are low and the formal specific informed consent process may lead to organ decline thereby increasing the risk of mortality on the waitlist. The WG emphasized the need for a contextualized discussion taking into account the following: mortality on the waitlist, risk of mortality associated with the decline of organs with risk factors for acute HIV, HBV and HCV, the risk of transmission, available therapies for these viruses, as well as the favorable outcomes associated with prompt detection and initiation of therapy. There was concern from some WG members that disclosure of specific donor risk factors could cause a breach in confidentiality. Members of the PHS WG made inquiries about how much should be disclosed to the recipient. Given the differences in transplant practices, the CDC ex-officio DTAC member explained that CDC did not want to be too prescriptive regarding this requirement.^{34,35}

4. Recipient testing and reporting

- Add specific timing and testing type requirements for candidate pre-transplant testing of HIV, HBV, and HCV (during hospital admission for transplant but before transplant)

³³ OPTN Ad Hoc Disease Transmission Advisory Committee, “Clarify Informed Consent Policy for Transmittable Conditions,” Briefing Paper to OPTN Board of Directors, June 2018, available at https://optn.transplant.hrsa.gov/media/2525/DTAC_BoardReport_201806.pdf.

³⁴ ML Volk, “The ‘PHS increased risk’ label”.

³⁵ TL Pruett, “Deceased organ donors and PHS risk identification”.

- Add universal post-transplant testing for all recipients, regardless of donor risk criteria
 - HIV, HBV, and HCV NAT testing at four to eight weeks post-transplant
 - HBV NAT testing at eleven to thirteen months post-transplant for liver recipients

PHS Workgroup and DTAC Rationale: The 2020 *Guideline* proposes universal post-transplant recipient testing for HIV, HBV, and HCV at four to six weeks, in order to detect, and if needed, begin treatment, as early as possible, an unexpected transmission of HIV, HBV, or HCV from the donor to the recipient. WG members, in particular transplant program representatives, requested allowing more time to acquire testing in OPTN policy. DTAC supported the suggestion to extend the time frame to eight weeks to provide a more realistic window to obtain the testing. For the requirement to test liver recipients for HBV at one year post-transplant, the WG suggested and DTAC agreed to propose a more realistic timeframe, eleven to thirteen months, to allow for logistical and operational factors that may influence timing of obtaining testing. The decision to slightly extend the timeframes would not impact the efficacy of early identification and treatment nor would it impact patient safety, based on current data that unexpected HCV and HBV impact a relatively small minority of the transplant population. From 2014-2017, there were unexpected transmissions for HCV from 9 donors into 20 recipients and for HBV from 7 donors into 7 recipients out of a total of 61,900 donors and 128,894 recipients during those years. These recipients who acquired infection did well despite not being identified for HCV until 20-195 days and for HBV until 119 to 459 days post-transplant.³⁶ The Committee believes that this recommendation is consistent with the 2020 *Guideline*.

HBV Vaccination: The 2020 *PHS Guideline* includes a recommendation that transplant programs vaccinate all candidates for HBV prior to transplant. This vaccine would reduce the transmission of HBV from a donor to the candidate. WG and DTAC members strongly support the CDC's recommendation for recipient HBV vaccination. They also noted that a vaccination requirement should not interfere with a candidate's ability to receive organ offers or transplant. This proposal would require transplant programs to assess the need for HBV vaccination. This proposal would also require transplant programs to report to the OPTN if HBV vaccination cannot be initiated or completed prior to transplant. The OPTN will require this data collection to assess HBV vaccination and immunity status. Currently the OPTN does collect data on recipient results for surface antibody testing (HBsAb). HBV infection can result in graft failure and HBV is a preventable infectious disease.

The proposed data collection is consistent with the CDC recommendation that all recipients receive HBV vaccination. Data collection on candidate HBV vaccination will offer insights on how many transplant programs are following the 2020 *Guideline* and whether there is a noticeable difference in infection transmission between vaccinated and unvaccinated recipients. These data are needed to assist with monitoring the preventable infectious disease spread of HBV. Public comment feedback is being sought on this topic.

5. Collection and storage of donor and recipient specimens

- Add requirement for living donor recovery hospitals to store specimens to ten years, the same requirement currently in place for OPOs and deceased donor specimen storage.
- Add OPO requirement to gather specimen for storage within 24 hours of organ procurement.
- Add living donor recovery hospital requirement to gather specimen for storage within 24 hours of organ recovery.

PHS Workgroup and DTAC Rationale: The revised *PHS Guideline* advises that OPO and living donor recovery hospitals store donor blood specimens for at least ten years. Two specimens (one for NAT and

³⁶ D Bixler, "Hepatitis B and C virus infections".

one for serology) should be collected within 24 hours before organ procurement/recovery. While the current *Guideline* recommends and OPTN policy already requires OPOs to store specimens for 10 years, the WG members raised significant concerns about the need to store living donor specimen for ten years. During meeting discussions, the CDC ex-officio DTAC member stressed the need to do this to support investigation into reported unexpected disease transmissions. Concerns from transplant hospital representatives include the additional capacity, cost, and logistics of storing more specimens for a longer duration. In addition, some on the WG noted that ten years is not necessary for detection of HIV, HBV, or HCV but may make sense as part of another type of recommendation separate from this topic. Overall, the WG supports including storage for some duration, but did not have consensus on the appropriate timeframe, as their opinions ranged between two years versus the requested ten years.³⁷ The DTAC did not express these same concerns and proposed including the ten year living donor storage requirement in policy, but is also requesting specific feedback on this issue during public comment.³⁸

In addition to policy language revisions, additional follow up solutions may be considered after this proposal is approved:

- Guidance for OPTN members and patients
- Educational webinars or other media products
- Informative Frequently Asked Questions (FAQ) website page
- Additional or changed donor and recipient collection in UNetSM
- Additional items may potentially require subsequent public comment

NOTA and Final Rule Analysis

This proposal revises OPTN policies to be in alignment with the most up to date PHS recommendations. The OPTN Final Rule requires the OPTN to develop policies that are "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."³⁹ The recommendations in this proposal are consistent with the recommendations in the 2020 *PHS Guideline*, as they are either identical or substantively consistent with those recommendations. The proposed vaccination assessment is authorized by §121.5(a) of the OPTN Final Rule. The proposed data collection related to HBV vaccination is considered to be under the authority of §121.11(b)(2) of the OPTN Final Rule which states that "An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN...information regarding transplant candidates, transplant recipients, [and] donors of organs...."⁴⁰

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Additional living donor, candidate and recipient testing may require additional visits, time, cost, and data entry. Modification of time intervals for testing and recipient follow-up may change workflow.

³⁷ OPTN DTAC PHS Workgroup Meetings, July 2, 8, and 14, 2020. Minutes available upon request.

³⁸ OPTN DTAC Meeting, July 15, 2020, Meeting Summary, available at (hyperlink pending)

³⁹ "Organ Procurement and Transplantation Network," *Code of Federal Regulations*, Title 42 (2019): 806-807.

