

At-a-Glance

Proposal to Align OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Solid Organ Transplantation.

- **Affected/Proposed Policies:** 2.2 (OPO Responsibilities); 2.4 (Deceased Donor Medical and Behavioral History); 2.7 (HIV Screening of Potential Deceased Donors); 2.9 (Required Deceased Donor Information); 14.4.B Living Kidney Donor Medical Evaluation Requirements; 15.3 (Informed Consent of Transmissible Disease Risk); 15.3.A (Deceased Donors with Additional Risk Identified Pre-transplant); 15.3B (Deceased Donors at Increased Risk for Blood-borne Pathogens); 16.7.B (Vessel Storage)

- **Ad Hoc Disease Transmission Advisory Committee (DTAC)**

The Final Rule §121.4 (OPTN policies: Secretarial review and appeals.) notes that the OPTN Board of Directors is responsible for developing policies that are consistent with recommendations of the Centers for Disease Control and Prevention (CDC) to test potential organ donors and following transplant recipients to prevent the spread of infectious disease. The June 19, 2013, release of the *PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation* led to a systematic review of related OPTN policies. This proposal seeks to modify some existing policy language and also create new policies to reflect recommendations outlined in this updated PHS document.

- **Affected Groups**

Directors of Organ Procurement
Lab Directors/Supervisors
OPO Executive Directors
OPO Medical Directors
OPO Coordinators
Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
PR/Public Education Staff
Transplant Program Directors
Transplant Social Workers
Organ Recipients
Organ Candidates
Living Donors
Donor Family Members
General Public

- **Number of Potential Candidates Affected**

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

- **Compliance with OPTN Strategic Plan and Final Rule**

This proposal seeks to promote transplant patient safety through updated policies that are consistent with PHS recommendations for organ donors and transplant candidates and recipients. These modifications are anticipated to improve OPO and transplant programs' understanding and adherence to infectious disease testing requirements and recognition of increased risk of disease transmission from donors. These modifications

may also facilitate clearer communication between OPOs and transplant hospitals regarding increased risk donors.

- **Specific Requests for Comment**

The Committee wants to better understand any concerns regarding implementing the proposed changes to both donor and recipient testing. The DTAC seeks feedback on any expected difficulties in putting these changes into practice, and offers the following specific questions for consideration:

1. Which implementation timeframe (6 months, 1 year, longer?) is appropriate, reasonable and practical to allow for OPOs to make necessary changes in policies and procedures, contracts, logistical practices, etc. to comply with revised donor testing requirements?
2. What, if any, is the impact of the revised policy on delay in organ procurement offers and procurement, and potential loss of organs (and donors) due to an initial positive HCV nucleic acid testing (NAT) result that may require completion of additional testing?
3. What are the consequences for recipient informed consent and acceptance of organ when an unsuspected initial HCV NAT positive result is reported after procurement but prior to transplant procedure?
4. What are potential legal and ethical impacts and consequences on OPOs and transplant centers for obtaining a delayed positive HCV NAT result after organ procurement and transplant of an organ? What about receiving an initial positive HCV NAT result after organ procurement and transplant?
5. How are the above questions affected by labs that run a “triplex” (combined HCV, HIV, HBV) NAT test even when only the HCV NAT is ordered? This could lead to the potential for multiple false positives that need to be investigated and resolved?
6. What are the potential legal, logistical, and ethical impacts and consequences on lab, OPO, and transplant center of running the “triplex” (HCV, HIV, and HBV) NAT test to comply with the revised policy? Must a lab report the results of the HIV and HBV NAT even if the test was not specifically ordered?
7. What sort of data are available that would assess the extent and variability of false positive rate (in deceased donors with no “increased risk” factors) of HCV NAT in the various high volume “batch” labs (e.g., regional blood donor testing labs) versus individual stand-alone and hospital based labs?
8. Might there be special subpopulations or subgroups of deceased and living donors where it may be reasonable to exempt “universal HCV NAT” testing to avoid a false positive scenario (e.g., pediatric deceased donors with no “increased risk” factors or living donors with well documented medical and social behavioral health history)?
9. Including additional wait list screening criteria for HCV and HBV NAT will carry substantial programming costs. Is it necessary to have separate wait list screening criteria for serology and NAT results for these two viruses?
10. The current medical-social criteria for determining increased risk include dialysis as a risk factor for HCV. Should short term dialysis or continuous veno-venous hemofiltration (CVVH) only at the time of the terminal hospitalization carry the same risk as chronic dialysis for potential transmission? Should this be clarified in policy or in a guidance document?

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Ad Hoc Disease Transmission Advisory Committee (DTAC)

Public comment response period: March 14 - June 13, 2014

Summary and Goals of the Proposal:

The Final Rule §121.4 (OPTN policies: Secretarial review and appeals.) notes that the OPTN Board of Directors is responsible for developing policies that are consistent with recommendations of the Centers for Disease Control and Prevention (CDC) to test potential organ donors and following transplant recipients to prevent the spread of infectious disease. The June 19, 2013, release of the *PHS Guideline for Reducing Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) Through Organ Transplantation* led to a systematic review of related OPTN policies. This proposal seeks to modify some existing policy language and also create new policies to reflect recommendations outlined in this updated PHS document.