<https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol1/pdf/CFR-2019-title42-vol1.pdf>.

⁴⁰ 42 CFR §121.11(b)(2).

Living donor recovery hospitals must arrange for additional storage for living donor specimens. This will require additional storage space, and development of storage protocols.

Modifications to living donor, candidate, and recipient testing may require modifications to medical record systems, particularly for transplant specific modules.

Transplant hospitals will need to assess candidates for the need for HBV vaccination and report data regarding reasons that HBV vaccination cannot be completed or initiated prior to transplant.

Hospitals must also educate staff on changed criteria and changed risk discussion.

Operations affecting Organ Procurement Organizations

OPOs will need to modify their donor screening questions and documentation for identifying donors that have any risk criteria. This may involve programming changes to their medical record systems and changes to data collection and reporting.

Additional testing and documentation in shorter timeframes may require additional communication with transplant programs.

Repeat NAT tests may be needed for donors if procurement does not occur within the 96 hour window of when infectious disease samples were first drawn. If samples need to be redrawn, these test results may not be available at the time of transplant.

Staff education on the revised screening questions, operational, and documentation changes will be needed.

Operations affecting Histocompatibility Laboratories

This proposal is anticipated to minimally affect the operations of Histocompatibility Laboratories. Since there are no changes in histocompatibility testing, any changes would affect labs that perform infectious disease testing and/or archive donor blood specimens for transplant members. Specifically, the requirement that donor specimens tested for HIV, HBV and HCV be collected within 96 hours of organ procurement may result in donors needing to be retested if the donation process exceeds the 96 hour timeframe. Additionally, the requirement that donor specimens for archive be collected within 24 hours before organ procurement may mean that additional sample(s) be obtained and processed to meet this requirement. It is minimal, but is an additional step to normal workflow.

Operations affecting the OPTN

The OPTN and the CDC will create a joint effort to provide community education about the changes.

This proposal will require programming in UNetSM. The programming for this proposal will be a medium effort.

- Terminology for “Increased Risk Donor” will be removed from programming.
- Other data fields used for risk identification of the donor will be updated to align with policy.
- Data collection will be required related to recipient HBV vaccination.
- Modifications to recipient registration and follow up forms may be needed.
- Labeling adjustments will need to be made for extra vessels.

Potential Impact on Select Patient Populations

This proposal will affect all potential organ donors, both living and deceased, and any organ transplant candidates receiving offers for donor organs.

This proposal is expected to enhance patient safety for recipients of all donor organs by aligning transplant policy with new recommendations from the PHS regarding the evaluation and testing of living and deceased donors, as well as transplant candidates and recipients.

Projected Fiscal Impact

Projected Impact on Organ Procurement Organizations

There may be costs associated with repeat NAT testing within 96 hours of procurement time. Staff training and updated protocol may be a one-time cost.

Projected Impact on Transplant Hospitals

There will be costs associated with universal testing (HIV, HCV, HBV) of all recipients, and it should be covered by the recipient's insurance. Insurers may not cover costs for HIV, HBV, and HCV unless there is a reason to test for it post-transplant. Staff training, protocol development, and changes to hospital systems of medical record management may also be one-time cost.

Living donor specimen storage cost would be required for ten years. There is a one-time storage cost per specimen, in addition to any costs associated with storage per unit and development of storage protocol (staff time and additional lab supplies). The cost will vary by transplant volume.

Projected Impact on Histocompatibility Laboratories

Any changes would minimally affect labs that perform infectious disease testing and/or archive donor blood specimens for OPOs. Specifically, the requirement that donor specimens tested for HIV, HBV and HCV are required to be collected within 96 hours of organ procurement may result in donors needing to be retested if the donation process exceeds the 96 hour timeframe. Any necessary retesting would incur an additional minimal cost, potentially delay procurement, and change allocation if the test results change.

Projected Impact on the OPTN

The programming effort will be medium for this proposal although some of the data needs and changes are still under evaluation. The OPTN may implement this proposal in phases. Education will be provided to members regarding the changes. The OPTN is collaborating with the CDC as this organization also has community and patient education plans.

Post-implementation Monitoring

Member Compliance

In addition to the monitoring described below, the OPTN Contractor may review any data entered in UNetSM and compliance with any OPTN policy or bylaws. Members must provide supporting documentation as requested.

OPO monitoring

Policy 2.2 OPO Responsibilities: Site surveyors will continue to review a sample of deceased donor records to verify that blood specimen archiving is noted in the donor chart. Based on the proposed policy change, surveyors will verify that the collection date of the archived blood specimens is no earlier than 1 day prior to the donor's recovery date.

Policy 2.4 Deceased Donor Medical and Behavioral History: Site surveyors will continue to review a sample of deceased donor records to verify:

- That the OPO assessed the donor for risk of acute HIV, HBV, or HCV infection according to the criteria in the *U.S. PHS Guideline*
- If risk factors are identified, that the OPO communicated this information to all receiving transplant programs

Policy 2.5 Hemodilution Assessment: Based on the proposed policy change, site surveyors will no longer verify that an OPO reported a donor as having an increased risk of HIV, HBV, or HCV transmission because HIV, HBV, or HCV testing was performed using a hemodiluted specimen. Site surveyors will continue to review a sample of deceased donor records to verify:

- The calculations used to assess hemodilution
- The date and time of the blood draw for the blood used for the screening tests
- The date and time of the blood draw used to determine hemodilution
- If the donor specimens are hemodiluted, that the following were communicated to the accepting transplant programs:
 - Any screening results from the hemodiluted specimens
 - The tests completed on the hemodiluted specimens
 - The hemodilution calculation used for the hemodiluted specimens, if requested

Policy 2.9 Required Deceased Donor Infectious Disease Testing: Site surveyors will continue to review a sample of deceased donor records to verify that the required infectious disease tests have been performed, and that the results of the tests reported in UNet are consistent with source documentation. Based on the proposed policy changes, surveyors will:

- Verify that an HIV ribonucleic acid (RNA) screening or diagnostic nucleic acid test (NAT) was performed
- Verify that an HBV deoxyribonucleic acid (DNA) screening or diagnostic NAT was performed
- Verify that samples used for all required HIV, HBV, and HCV tests were drawn no earlier than 4 days prior to the donor recovery date

Living donor recovery hospital monitoring

Policy 14.1.A Living Donor Psychosocial Evaluation Requirements: Site surveyors will continue to review a sample of living donor medical records for documentation that the donor psychosocial evaluation was completed and addressed the elements required in policy. This includes verifying that the recovery

hospital assessed the donor for risk of acute HIV, HBV, or HCV infection according to the criteria in the *U.S. PHS Guideline*.

Policy 14.4.A Living Donor Medical Evaluation Requirements: Site surveyors will continue to review a sample of living donor medical records for documentation that the medical evaluation of the donor included an assessment of risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. PHS Guideline*. Surveyors will also continue to review a sample of living donor medical records to verify that required infectious disease tests have been performed, and that required HIV, HBV, and HCV tests have been performed no earlier than 28 days prior to the donor's recovery date. Based on the proposed policy changes, surveyors will:

- Verify that an HIV ribonucleic acid (RNA) nucleic acid test (NAT) was performed
- Verify that an HBV deoxyribonucleic acid (DNA) NAT was performed

Proposed Policy 14.8.B Living Donor Specimen Collection and Storage: Based on the proposed policy, site surveyors will review a sample of living donor medical records to verify that blood specimen archiving is noted in the donor chart, and that the collection date of the archived blood specimens is no earlier than 1 day prior to the donor's recovery date.

Transplant hospital monitoring

Proposed Policy 15.2 Candidate Pre-Transplant Infectious Disease Reporting and Testing Requirements: Based on the proposed policy changes, site surveyors will review a sample of medical records to verify that the candidate was tested for HIV, HBV, and HCV via the tests specified in this policy, using blood samples collected during hospital admission for transplant and prior to first anastomosis. If the candidate was not tested for HIV, HBV, or HCV because the candidate was known to be positive for that viral infection prior to hospital admission for transplant, site surveyors will request documentation of the candidate's known positive status for that infection.

Policy 15.3.B Donors with Risk Identified Pre-Transplant: Based on the proposed policy changes, site surveyors will review a sample of medical records for documentation that the transplant program informed the intended recipient or recipient's agent after the organ offer but before transplant that an assessment of the donor for risk criteria for acute HIV, HBV, or HCV infection according to the *U.S. PHS Guideline* identified the presence of one or more risk criteria in the donor. Surveyors will no longer verify that the transplant program obtained informed consent from a potential recipient or recipient's agent when a donor met risk criteria according to the *U.S. PHS Guideline*, or when hemodiluted specimens were used for donor HIV, HBV, or HCV testing.

Proposed Policy 15.3.C Required Post-Transplant Infectious Disease Testing: Based on the proposed policy changes, site surveyors will review a sample of medical records to verify that the recipient was tested for HIV, HBV, and HCV between 28 and 56 days after the date of transplant using HIV RNA NAT, HBV DNA NAT, and HCV RNA NAT. If the recipient was not tested for HIV, HBV, or HCV because the recipient was known to be positive for that viral infection, site surveyors will request documentation of the recipient's known positive status for that infection.

Policy Evaluation

This policy will be formally evaluated approximately 1 year and 2 years post-implementation.

The following metrics, and any others subsequently requested by the Committee, will be evaluated as data become available to compare performance before and after the implementation of this policy:

- The number/percent of ‘donors with risk factors for HIV, HBV and HCV’ by donor type.
- The number/percent of living donors reporting HBV and HIV NAT test, overall and by organ (kidney and liver) and ‘donor with risk factors for HIV, HBV and HCV’ status.
- For living donors reporting HBV and HIV NAT test results, the number/percent by test result and organ and ‘donor with risk factors for HIV, HBV and HCV’ status.
- The number/percent of recipients receiving an HIV, HBV and HCV NAT testing post-transplant, as reported on the TRR, by ‘donor with risk factors for HIV, HBV and HCV’ and infectious disease test result.
- HBV NAT test results for liver recipients at one-year post-transplant by ‘donor with risk factors for HIV, HBV and HCV’ status and test results.
- Deceased donor organ utilization rates pre and post-policy by ‘donor with risk factors for HIV, HBV, and HCV’ status and organ.
- One-year unadjusted graft and patient survival rates pre and post-policy by ‘donor with risk factors for HIV, HBV, and HCV’ status and organ.

Conclusion

The *PHS Guideline* and aligned OPTN policy exist to help prevent transmission of HIV, HBV, and HCV from organ donors. The proposal changes intend to increase the number of transplants by contracting language that may have prevented low risk organs from being transplanted, as evidence demonstrates in this proposal. While criteria is proposed to be overall less restrictive, additional testing, documentation of potential risk, and longer storage of specimen are safeguards to continue to maintain a very low rate of unexpected disease transmission. The policy language aligns policy to CDC recommendations, as required by the Final Rule.⁴¹

Overall feedback on this proposal, in addition to the following specific topics, is requested:

1. Data collection related to HBV immunity status may be expanded to include more specific information on HBV vaccination status and barriers to completion. Feedback is requested on the feasibility of and support for collecting additional data related to HBV vaccination status.
2. What is the appropriate length of time to require living donor specimens be stored by recovery hospitals? Why?
3. In order to evaluate the effectiveness of the revised *PHS Guideline*, reporting of additional specific risk criteria by OPOs would be needed. Feedback is sought on the feasibility of reporting additional specific risk criteria.
4. Hemodilution was removed from the PHS risk criteria for 2020. Please comment on whether hemodilution should remain in policy.
5. Please comment on the post-transplant testing requirements in policy, as part of this proposal:
 - HIV, HBV, and HCV NAT testing at four to eight weeks post-transplant
 - HBV NAT testing at eleven to thirteen months post-transplant for liver recipients

⁴¹ “Organ Procurement and Transplantation Network,” *Code of Federal Regulations*, Title 42 (2019): 806-807. <https://www.govinfo.gov/content/pkg/CFR-2019-title42-vol1/pdf/CFR-2019-title42-vol1.pdf>.

Policy and/or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 1.2 Definitions:

2

3 **Hepatitis B Virus (HBV)**

4 Hepatitis B is a vaccine-preventable liver infection caused by the hepatitis B virus (HBV).

5

6 **Hepatitis C Virus (HCV)**

7 Hepatitis C is a liver infection caused by the hepatitis C virus (HCV).

8

9 **Human Immunodeficiency Virus (HIV)**

10 Human Immunodeficiency Virus (HIV) is a virus that attacks the body's immune system. If HIV is not
 11 treated, it can lead to Acquired Immunodeficiency Syndrome (AIDS).

12

13 **United States (U.S.) Public Health Service (PHS) Guideline**

14 ~~The PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and~~
 15 ~~Hepatitis C Virus (HCV) through Organ Transplantation (2013).~~

16

17 The Guideline issued by the U.S. Public Health Service in 2020 that provides recommendations for organ
 18 transplantation related to Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C
 19 Virus (HCV) transmission.

20

21 2.2 OPO Responsibilities

22 15. Maintaining blood specimens appropriate for serologic and nucleic acid testing (NAT), as available,
 23 for each deceased donor for at least 10 years after the date of organ transplant, and ensuring these
 24 samples are available for retrospective testing. The samples must be collected within 24 hours prior
 25 to organ procurement. The host OPO must document the type of sample in the deceased donor
 26 medical record and, if possible, should use qualified specimens.