Background and Significance of the Proposal:

The PHS' original 1994 [*Guidelines for Preventing Transmission of HIV through Transplantation of Human Tissue and Organs*](#) covered only the risk of HIV transmission through organ and tissue donation. Over the course of the last five years, the CDC worked with the Center for Evidence-Based Practice at the University of Pennsylvania Health System as well as experts in the field for review and feedback to develop an updated set of recommendations that would also include HBV and HCV in addition to potential HIV transmission. The proposed guidelines were released for public comment on September 21, 2011. The DTAC and other OPTN Committees held a series of calls to review the proposed recommendations and provide feedback.

The CDC reviewed all feedback, and ultimately released its final [*PHS Guideline for Reducing Human Immunodeficiency Virus \(HIV\), Hepatitis B Virus \(HBV\), and Hepatitis C Virus \(HCV\) Through Organ Transplantation*](#) on June 19, 2013. In addition to outlining twelve criteria to assess donor risk for HIV, HBV, and HCV (usually addressed by organ procurement organization (OPO) staff through the completion of a medical-social history interview with next of kin, cohabitant, etc.), the updated Guideline also provides 34 specific recommendations (and subrecommendations) regarding living and deceased donor testing, pre- and post-transplant recipient testing, and vessel usage. These recommendations appear on pages 251-256 of the document that is linked above.

The Final Rule, §121.4 (OPTN policies: Secretarial review and appeals.)¹, notes that the OPTN Board of Directors is responsible for developing policies that are consistent with recommendations of the CDC to test potential organ donors and following transplant recipients to prevent the spread of infectious disease. Current policy references the PHS Guideline only in relation to identifying which potential deceased or living donors might be at increased risk for transmitting these blood-borne pathogens as part of the medical-social evaluation process.

After release of the new Guideline, the DTAC formed a Joint Subcommittee with representation from the OPO, Operations & Safety, and Living Donor Committees, as well as representation from the four major transplantation societies. These societies include: Association of Organ Procurement Organizations (AOPO), North American Transplant Coordinators Organization (NATCO), American Society of Transplantation (AST) and American Society of Transplant Surgeons (ASTS). This Joint Subcommittee completed a page-by-page review of all of the 2013 PHS Guideline recommendations to determine if there are new policies or additional policy modifications related to testing recommendations for donors and organ transplant candidates, as well as post-transplant recipient care, that may be warranted based upon these new areas of inclusion in the Guideline.

The Joint Subcommittee was divided into four working groups to review the various recommendations in detail:

- Donor and Recipient Testing
- Donor and Recipient Specimen Collection and Storage and Tracking and Reporting of HIV, HBV, and HCV Subgroup
- Informed Consent
- Risk Assessment and Screening

The four working groups were assigned corresponding lists of recommendations for discussion and asked to consider the following points for each:

- Is the PHS recommendation covered by the Final Rule?
- Is there policy already in place to address this? If so, does it need to be changed?
- Should there be policy in place to address this, or should it remain as a PHS recommendation only?

Each working group met by teleconference to review its assigned recommendations and respond to the questions outlined above. Upon completion of this task, the full Joint Subcommittee reconvened on November 7, 2013, to consider feedback from each of the working groups. Their feedback is captured in Table 1, below.

¹ To view the full text of the Final Rule, please visit the following link: http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp

Table 1: 2013 PHS Guideline Recommendations

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
1	All living potential donors and individuals interviewed about deceased potential organ donors (e.g., next of kin, life partner, cohabitant, caretaker, friend, or primary treating physician) should be informed of the donor evaluation process, including the review of medical and behavioral history, physical examination, and laboratory tests to identify the presence of infectious agents or medical conditions that could be transmitted by organ transplantation.	Policy 2.3 Policy 14.3A Policy 2.4	<p>No changes to current policy recommended.</p> <p><u>Comments:</u> The new "universal" Med/Soc history has a nice statement in the beginning. This could be included in a "guidance document" if the committee decides one is necessary.</p> <p>The medical /social history is now referred to as the DARI, this is a new form in 2013.</p> <p>Given that this is seen as good practice, it may be worth communicating with the procurement council of AOPO to recommend some education or policy change at the OPO level.</p>
2	To ascertain whether potential organ donors are at increased risk for HIV, HBV, or HCV infection, living donors, or individuals contacted about deceased donors, should be interviewed in a confidential manner about behaviors that may have increased the potential donor's probability of having HIV, HBV, or HCV infection.	Policy 2.3 and 2.4 Policy 14.4B	<p>No changes to current policy recommended.</p> <p><u>Comments:</u> This is good medical practice, but probably does not need specific policy around it. The same is true for living donors.</p>
3	Living potential donors with behaviors associated with an increased risk of acquiring HIV, HBV, or HCV identified during evaluation should receive individualized counseling on specific strategies to prevent exposure to these viruses during the time period prior to surgery.	Policy 14.5A (#2, #4, and #5)	<p>Consider a guidance document or addition to current living donor checklist to address this</p> <p><u>Comments:</u> I think the combination of 14.5's sections cover this; agree with considering a guidance document but no change to policy)</p> <p>No policy BUT yes to considering guidance or addition to check list. Who will be responsible for generating guidance or adding to check list?</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
4	If a potential donor is < 18 months of age or has been breastfed within the preceding 12 months, the birth mother, if available, should be interviewed about behaviors that may have placed her at risk for HIV, HBV, or HCV infection.	None This is a question on the med-soc that is required in policy 2.4 (but no standard form provided by AOPO in some time. OPOs can modify based upon specific regional concerns, etc	Now outlined in PHS med-soc "increased risk" criteria. Specific policy probably not necessary here. <u>Comments:</u> Policy does not need to specifically state the review when this is covered in obtaining the med/soc history I think adequately covered in 2.4 and I don't think we should make policy for every conceivable situation, general language (as exists) is adequate
5a	When a deceased potential organ donor's medical/behavioral history cannot be obtained or risk factors cannot be determined, the donor should be considered at increased risk for HIV, HBV, and HCV infection because the donor's risk for infection is unknown.	Not specifically stated in Policy 2.4, but seems to be a common OPO practice. CMS Interpretative Guidelines for OPOs address donors with no history (486.48344 (B3))	Add this as a new policy requirement. (See proposed modifications to Policy 2.4.) <u>Comments:</u> Might want to discuss if this should be a different category (similar to European system) - they truly have an unknown risk instead of a known increased risk Policy statement is needed - this is a gray area in OPO land. Draft policies could be obtained from OPOs to use in the language/policy development. This is supported by data on donors with unobtainable history (at least for prevalent infection)
5b	When a deceased potential organ donor's blood specimen is hemodiluted, the donor should be considered at increased risk for HIV, HBV, and HCV infection because the donor's risk for infection is unknown.	Policy 2.5	No policy addition recommended <u>Comments:</u> This is clearly covered in current policy, but it should be noted that there is no data to back the scientific validity regarding dilution and Hepatitis. There is published evidence that heavily diluted reactive samples can be tested without loss of detection (studies were conducted in vitro).