27

28 2.4 Deceased Donor Medical and Behavioral History

29

30 2. Whether the potential deceased donor has any risk factors associated with ~~an increased risk for~~
 31 ~~disease transmission, including blood-borne pathogens. If the deceased donor meets the~~ has any
 32 risk criteria for increased risk for acute HIV, Hepatitis B HBV, and or Hepatitis C transmission HCV
 33 infection as set forth in ~~according to the current U.S. Public Health Services (PHS) Guideline or the~~
 34 ~~host OPO cannot obtain the information necessary to make this determination, the host OPO must~~
 35 ~~identify the donor as having increased risk for transmission of HIV, Hepatitis B, and Hepatitis C and~~
 36 ~~communicate this information to all transplant programs receiving organs from the deceased~~
 37 ~~donor.~~

38

39 2.5 Hemodilution Assessment

40 OPOs must use qualified (non-hemodiluted) blood samples for deceased donor ~~serological~~ screening
 41 tests if available. If a qualified sample is not available for testing, a hemodiluted sample may be used for



42 deceased donor screening tests.

43

44 ~~If serological testing occurs on a hemodiluted blood sample, the host OPO must treat the deceased~~
 45 ~~donor as presenting an increased risk for disease transmission as specified in the U.S. Public Health~~
 46 ~~Services (PHS) Guideline.~~

47

48 Prior to screening, the host OPO must assess all potential deceased donor blood samples that were
 49 obtained for ~~serological~~ screening tests for hemodilution using a U.S. Food and Drug Administration
 50 (FDA) approved hemodilution calculation. The host OPO must document in the deceased donor medical
 51 record a complete history of all blood products and intravenous fluid transfusions the deceased donor
 52 received since admission to the donor hospital.

53

54 Additionally, the host OPO must report *all* of the following to the accepting transplant programs when a
 55 hemodiluted specimen is used in deceased donor screening tests:

56

- 57 1. Any screening results from the hemodiluted specimens.
- 58 2. The tests completed on the hemodiluted specimens.
- 59 3. The hemodilution calculation used for the hemodiluted specimens, if requested.

60

61 **2.7.A Exceptions to HIV Screening Requirement**

62 Exceptions to the HIV screening requirement may be made for organs *other than* kidneys, when,
 63 in the medical judgment of the host OPO and recipient transplant hospital or OPO, an extreme
 64 medical emergency warrants the transplantation of an organ that has not been tested for HIV.

65

66 In this case the host OPO must do *both* of the following:

67

- 68 1. Provide all available deceased donor medical and social history to the transplant program.
- 69 2. Treat the deceased donor as having ~~an increased~~ any risk criteria for ~~disease transmission~~
 70 acute HIV, HBV or HCV infection based on current according to the U.S. Public Health
 71 Services (PHS) Guideline.

72

73 In this case the receiving transplant hospital must:

74

- 75 • ~~Obtain and document informed consent from~~ Inform the potential transplant recipient or
 76 the recipient's authorized agent before transplantation according to Policy 15.3.B: Donors
 77 with Risk Identified Pre-Transplant
- 78 • Obtain HIV screening test results prior to storing, sharing, or using the extra vessels in
 79 another recipient, according to *Policy 16.6: Extra Vessels Transplant and Storage*

80

81 **2.9 Required Deceased Donor Infectious Disease Testing**

82 The host OPO is responsible for ensuring that *all* of the following infectious disease testing is completed in
 83 CLIA-certified laboratories, or in laboratories meeting equivalent requirements as determined by the
 84 Centers for Medicare and Medicaid Services (CMS):

85

- 86 1. Blood and urine cultures

- 87 2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or
 88 cleared tests, as listed below:
 89 a. HIV antibody (anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
 90 b. HIV ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
 91 c. Hepatitis B surface antigen (HBsAg) donor screening test
 92 d. Hepatitis B core antibody (anti-HBc) donor screening test
 93 e. Hepatitis B deoxyribonucleic acid (DNA) by donor screening or diagnostic nucleic acid test (NAT)
 94 f. Hepatitis C antibody donor screening test (anti-HCV)
 95 g. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
 96 h. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening or diagnostic test
 97 i. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening or diagnostic test
 98 j. Syphilis donor screening or diagnostic test
 99 k. Toxoplasma Immunoglobulin G (IgG) antibody test
- 100 3. ~~If the donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to~~
 101 ~~the U.S. Public Health Services (PHS) Guideline. HIV RNA by donor screening or diagnostic NAT or HIV~~
 102 ~~antigen/antibody (Ag/Ab) combination is also required unless either of the following is true:~~
 103 ~~• The donor has already been tested for HIV using the HIV Ag/Ab combination test according to~~
 104 ~~section 2.a above.~~
 105 ~~• The donor's only increased risk factor is having received hemodialysis within the past 12 months.~~
 106 Donor samples for all required HIV, HBV, and HCV testing must be obtained within 96 hours prior to
organ procurement.

13.11 Receiving and Accepting KPD Match Offers

Each OPTN KPD program must designate a KPD contact to receive notification of match offers.

Table 13-4: Deadlines for Performing Responsibilities upon Receiving a KPD Match Offer

The following members:	Must:	Within:
Each transplant hospital receiving a match offer	Report to the OPTN Contractor a preliminary response	2 business days of receiving the match offer.
The matched candidate's transplant hospital and the matched donor's transplant hospital	Agree in writing upon all of the following: <ul style="list-style-type: none"> • Contents required in the crossmatch kit • Instructions for the donor • Address at which to send the completed blood samples 	4 business days of receiving the match offer.
The matched donor's transplant hospital	Report to the OPTN Contractor the agreed upon date of the crossmatch	4 business days of receiving the match offer.

The following members:	Must:	Within:
The matched donor's transplant hospital	<p>Make all of the following matched donor's records accessible to the matched candidate's transplant hospital:</p> <ul style="list-style-type: none"> • Any serologic and nucleic acid testing (NAT) results that have not already been shared with the matched candidate's transplant hospital • Whether the matched donor is <u>increased risk has any risk criteria for acute HIV, HBV, or HCV infection</u> according to the <i>U.S. Public Health Services (PHS) Guideline</i> • Additional records requested by the matched candidate's transplant hospital 	4 business days of receiving the match offer.
The matched candidate's transplant hospital	Report to the OPTN Contractor the results of the crossmatch	15 business days of receiving the match offer.
The matched candidate's transplant hospital	Review the matched donor's records and confirm acceptance or report a refusal of the match offer to the OPTN Contractor	15 business days of the match offer.

107

108 If the matched candidate's and matched donor's transplant hospitals do not meet any of the deadlines
 109 above, then the exchange will be terminated unless a transplant hospital requests an extension. If a
 110 transplant hospital submits an extension request before the deadline, the exchange will not terminate
 111 until the resolution of the extension request or the deadline is reached, whichever comes last.

112

113 **14.1.A Living Donor Psychosocial Evaluation Requirements**

114 Living donor psychosocial evaluation requirements apply to living kidney, liver, pancreas, lung,
 115 and intestine donors.

116

117 The living donor psychosocial evaluation must be performed by a psychiatrist, psychologist,
 118 masters prepared social worker, or licensed clinical social worker prior to organ recovery.

119 Documentation of the psychosocial evaluation must be maintained in the living donor medical
 120 record and include *all* of the following components:

121

- 122 1. An evaluation for any psychosocial issues, including mental health issues, that might
 123 complicate the living donor's recovery and could be identified as risks for poor psychosocial
 124 outcome.
- 125 2. An ~~evaluation for the presence of behaviors that may increase~~ assessment of risk criteria for
 126 disease transmission acute HIV, HBV, and HCV infection as defined by according to the U.S.
 127 Public Health Service (PHS) Guideline.

- 128 3. A review of the living donor’s history of smoking, alcohol, and drug use, including past or
- 129 present substance abuse disorder.
- 130 4. The identification of factors that warrant educational or therapeutic intervention prior to
- 131 the final donation decision.
- 132 5. The determination that the living donor understands the short and long-term medical and
- 133 psychosocial risks for both the living donor and recipient associated with living donation.
- 134 6. An assessment of whether the decision to donate is free of inducement, coercion, and other
- 135 undue pressure by exploring the reasons for donating and the nature of the relationship, if
- 136 any, to the transplant candidate.
- 137 7. An assessment of the living donor’s ability to make an informed decision and the ability to
- 138 cope with the major surgery and related stress. This includes evaluating whether the donor
- 139 has a realistic plan for donation and recovery, with social, emotional and financial support
- 140 available as recommended.
- 141 8. A review of the living donor’s occupation, employment status, health insurance status, living
- 142 arrangements, and social support.
- 143 9. The determination that the living donor understands the potential financial implications of
- 144 living donation.
- 145

14.4.A Living Donor Medical Evaluation Requirements

147 Living donor medical evaluation requirements only apply to living kidney, liver, pancreas, lung or
 148 intestine donors.

149
 150 A medical evaluation of the living donor must be performed by the recovery hospital and by a
 151 physician or surgeon experienced in living donation. Documentation of the medical evaluation
 152 must be maintained in the donor medical record.

153
 154 The medical evaluation must include *all* of the components in *Tables 14-5* through *14-8* below.

Table 14-5: Requirements for Living Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
General donor history	1. A personal history of significant medical conditions which include but are not limited to: <ul style="list-style-type: none"> a. Hypertension b. Diabetes c. Lung disease d. Heart disease e. Gastrointestinal disease f. Autoimmune disease g. Neurologic disease h. Genitourinary disease i. Hematologic disorders j. Bleeding or clotting disorders k. History of cancer including melanoma

This evaluation must be completed:	Including evaluation for and assessment of this information:
	<ol style="list-style-type: none"> 2. History of infections 3. Active and past medications with special consideration for known nephrotoxic and hepatotoxic medications or chronic use of pain medication 4. Allergies 5. An evaluation for coronary artery disease
General family history	<ul style="list-style-type: none"> • Coronary artery disease • Cancer
Social history	<ul style="list-style-type: none"> • Occupation • Employment status • Health insurance status • Living arrangements • Social support • Smoking, alcohol and drug use and abuse • Psychiatric illness, depression, suicide attempts • Increased risk behavior Risk criteria for acute HIV, HBV, and HCV infection as defined by <u>according to the U.S. Public Health Services (PHS) Guideline</u>
Physical Exam	<ul style="list-style-type: none"> • Height • Weight • BMI • Vital signs • Examination of all major organ systems
General laboratory and imaging tests	<ul style="list-style-type: none"> • Complete blood count (CBC) with platelet count • Blood type and subtype as specified in 14.5: Living Donor Blood Type Determination and Reporting and its subsections • Prothrombin Time (PT) or International Normalized Ratio (INR) • Partial Thromboplastin Time (PTT) • Metabolic testing (to include electrolytes, BUN, creatinine, transaminase levels, albumin, calcium, phosphorus, alkaline phosphatase, bilirubin) • HCG quantitative pregnancy test for premenopausal women without surgical sterilization • Chest X-Ray • Electrocardiogram (ECG)
Transmissible disease screening	<p>Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services (CMS) using FDA-licensed, approved, or cleared tests. Testing must include <i>all</i> the following:</p> <ol style="list-style-type: none"> 1. CMV (Cytomegalovirus) antibody 2. EBV (Epstein Barr Virus) antibody

This evaluation must be completed:	Including evaluation for and assessment of this information:
	<ol style="list-style-type: none"> 3. HIV antibody (anti-HIV) testing or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery 4. <u>HIV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery</u> 5. Hepatitis B surface antigen (HBsAg) testing as close as possible, but within 28 days prior to organ recovery 6. Hepatitis B core antibody (anti-HBc) testing as close as possible, but within 28 days prior to organ recovery 7. <u>HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery</u> 8. Hepatitis C antibody (anti-HCV) testing as close as possible, but within 28 days prior to organ recovery 9. HCV ribonucleic acid (RNA) by nucleic acid test (NAT) as close as possible, but within 28 days prior to organ recovery 10. Syphilis testing <p>If a living donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to the <i>U.S. Public Health Services (PHS) Guideline</i>, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the <i>U.S. Public Health Services (PHS) Guideline</i>.</p> <p>For tuberculosis (TB), living donor recovery hospitals must determine if the donor is at increased risk for this infection. If TB risk is suspected, testing must include screening for latent infection using <i>either</i>:</p> <ul style="list-style-type: none"> • Intradermal PPD • Interferon Gamma Release Assay (IGRA)
<p>Endemic transmissible diseases</p>	<p>Each living donor hospital must develop and follow a written protocol for identifying and testing donors at risk for transmissible seasonal or geographically defined endemic disease as part of its medical evaluation.</p>
<p>Cancer screening</p>	<p>Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) or the U.S. Preventive Services Task Force to screen for:</p> <ul style="list-style-type: none"> • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Lung cancer

158 **14.8.B Living Donor Specimen Collection and Storage**

159 The recovery hospital must obtain specimens appropriate for serological and NAT testing within
 160 24 hours prior to organ recovery. The recovery hospital is responsible for arranging storage of
 161 these specimens for at least 10 years after the date of transplant and ensuring these samples
 162 are available for retrospective testing. The recovery hospital must document the type of sample
 163 in the living donor medical record.

165 **14.9.B Psychosocial and Medical Evaluation Requirements for Domino and Non-**
 166 **Domino Therapeutic Donors**

167
 168 Recovery hospitals must evaluate domino donors and non-domino therapeutic donors according
 169 to *all* of the following requirements:

- 170 1. Perform an ~~evaluation for the presence of behaviors that may increase risk for disease~~
 171 ~~transmission~~ assessment for risk criteria for acute HIV, HBV, and HCV infection as defined by
 172 according to the U.S. Public Health Service (PHS) Guideline
 173 2. Screen the domino donor or non-domino therapeutic donor for all of the following
 174 according to *Policy 14.4: Medical Evaluation Requirements for Living Donors, Table 14-5:*
 175 *Requirements for Living Donor Medical Evaluations:*
 176 a. Transmissible diseases screening
 177 b. Endemic transmissible diseases
 178 c. Cancer screening
 179 3. Develop and comply with written protocols for the domino donor and non-domino
 180 therapeutic donor exclusion criteria considering incorporating as appropriate the elements
 181 of *Table 14-8: Living Donor Exclusion Criteria*
 182 4. Register and verify the blood type of the domino donor or non-domino therapeutic donor
 183 according to *Policy 14.5: Registration and Blood Type Verification of Living Donors before*
 184 *Donation*

185
 186 Documentation of the psychosocial and medical evaluation must be maintained in the donor
 187 medical record.