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
6	All living potential donors should be tested for HIV, HBV, and HCV as close as possible to the date of the organ recovery operation, but at least within the 28-day time period prior to surgery.	Policy 14.4B (but no time requirement within this language)	<p>Add this as a new policy requirement, See Policies 2.9 (Required Disease Donor Infectious Disease Testing) and 14.4.B (Living Kidney Donor Medical Evaluation Requirements) for proposed modifications.</p> <p><u>Comments:</u> Consider policy to require that testing be completed, "as close as possible but within 28 days prior to organ recovery." This promotes patient safety and makes it monitorable.</p> <p>Accompanying guidance doc or evaluation plan could recommend the sooner the better to enhance patient safety.</p>
7	All potential organ donors (living or deceased) should be tested for antibodies to HIV (i.e., anti-HIV 1/2 or HIV antigen/antibody [Ag/ Ab] combination assay). All potential organ donors identified as being at increased risk for HIV infection should also be tested for HIV ribonucleic acid (RNA) by NAT or HIV antigen (e.g., HIV Ag/Ab combination assay). Donor blood specimens should be obtained before procurement. Ab or Ag/Ab test results should be made available before transplantation. (Note: Optimally, all NAT results for deceased donors should be available before the transplant occurs; however, if having NAT results before transplantation is not feasible, test results can be useful to guide recipient treatment.)	<p>Policy 2.9 for deceased donors</p> <p>Policy 14.4B (table) for living donors.</p> <p>Both require antibody screening only currently.</p> <p>NAT is not required for anyone at this time.</p> <p>DTAC Fall 2013 public comment proposal offers combined Ag/Ab testing for deceased donors</p>	<p>Add a new policy requirement to require HIV NAT or combo Ag/Ab test for increased risk donors prior to transplant. See Policies 2.9 (Required Disease Donor Infectious Disease Testing) and 14.4.B (Living Kidney Donor Medical Evaluation Requirements) for proposed modifications.</p> <p><i>(Fall 2013 DTAC public comment proposal already requests inclusion of combination HIV Ag/Ab test.)</i></p> <p><u>Comments:</u> OK with this, but Ag/Ab combo test does muddy the waters a bit</p> <p>Agree – Increased risk HIV NAT and Antibody AND Agree HIV antibody or antigen/antibody for all donors</p> <p>Disagree with parenthetical remark</p> <p>Prefer that ALL donors undergo NAT testing – widely available and unless there is a “rapid recovery”, NAT results are attainable in time from consent to recovery. There is really no such thing as a “normal” donor – universal protocol should play out in organ donation. This should apply to living and deceased.</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
8	<p>All potential organ donors (living or deceased) should be tested for both anti-HCV and for HCV RNA by NAT. Donor blood specimens should be obtained before procurement. Ab test results should be made available before transplantation. (Note: Optimally, all NAT results for deceased donors should be available before the transplant occurs; however, if having NAT results before transplantation is not feasible, test results can be useful to guide recipient treatment.)</p>	<p>Policy 2.9 for deceased donors</p> <p>Policy 14.4B for living donors.</p> <p>Both require antibody screening only currently.</p> <p>NAT is not required for anyone at this time.</p>	<p>Split vote. All members (recognizing 2 abstentions) were supportive of requiring HCV NAT for increased risk donors, but only six of the 15 voters supported HCV NAT for all as recommended by the PHS</p> <p><u>Comments:</u> Am on the fence (i.e., abstain) – this will defacto wind up resulting in NAT testing for HIV and HBV too. I think this really needs more study before it becomes policy. What is the impact on the donor pool at large? Will OPOs be able to perform this, even if the results are post tx? I do agree that it is probably a useful bit of information since we don't fully understand the risk pool and it does go along with current USPHS guidelines for more widespread testing for HCV (although that is antibody)</p>
9	<p>All potential organ donors (living or deceased) should be tested for anti-HBc and for HBsAg. Donor blood specimens should be obtained before procurement. Ab/Ag test results should be made available before transplantation.</p>	<p>Policy 2.9</p> <p>Policy 14.4B</p>	<p>No policy addition recommended</p> <p><u>Comments:</u> This is clearly covered in current policy</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
10	<p>An informed consent process discussion between the transplant candidate, or medical decision maker, and the listing clinician should start before the patient is placed on the transplant wait list. Patients should be counseled to consider potential risks of both accepting and rejecting organs from donors known to be infected with HBV or HCV, or donors at increased risk for HBV, HCV, or HIV infection.</p>	<p>Policy 15.3 and its subsections</p>	<p>Guidance document or promotion of best practice, but no additional policy language here.</p> <p><u>Comments:</u> Time requirements are not specified in policy, but seem to be practical common sense.</p> <p>Is it necessary to put this level of detail in consent language?</p> <p>We don't have all the science/data at this point to dictate the best point in time to cover informed consent effectively with candidates. Might be better to spread out this process over time to avoid information overload for the candidate.</p> <p>CMS CoPs might be more specific here, with specific requirements for consent at time of evaluation- these focus on surgical risk, not transmission of disease.</p> <p>Agree that this should be SOP and may be better suited for a guideline rather than policy, though I don't have issues with this being policy.</p>
11	<p>The transplant candidate, or medical decision maker, should have opportunities to discuss with clinicians issues related to the associated risk of HIV, HBV, or HCV transmission with organ acceptance while the patient is on the transplant wait list.</p>	<p>Policy 15.3 and its subsections</p>	<p>Guidance or best practice, but not policy (may be more effective or well received if developed through professional societies rather than OPTN?)</p> <p><u>Comments:</u> How do we request one of the societies to take the lead on guidance? Which one?</p> <p>This is just common sense does not need to be stated in policy</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
12	At the time of the organ offer, if a donor is identified as being at increased risk for HIV, HBV, or HCV infection, the transplant center team primarily responsible for the patient's care should include this risk information in the informed consent discussion with the transplant candidate or medical decision maker.	Policy 15.3 and its subsections (not specifically, but this would be expected as part of the discussion process?)	<p>Modify current policy to clarify expectation, but not to add or increase requirements. See proposed modifications to Policy 15.3.</p> <p><u>Comments:</u> Rework policy language in 15.3. Re-order bullets (removing duplicative language and referring only to PHS Guideline) and pull medical judgment phrase into new second bullet.</p>
13	If prior to transplantation or repair of a trans-planted organ it is known or anticipated that stored blood vessel conduits (from a donor who is different from the donor of the primary organ being transplanted or repaired) may be used, and the donor is identified as being at increased risk for HIV, HBV, or HCV infection, then the transplant center team should include this risk information in the informed consent discussion.	Policy 15.3 Policy 16.7B	<p>No changes to current policy recommended.</p> <p><u>Comments:</u> You will rarely know if you need extra vessels before you get into the OR and visualize the anatomy. Superfluous... Policy prevents storage of many of these vessels for later use (Policy 5.10.2). Existing policy is adequate and covers this.</p>
14	When organs from HBV or HCV infected donors will be used, the transplant center team primarily responsible for the patient's care should have an informed consent discussion with the transplant candidate, or medical decision maker, prior to transplantation regarding the risks related to disease transmission.	Policy 15.3B and its subsections	<p>Modify current policy to clarify expectation, but not to add or increase requirements. See proposed modifications to Policy 15.3.</p> <p><u>Comments:</u> "At increased risk or proven to be infected with HBV or HCV" added to first bullet in new 4.2 layout as recommended above.</p>
15	Transplant candidates should be informed that although all donors are screened for HIV, HBV, and HCV, donor screening has limitations and no screening question or laboratory test can completely eliminate the risk for transmitting these infections (or any other infection).	Policy 15.3	<p>No policy addition recommended. This is already clearly stated in current policy.</p> <p><u>Comments:</u> Should not be in policy, should be guidance or best practice</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
16	<p>Pre-transplant testing of transplant candidates for HIV, HBV, and HCV should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HIV, HBV, and HCV infection (Note: If the donor is only identified as being at risk for HCV infection due to hemodialysis in the preceding 12 months, then testing for HCV only is recommended); (2) screening specimens are hemodiluted; or (3) the medical/behavioral history is unavailable. When the donor meets any of the three conditions, transplant candidate testing should occur during hospital admission for the organ transplant but prior to implantation of the organ, unless the transplant candidate is known through prior testing to be infected.</p>	<p>Policy 5.4F (#4) Policy 15.2</p>	<p>No policy addition recommended.</p> <p><u>Comments:</u> This is best practice as pre-transplant testing order but does not enhance safety of recipient or impact risk of transmission</p> <p>When investigating a possible transmission recent serologies can help clarify transmission vs pre-transplant disease transmission</p> <p>It would be interesting to compile the national perspective on this</p>
17	<p>Pre-transplant testing of transplant candidates for HBV or HCV should be conducted when the donor (living or deceased) is known to be infected with HBV or HCV. Transplant candidate testing should occur during hospital admission for the organ transplant but prior to organ implantation, unless the transplant candidate is known through prior testing to be infected.</p>	<p>Policy 15.2</p>	<p>Testing us required for all candidates, but time of testing is not specified.</p> <p>No additions to policy recommended. This is a best practice as a pre-transplant testing order, but does not enhance safety of recipient or impact risk of transmission.</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
18	<p>Post-transplant HBV testing of recipients should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HBV infection, (2) screening specimens are hemodiluted, (3) the medical/behavioral history is unavailable, or (4) the donor is infected with HBV. Recipient testing should be performed sometime between one and three months post-transplant to include HBV NAT and HBsAg, and at 12 months post-transplant to include antibody to hepatitis B surface antigen (anti-HBs), anti-HBc, and either HBV NAT or HBsAg (unless infection was documented pre-transplant).</p>	<p>Policy 15.3B:</p> <p>TX programs must offer the recipients of organs from donors at increased risk for blood borne pathogens:</p> <ul style="list-style-type: none"> • additional post-transplant testing for HIV, HCV, and/or HBV (as appropriate based upon the recipient's pre-transplant status); and • monitoring and/or therapy to treat or provide prophylaxis as appropriate to minimize the risk of infection in addition to routine post-transplant follow-up care. 	<p>Develop new policy language that will require programs to develop their own internal process/protocol for post-transplant testing. Review of whether a center is following its own outlined process/protocol may be considered as part of OPTN site survey. See Policy 15.3.B</p> <p>The Joint Subcommittee was not supportive of developing prescriptive policy language to include time intervals for this testing.</p> <p><u>Comments:</u> This agrees with recommendations from LD consensus conference regarding time periods for follow-up testing.</p> <p>Is there more value in testing for all three viruses at 1-3 months only (recognizing that a few HBV cases may develop later)? Too broad of sweep at a later time may capture reactivations and cause potential confusion. Policy should set a minimum standard, with members wondering if the PHS rec takes this too far... Current policy requires follow up without time requirements.</p> <p>Is it appropriate to create a guidance or best practices list on recommendations not folded directly into policy- UNOS, prof societies, etc develop?</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
19	<p>Post-transplant HIV testing of recipients should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HIV infection, (2) screening specimens are hemodiluted, or (3) the medical/behavioral history is unavailable. Recipient testing should be performed sometime between one and three months post-transplant to include HIV NAT or an HIV Ag/Ab combination assay (unless infection was documented pre-transplant). NAT or an Ag/Ab combination assay for HIV detection is important as infected recipients may remain Ab-negative due to immunosuppression.</p>	<p>Policy 15.3B</p>	<p>Develop new policy language that will require programs to develop their own internal process/protocol for post-transplant testing. Review of whether a center is following its own outlined process/protocol may be considered as part of OPTN site survey. See Policy 15.3.B.</p> <p>The Joint Subcommittee was not supportive of developing prescriptive policy language to include time intervals for this testing.</p> <p><u>Comments:</u> Policy should reflect that each tx center must perform post-testing and must have a protocol to reflect their process. We shouldn't dictate what their process is, but we can dictate that follow-up testing is performed in suggested timeline – if it's not a "must" then it's not enforceable. Guideline should also be developed for centers to use as they develop their protocols.</p>
20	<p>Post-transplant HCV testing of recipients should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HCV infection, (2) screening specimens are hemodiluted, (3) the medical/behavioral history is unavailable, or (4) the donor is infected with HCV. Recipient testing should be performed sometime between one and three months post-transplant to include HCV NAT (unless infection was documented pre-trans- plant). NAT is important for HCV detection as infected recipients may remain Ab-negative due to immunosuppression.</p>	<p>Policy 15.3B Transplant programs must</p>	<p>Develop new policy that will require programs to develop internal process for post-transplant testing (rather than specify timelines for testing in policy). Review of whether a center is following its own outlined process/protocol may be considered as part of OPTN site survey. See Policy 15.3.B</p> <p><u>Comments:</u> Policy should reflect that each txp center must perform post-testing and must have a protocol to reflect their process. We shouldn't dictate what their process is, but we can dictate that follow-up testing is performed in suggested timeline.</p> <p>Agree with statement in spreadsheet – programs should develop local policy, follow local policy and be surveyed to document they follow their policy</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
21	For deceased donors, the OPO should consider collecting two blood specimens, when possible, for HIV, HBV, and HCV real-time testing (i.e., prior to organ recovery) an ethylenediaminetetraacetic acid (EDTA) plasma specimen or serum specimen for serologic assays and a separate EDTA plasma specimen for NAT. Additionally, the OPO should consider collecting two blood specimens for archiving, when possible. If it is only feasible to collect one specimen, a plasma specimen collected in EDTA, rather than a serum specimen, is optimal.	Policy 2.2 (#15)	<p>Modify current policy to add recommended language and out clause (guidance may also be helpful here)</p> <p><u>Comments:</u> Current policy covers part of recommendation. Add: "Specimens appropriate for serologic and NAT"</p> <p>Guidance could further define tube types, etc without policy getting too specific or creating risk of it becoming quickly outdated with laboratory practice changes</p>
22	The OPO should consider archiving blood specimens from deceased donors for at least 10 years.	Policy 2.2 (#15)	<p>No policy addition recommended. This is already clearly stated in current policy.</p> <p><u>Notes:</u> Already an AOPO standard</p>
23	For living donors, transplant candidates, and recipients, two blood specimens should be collected when HIV, HBV, or HCV testing is planned an EDTA plasma specimen or serum specimen for serologic assays and a separate EDTA plasma specimen for NAT.	This is not a current requirement.	<p>Appears to indicate storage of specimens for candidates, recipients and living donors without specifically stating such a recommendations. What would one do with the tubes collected? Request to HRSA to reach out to PHS for clarification on the intended meaning of this recommendation.</p> <p>Joint Subcommittee supports testing without granular requirements and without long term storage. May need feedback from CDC here on whether storage was implied.</p> <p><u>Comments:</u> Tough to operationalize and is expensive – doesn't need to be policy as there is no way to justify the expense.</p> <p>Such specific tube requirements in policy language are unnecessary and will prove problematic to update quickly as technology changes.</p> <p>Overall, the Joint Subcommittee believes that this recommendation is nonsensical, as there is no specific reference with what to do with these tubes once they are drawn.</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
24	<p>Infusion of crystalloid and colloid solutions and transfusion of blood products can cause hemodilution and produce false-negative results for HIV, HBV, and HCV testing. Therefore, the OPO should make an effort to collect a qualified (non-hemodiluted) specimen that is, a specimen that is deemed acceptable for testing according to an appropriate hemo- dilution algorithm and calculation method, such as provided by the FDA.2 Furthermore, a hemodilution calculation should be performed on archived specimens of deceased donors to facilitate interpretation of test results.</p>	<p>Policy 2.2 (#15) Policy 2.5</p>	<p>No policy addition recommended. This is already clearly stated in current policy.</p> <p><u>Notes:</u> none</p>
25	<p>All stored blood vessel conduits from a donor found to be infected with HIV, HBV, or HCV should be quarantined immediately and not released for clinical use unless the HBV or HCV infected vessel conduits are needed for the initial transplant procedure in the recipient. After completing the initial transplant procedure, any remaining vessel conduits should be disposed of in accordance with hospital policy to prevent inadvertent release from quarantine and unintentional use in other patients.</p>	<p>Policy 16.7B</p> <p>Includes:</p> <ul style="list-style-type: none"> • Hepatitis C antibody positive and hepatitis B surface antigen positive extra vessels may not be stored for subsequent use. 	<p>Add reference to NAT positive vessels in current language (see discussion below).</p> <p>Current policy may require modifications to address changing HIV use status due to passage of the Hope Act- clarification may benefit community</p> <p><u>Comments:</u> Agree HIV vessels should be quarantined and discarded</p> <p>Consider incorporating “NAT if available” or “infected with...”</p> <p>NAT positive- reasonable to change now as pretty straightforward (would favor hep C or hep B infected 2) HIV should be changed if HIV infected organs allowed by law</p>
26a	<p>When an OPO receives information before organ recovery that a deceased potential donor is at increased risk for or is infected with HIV, HBV, or HCV, the OPO should notify (1) the OPTN, (2) the transplant centers receiving organ offers, and (3) any institutions considering tissue and eye recovery.</p>	<p>Policy 2.3</p> <p>Policy does not specifically outline notifications regarding status, but DonorNet® and DDR forms denote this.</p>	<p>This is captured in DonorNet/DDR and communicated as part of organ offer to OPOs. OPOs have separate pathways for communicating to tissue and eye banks (not covered in OPTN policy).</p> <p><u>Comments:</u> No purpose for policy since collecting already</p>