188
 189 **15.2 ~~Potential Candidate Screening~~ Potential Candidate Screening Pre-Transplant Infectious Disease Reporting and Testing**
 190 **Requirements**

191 As part of the candidate's medical evaluation, an assessment for the need to provide HBV
 192 vaccination must occur. If the transplant program determines that vaccination cannot be
 193 initiated or completed due to timing related to transplant, medical contraindication, or other
 194 reasons in the transplant program's medical judgment, the reason for not initiating or
 195 completing HBV vaccination must be documented in the candidate's medical record and
 196 reported to the OPTN.

197
 198 To be eligible for an organ transplant, ~~potential~~ transplant candidates must be tested for:

- 199 1. ~~human immunodeficiency virus (HIV)~~ using a CDC recommended laboratory HIV testing
 200 algorithm
 201 2. ~~hepatitis B~~, Hepatitis B surface antigen (HBsAg)
 202 3. Hepatitis B core antibody (anti-HBc)

- 203 4. Hepatitis B surface antibody (HBsAb)
- 204 5. and hepatitis C, Hepatitis C antibody (anti-HCV)
- 205 6. Hepatitis C ribonucleic acid (RNA) by nucleic acid test (NAT)

206
207 unless the testing would violate state or federal laws.

208
209 Infectious disease testing must be performed in a CLIA-certified laboratory or in a laboratory
210 meeting equivalent requirements as determined by Centers for Medicare and Medicaid Services
211 (CMS) using FDA-licensed, approved, or cleared tests.

212
213 Candidate samples must be drawn during the hospital admission for transplant but prior to
214 anastomosis of the first organ.

215
216 If the candidate is known to be infected with HIV, HBV, or HCV, then testing for the known viral
217 infection or infections is not required, however the other tests required according to this policy
218 must still be performed.

219
220 Potential € Candidates who test positive for HIV, hepatitis B, or hepatitis C must be offered
221 appropriate counseling.

222
223 The OPTN permits HIV test positive individuals as organ candidates if permitted by the
224 transplant hospital. Care of HIV test positive organ candidates and recipients must not deviate
225 from general medical practice.

226 **15.3.B Donors with Risk Identified Pre-Transplant**

227
228 Transplant programs must meet the requirements according to *Table 15-1* below when the
229 deceased or living donor has risk of disease transmission identified pre-transplant.

230

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Table 15-1: Requirements for Donors with Risk Identified Pre-Transplant

Each time any of the following occurs:	Then transplant programs must do <i>all</i> of the following:
<ul style="list-style-type: none"> • The donor tests positive for <i>any</i> of the following: <ul style="list-style-type: none"> a. Hepatitis B surface antigen (HBsAg) b. Hepatitis B nucleic acid test (NAT) c. Hepatitis C NAT • The donor meets any of the criteria for increased risk of transmitting HIV, hepatitis B, or hepatitis C, as specified in the U.S. Public Health Services (PHS) Guideline • A hemodiluted specimen is used for the donor HIV, hepatitis B, or hepatitis C testing, according to Policy 2.5: Hemodilution Assessment • The donor tests positive for HIV antibody (anti-HIV), HIV antigen/antibody (Ag/Ab), or HIV NAT, and the transplant hospital participates in an approved variance according to <i>Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from HIV-positive Donors</i> 	<ol style="list-style-type: none"> 1. Explain the risks and obtain informed consent from the intended recipient or the intended recipient’s agent after the organ offer but before transplant 2. Document this consent in the intended recipient’s medical record 3. Follow the recipient for the development of potential donor-derived disease after transplant
<ul style="list-style-type: none"> • <u>The donor has any risk criteria for acute HIV, HBV, or HCV infection according to the U.S. Public Health Service (PHS) Guideline</u> 	<ol style="list-style-type: none"> 1. <u>Inform the intended recipient or the intended recipient’s agent after the organ offer but before transplant that risk criteria are present in the donor</u> 2. <u>Document that this information was provided in the intended recipient’s medical record</u>

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Exceptions to the informed consent requirement may be made for extra vessels when, ~~if~~ in the medical judgment of the transplanting physician, ~~the~~ extra vessels are required for use in an emergency transplant procedure for an organ other than the organ with which they were recovered. ~~In this case, then~~ the transplant hospital must do *both* of the following post-transplant:

1. Inform the recipient of the use of the extra vessels and if the donor had any risk criteria for acute HIV, HBV, or HCV infection according to the U.S. Public Health Service (PHS) Guideline ~~the increased risk status~~
2. Provide follow up to the recipient according to *Policy 15.3.B: Donors with Risk Identified Pre-Transplant* ~~15.3.C: Required Post-Transplant Infectious Disease Testing~~

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15.3.C Recipients of Organs from Donors with Increased Risk of Disease Transmission Required Post-Transplant Infectious Disease Testing

- 242 1. ~~Transplant programs must test all recipients post-transplant for: develop and comply with a~~
 243 ~~written protocol for post transplant testing for HIV, hepatitis B, or hepatitis C, for recipients~~
 244 ~~who receive an organ from a donor who meets any of the criteria for increased risk of~~
 245 ~~transmitting HIV, hepatitis B, or hepatitis C, as specified in the U.S. Public Health Services~~
 246 ~~(PHS) Guideline.~~
- 247 A. HIV ribonucleic acid (RNA) by nucleic acid test (NAT)
 248 B. HBV deoxyribonucleic acid (DNA) by nucleic acid test (NAT)
 249 C. HCV ribonucleic acid (RNA) by nucleic acid test (NAT)
 250
- 251 2. Testing must be performed on the recipient at least 28 days but no later than 56 days post-
 252 transplant.
- 253 3. If the candidate is known to be infected with HIV, HBV, or HCV, then testing for the known
 254 viral infection or infections is not required, however the other tests required according to
 255 this policy must still be performed.
- 256
- 257 4. The transplant program must offer recipients ~~of these donor organs~~ both of the following:
1. ~~Additional post transplant testing for HIV, hepatitis B , and hepatitis C according to the~~
~~transplant program’s protocol~~
2. ~~Treatment of or prophylaxis for the transmissible disease HIV, HBV, or HCV, when medically~~
~~appropriate.~~
5. Transplant programs must conduct HBV NAT testing on liver recipients at least 335 days but
no later than 395 days post-transplant.

258 **16.3.D Internal Labeling of Extra Vessels**

259 The rigid container holding the extra vessels and the outermost layer of the triple sterile barrier
 260 must each have a completed OPTN extra vessels label. The OPTN Contractor distributes
 261 standardized labels that must be used for this purpose. The internal label on the outermost
 262 layer of the triple sterile barrier must be completed using the OPTN organ tracking system. The
 263 labels must include *all* of the following information according to *Table 16-1* below.
 264
 265

Table 16-1: Required Information on Internal Labels for Vessels

This information must be included:	On the rigid container:	On the outermost layer of the triple sterile barrier:
1. Donor ID	●	●
2. Donor blood type	●	●
3. Donor blood subtype, if used for allocation	●	●
4. Recovery date	●	●

This information must be included:	On the rigid container:	On the outermost layer of the triple sterile barrier:
5. Description of the container contents	●	●
6. That the extra vessels are for use in organ transplantation only	●	●
7. All infectious disease testing results for <i>all</i> of the following: <ul style="list-style-type: none"> a. anti-HIV I/II b. HIV Ag/Ab combo c. HIV NAT d. anti-HBc e. HBsAg f. HBV NAT g. anti-HCV h. HCV NAT 		●
8. Whether the extra vessels are from a donor with a positive result (NAT included) for <i>any</i> of the following: <ul style="list-style-type: none"> ● HIV, HBV, or HCV ● Anti-HBc 	●	
9. Whether the extra vessels are from a donor that meets the <u>has any risk criteria for increased risk of transmitting for acute HIV, hepatitis B HBV, or hepatitis C HCV infection, as specified in</u> according to the U.S. <i>Public Health Service (PHS) Guideline</i>	●	●

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Appendix A: Crosswalk between 2013 and 2020 US Public Health Service Guidelines and OPTN Policy¹

Note: References to OPTN Policy are subject to updates based on ongoing review for consistency with the PHS Guidelines

Recommendation Category	2013	2020	OPTN Policy
Risk assessment of living and deceased donors	<ul style="list-style-type: none"> • OPOs should ascertain whether any of the following 14 risk criteria were present in potential organ donors. 	<ul style="list-style-type: none"> • OPOs should ascertain whether any of the following 10 risk criteria were present in potential organ donors. 	<ul style="list-style-type: none"> • 2.4 Deceased Donor Medical and Behavioral History • 14.1.A Living Donor Medical Evaluation Requirements <p>Current policy requires the medical and behavioral/social assessments including whether the donor would meet “increased risk” designation under the PHS Guideline.</p> <p>Proposed policy requires the same assessments, however the term “increased risk” is removed and the OPTN policy definition for the US PHS Guideline will be updated to use 2020 as the standard.</p>
	<p>Risk criteria (during the 12 months before organ procurement):</p> <ol style="list-style-type: none"> 1. Sex with a person known or suspected to have HIV, HBV, or HCV infection 2. Drug injection for nonmedical reasons 3. Man who has had sex with another man 4. Incarceration (confinement in jail, prison, or juvenile correction facility) for ≥72 consecutive hours 5. Sex in exchange for money or drugs 6. Sex with a person who injected drugs for nonmedical reasons 7. Sex with a person who had sex in exchange for money or drugs 8. Unknown medical or social history 9. Child aged ≤18 months born to a mother known to be infected with or at increased risk for HIV, HBV, or HCV infection 10. Child who has been breastfed by a mother who is known to be infected with or at increased risk for HIV infection 11. Woman who has had sex with a man who has had sex with another man 12. Newly diagnosed or treated syphilis, gonorrhea, chlamydia, or genital ulcers 13. Hemodialysis 14. Hemodilution of the blood sample used for infectious disease testing 	<p>Risk criteria (during the 30 days before organ procurement):</p> <ol style="list-style-type: none"> 1. Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV, or HCV infection 2. Man who has had sex with another man 3. Sex in exchange for money or drugs 4. Sex with a person who had sex in exchange for money or drugs 5. Drug injection for nonmedical reasons 6. Sex with a person who injected drugs for nonmedical reasons 7. Incarceration (confinement in jail, prison, or juvenile correction facility) for ≥72 consecutive hours 8. Child breastfed by a mother with HIV infection 9. Child born to a mother with HIV, HBV, or HCV infection 10. Unknown medical or social history 	<ul style="list-style-type: none"> • 1.2: Definitions: <p><i>United States Public Health Service (PHS) Guideline: The PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) through Organ Transplantation (2013).</i></p> <p>Definition modified to indicate “2020” Guideline.</p> <ul style="list-style-type: none"> • 2.5 Hemodilution Assessment <p>Current policy requires members to use the 2013 PHS Guideline to determine if a donor is considered “increased risk”.</p> <p>Proposed policy requires the same criteria as 2020 Guideline, but continues to require Hemodilution Assessment in Policy 2.5.</p>

¹Adapted from TABLE2. Comparison of 2013 and 2020 U.S. Public Health Service guideline recommendations* for solid organ donor assessment and transplant recipient monitoring for human immunodeficiency virus, hepatitis B virus, and hepatitis C virus infection in Jones, JM, Kracalik, I, Levi, ME “Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020” MMWR Recomm Rep 2020;69 (7-8) available at: <https://www.cdc.gov/mmwr/volumes/69/rr/rr6904a1.htm>.

This crosswalk is intended to assist transplant hospitals in comparing the 2013 PHS Guidelines and 2020 PHS Guidelines to current and proposed OPTN Policies. Use of this crosswalk is not an OPTN obligation and does not guarantee an assessment of compliance with OPTN obligations.