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
26b	The OPO should also notify the public health authorities where the potential donor is admitted, in accordance with state requirements for reporting notifiable infections, if the deceased potential donor is infected.	Not in current policy. If a nationally notifiable disease is reported to the OPTN, patient safety staff notifies CDC per CDC/HRSA working agreement	No policy addition recommended <u>Comments:</u> This is handled variably by states and policy would be cumbersome here. AOPO standard requiring state requirements. Already exists in state jurisdiction and does not promote patient safety.
27a	When an OPO receives information after organ recovery that a deceased donor was infected with HIV, HBV, or HCV, or that an organ recipient infection with HIV, HBV, or HCV is suspected of being donor derived, the OPO should notify (1) the OPTN, (2) the transplant centers that received organs and/or blood vessel conduits from the deceased donor, and (3) any institutions that recovered tissues and eyes from the donor.	Policy 15.4B 3a(i)	No changes to current policy recommended. <u>Comments:</u> Already in current policy. No further additions needed.
27b	The OPO should also notify public health authorities where the organ recovery took place, in accordance with state requirements for reporting notifiable infectious diseases, if the deceased donor was infected.	Not in current policy. If a nationally notifiable disease is reported to the OPTN, patient safety staff notifies CDC per CDC/HRSA working agreement	No policy addition recommended <u>Comments:</u> This is handled variably by states and policy would be cumbersome here. AOPO standard requiring state requirements. Already exists in state jurisdiction and does not promote patient safety.
28a	When a transplant center receives information that a recipient of an organ or blood vessel conduit from any deceased donor is newly infected with HIV, HBV, or HCV post-transplant and the infection is suspected of being donor derived, the transplant center should notify (1) the OPTN and (2) the OPO that procured the organs and any blood vessel conduits.	Policy 15.4A	No policy addition recommended. This is already clearly stated in current policy. <u>Notes:</u> none
28b	In accordance with state requirements for reporting notifiable infectious diseases, the transplant center where the transplant took place should also notify public health authorities of the recipient infection.	Not in current policy. If a nationally notifiable disease is reported to the OPTN, patient safety staff notifies CDC per CDC/HRSA working agreement	No policy addition recommended <u>Comments:</u> This is handled variably by states and policy would be cumbersome here. Already exists in state jurisdiction and does not promote patient safety.

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
29a	When a living donor recovery center receives information before organ recovery that a living potential donor is infected with HIV, HBV, or HCV, the living donor recovery center should notify the transplant center intended to receive the organ. If the organ from an HBV or HCV infected donor is used for transplantation, the living donor recovery center should also notify the OPTN.	Policy 15.3A Policy 15.4A	No policy addition recommended. <u>Notes:</u> Covered appropriately in current policy.
29b	In accordance with state requirements for reporting notifiable infectious diseases, the living donor recovery center should also notify public health authorities where the potential donor lives of the potential living donor's infection.	Not in current policy. If a nationally notifiable disease is reported to the OPTN, patient safety staff notifies CDC per CDC/HRSA working agreement	No policy addition recommended <u>Comments:</u> This is handled variably by states and policy would be cumbersome here. Already exists in state jurisdiction and does not promote patient safety. Check CMS regs for this
30a	When a living donor recovery center receives information after organ recovery that a living donor is infected with HIV, HBV, or HCV, the living donor recovery center should notify (1) the OPTN and (2) the transplant center that received an organ from the living donor. Disclosure to the OPTN and transplant center should be in accordance with state requirements.	Policy 15.4B	No policy addition recommended. <u>Notes:</u> Covered appropriately in current policy.
30b	In accordance with state requirements for reporting notifiable infectious diseases, the living donor recovery center should also notify public health authorities where the organ recovery took place of the living donor's infection.	Not in current policy. If a nationally notifiable disease is reported to the OPTN, patient safety staff notifies CDC per CDC/HRSA working agreement	No policy addition recommended <u>Comments:</u> This is handled variably by states and policy would be cumbersome here. Already exists in state jurisdiction and does not promote patient safety. Check CMS regs for this
31	When a living donor recovery center receives information after organ recovery that an organ recipient infection with HIV, HBV, or HCV is suspected of being donor derived, the living donor recovery center should notify the OPTN.	Policy 15.4B	Already covered appropriately in current policy. <u>Comments:</u> None