Recommendation Category	2013	2020	Current OPTN Policy
	<ul style="list-style-type: none"> Donors with any risk criteria should be designated as IRDs for an acute HIV, HBV, and HCV infection. 	<ul style="list-style-type: none"> Remove any specific label (e.g., “increased risk donor”) to describe donors with risk factors for acute HIV, HBV, and HCV infection. 	<p>Numerous OPTN policies and sections within reference and have requirements for “increased risk” donors:</p> <ul style="list-style-type: none"> 2.4 Deceased Donor Medical and Behavioral History 2.5 Hemodilution Assessment 2.7 HIV Screening of Potential Donors 2.9 Required Deceased Donor Infectious Disease Testing 13.11 Receiving and Accepting KPD Match Offers 14.4 Medical Evaluation Requirements for Living Donors 15.3 Informed Consent of Transmissible Disease Risk 16.2 Packaging and Labeling Responsibilities <p>Proposed policy replaces references to “increased risk donor,” and instead uses terms such as “risks,” “risk criteria” or “risk factors.”</p>
Living and deceased solid organ donor testing	<ul style="list-style-type: none"> Test all potential organ donors (living and deceased) <ul style="list-style-type: none"> HIV: anti-HIV-1/2 or HIV Ag/Ab combination assay HBV: Anti HBc and HBsAg HCV: NAT and anti-HCV For IRD only, HIV NAT or HIV Ag/Ab combination 	<ul style="list-style-type: none"> Test all potential organ donors (living and deceased) <ul style="list-style-type: none"> HIV: NAT and anti-HIV HBV: NAT, anti-HBc, and HBsAg HCV: NAT and anti-HCV 	<ul style="list-style-type: none"> Policy 2.9 Required Deceased Donor Infectious Disease Testing 14.4.A Living Donor Medical Evaluation Requirements <p>Current policy allows HIV Ab/Ag testing. Current policy does not require HBV NAT testing. Current policy only requires either HIV NAT or HIV Ab/Ag testing on IRD donors.</p> <p>Proposed policy requires the same tests as 2020 Guideline including NAT testing for HIV and HBV.</p>
Transplant candidate informed consent	<ul style="list-style-type: none"> No time frame is specified for pretransplant deceased donor testing; however, results should be available at the time of transplant. Living donors should be tested within 28 days before transplantation. Transplant center to obtain separate, specific informed consent from transplant candidates when donors are designated as IRDs 	<ul style="list-style-type: none"> For deceased potential donors, the donor specimen should be collected within 96 hours before organ procurement with results of these screening tests available at the time of organ procurement. For living potential donors, testing should be performed as close as possible to the surgery but at least within the 28 days before organ procurement. When donors with one or more of the criteria as specified under Risk Assessment of Living and Deceased Donors are identified, OPOs should communicate this information to the appropriate transplant centers. Transplant centers should include this information in informed consent discussions with transplant candidates or their medical decision-makers. No separate, specific informed consent is recommended. Transplant centers should contextualize these discussions by including that risk for undetected HIV, HBV, and HCV infection is very low but not zero; should transmission occur effective therapies are available, and accepting organs from donors with risk factors might increase the chance for survival. 	<ul style="list-style-type: none"> Policy 2.9 Required Deceased Donor Infectious Disease Testing 14.4.A Living Donor Medical Evaluation Requirements 15.3.A General Risks of Potential Malignancy or Disease Transmission 15.3.B Donors with Risk Identified Pre-Transplant <p>Current OPTN policy does not have timelines for deceased donor infectious disease test collection or result availability.</p> <p>Proposed policy requires the same time frame (96 hours) for obtaining specimen as 2020 Guideline.</p> <p>Current policy matches the timing requirement.</p> <p>No changes needed for proposed policy.</p> <p>Current policy requires informed consent for use of IRD donor and use of hemodiluted sample for infectious disease testing. The informed consent must be done after the organ offer but before transplant and the consent must be documented in the medical record.</p> <p>Proposed policy removes “informed consent” and includes requirement to document informing the recipient or their agent of presence of risk (Table 15-1: Requirements for Donors with Risk Identified Pre-Transplant).</p>

Recommendation Category	2013	2020	Current OPTN Policy
Recipient testing and vaccination	<ul style="list-style-type: none"> • Pretransplant testing of transplant candidates for HIV, HBV, and HCV infections is recommended when the donor (living or deceased) is designated as IRD or infected with HBV or HCV. <ul style="list-style-type: none"> o Type of assay not specified o Timing: during hospital admission for transplant but before transplant 	<ul style="list-style-type: none"> • Pretransplant testing for HIV, HBV, and HCV infections should be conducted for all candidates, regardless of donor risk criteria. <ul style="list-style-type: none"> o HIV: testing algorithm§ o HBV: anti-HBc, anti-HBs, and HBsAg o HCV: NAT and anti-HCV o Timing: During hospital admission for transplant but before transplant 	<ul style="list-style-type: none"> • <i>15.2 Potential Candidate Screening Requirements</i> <p>Current policy only specifies that candidates must have HIV, HBV, and HCV testing to be eligible for organ transplant. It does not specify testing type or more specific timing.</p> <p>Proposed policy would require the same as the PHS Guideline recommendations for specific HIV, HBV, and HCV tests and timing.</p>
	<ul style="list-style-type: none"> • Posttransplant testing of organ recipients for HIV, HBV, and HCV infections should be conducted when the donor (living or deceased) is designated as IRD or infected with HBV or HCV. <ul style="list-style-type: none"> o Type of testing is not specified. o Timing: testing should be performed at 1–3 months posttransplant for HIV, HBV, and HCV and again at 12 months for HBV. 	<ul style="list-style-type: none"> • Posttransplant testing for HIV, HBV, and HCV infections should be conducted for all recipients, regardless of donor risk criteria. <ul style="list-style-type: none"> o Type of testing: NAT for HIV, HBV, and HCV o Timing: 4–6 weeks posttransplant o Clinicians caring for liver recipients should maintain heightened awareness of the potential for delayed appearance of HBV infection and consider additional testing for HBV NAT at 1 year. o Recipients who develop signs or symptoms of liver injury after transplantation should be retested for viral hepatitis. 	<ul style="list-style-type: none"> • <i>15.3 Recipients of Organs from Donors with Increased Risk of Disease Transmission</i> <p>Current policy does not contain specific timing or test type. It requires that the transplant program have a protocol for post-transplant testing of IRD organ recipients and to follow their own protocol. No current policy requirement exists for universal posttransplant testing (for all recipients).</p> <p>Proposed policy would require universal post-transplant NAT testing for HIV, HBV, or HCV at 4-8 weeks post-transplant and HBV NAT for liver recipients at 11-13 months post-transplant. The recommendations are proposed for adoption with slightly revised time frames.</p>
	<ul style="list-style-type: none"> • No previous PHS guideline recommendation exists for HBV vaccination of transplant candidates. 	<ul style="list-style-type: none"> • All organ transplant candidates should be vaccinated against HBV infection. 	<ul style="list-style-type: none"> • No current OPTN policy. • OPTN Policy to require assessment for the need to provide HBV vaccination during candidate medical evaluation. • OPTN Policy to require reporting regarding vaccination status.
Collection and storage of donor and recipient specimens	<ul style="list-style-type: none"> • OPOs should consider archiving a deceased donor blood sample for 10 years. 	<ul style="list-style-type: none"> • OPOs and living donor recovery centers should archive donor blood specimens for at least 10 years. These specimens should be collected within 24 hours before organ procurement. 	<ul style="list-style-type: none"> • <i>2.2 OPO Responsibilities</i> <p>OPOs are currently required to keep blood specimens for serology and NAT testing for 10 years.</p> <p>No OPTN policy requirement exists for living donor recovery hospitals and storage of blood specimens.</p> <p>Proposed policy would require living donor recovery hospitals to arrange for living donor specimen storage for 10 years. Specimens would need to be collected within 24 hours of organ recovery.</p>
Tracking and reporting of donor-derived disease transmission events	<p>No recommendations in this category were substantially modified from 2013 to 2020.</p>	<p>No recommendations in this category were substantially modified from 2013 to 2020.</p>	<ul style="list-style-type: none"> • <i>2.12 Post Procurement Follow Up and Reporting</i> • <i>15.1 Patient Safety Contact</i> • <i>15.4 Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions</i> • <i>15.5 Transplant Program Requirements for Communicating Post-Transplant Discovery of Disease or Malignancy</i> • <i>15.6 Living Donor Recovery Hospital Requirements for Reporting</i> • <i>Post-Donation Discovery of Disease or Malignancy</i> <p>OPTN policies require reporting of potential donor-derived disease transmission events. This includes blood-borne illnesses as well as other infections and malignancies. No proposed changes.</p>