Rec #	PHS Recommendation	Related Current Policy References	Joint Subcommittee Response
32a	When a transplant center receives information that a recipient of an organ from a living donor is newly infected with HIV, HBV, or HCV post-transplant and the infection is suspected of being donor derived, the transplant center should notify (1) the OPTN and (2) the living donor recovery center that procured the organ.	Policy 15.4A	No policy addition recommended. <u>Notes:</u> Covered appropriately in current policy.
32b	In accordance with state requirements for reporting notifiable infectious diseases, the transplant center should also notify public health authorities where the transplant took place of the recipient's infection	Not in current policy. If a nationally notifiable disease is reported to the OPTN, patient safety staff notifies CDC per CDC/HRSA working agreement	No policy addition recommended <u>Comments:</u> This is handled variably by states and policy would be cumbersome here. APO standard requiring state requirements. Already exists in state jurisdiction and does not promote patient safety. Checks CMS regs.
33	A living donor whose blood specimen is positive for HIV, HBV, or HCV when tested by the living donor recovery center should be notified by the living donor recovery center of his or her infectious disease status.	Policy 14.3A(ii) (#11)	No policy addition recommended. <u>Notes:</u> Covered appropriately in current policy.
34	OPOs should have a system in place allowing tracking between a common deceased donor and (1) recovered organs, (2) recovered associated blood vessel conduits, and (3) recovered tissues and eyes to facilitate notification when a donor derived disease transmission is suspected. This system should include accurate records of the distribution and disposition of each organ and initial distribution of associated blood vessel conduits, along with procedures to facilitate the timely notification of transplant centers and tissue and eye recovery establishments when a donor derived disease transmission is suspected. To facilitate notification by the OPO, transplant centers should keep accurate records of all organs and associated blood vessel conduits received and the disposition of each.	Policy 15.4B Policy 16.6 Policy 16.7A Policy 16.7B Policy 16.7C	No policy addition recommended <u>Comments:</u> Encourage development of better tracking system for vessels to promote patient safety. The OPOs should <u>not</u> be responsible for tracking vessels. This really needs to be done within UNet. Who will be responsible for championing this?

In summary, the Joint Subcommittee review yielded the following for consideration by DTAC:

- 18 Items already Covered in existing OPTN Policy (with no changes recommended)
 - Recommendations 1, 2, 5b, 9, 13, 15, 16, 22, 24, 26a, 27a, 28a, 29a, 30a, 31, 32a, 33, and 34
- 4 Items with modifications recommended to existing Policy
 - Recommendations 12, 14, 21, and 25
- 6 Items where new Policy is recommended
 - Recommendations 5a, 6, 7, 18, 19, and 20
- 8 Items not currently in Policy and not recommended for inclusion in Policy
 - Recommendations 4, 17, 26b, 27b, 28b, 29b, 30b, and 32b
- 3 Items with guidance or promotion of best practice recommended rather than policy
 - Recommendations 3, 10, and 11
- 2 Items without consensus from the Joint Subcommittee
 - Recommendations 8 and 23

Prior to reporting to the full Committee, DTAC leadership presented this feedback to HRSA's Division of Transplantation staff. Discussion centered around the Final Rule requirement to develop policies that are consistent with recommendations of the Centers for Disease Control and Prevention (CDC) to test potential organ donors and following transplant recipients to prevent the spread of infectious disease. While not all of the recommendations are specific to testing potential organ donors and following transplant recipients, the Joint Subcommittee did not support inclusion of all recommendations that fell into these two categories in policy language.

The full DTAC reviewed and discussed the Joint Subcommittee recommendations during a series of phone calls as they considered the value of including each in OPTN policy. In some instances, the Committee may pursue future guidance documents or other educational efforts rather than policy in order to help in educating the transplant community and further enhance patient safety (if such projects are approved by the Policy Oversight Committee and the Board of Directors).

With one exception, the Committee supported recommendations as proposed by the Joint Subcommittee. However, interpretation of Final Rule led to the inclusion of HCV NAT for all donors, both living and deceased, to follow the PHS Guideline recommendation. The Committee requests careful consideration and feedback regarding this proposed new requirement, recognizing its potential impact on donors being classified as at increased risk for potential transmission of HCV if false positive NAT results arise during testing.

The following recommendations were discussed at length by both the Joint Subcommittee and the DTAC:

Recommendation 7: *(All potential organ donors (living or deceased) should be tested for antibodies to HIV (i.e., anti-HIV 1/2 or HIV antigen/antibody [Ag/ Ab] combination assay).)*

In addition to the window period (approximately 7-16 days for the combination test versus 5-6 days for NAT), the limit of detection for each test should be considered. The number of viral copies for a positive test result is much lower for a NAT than for the antigen portion of the combination test. Sensitivity and specificity were discussed thoroughly by the working group as this relates to potential false positive results that could eliminate donors from the pool. Review

of package inserts showed very similar rates of false negatives and false positives. There was limited concern voiced regarding use of the combination antigen/antibody test as compared to NAT.

It was suggested that confusion could arise when given the choice of tests. If an OPO is already using donor screening NAT, there would be no need to employ the combination test as well. Additionally, many OPOs are using duplex or triplex testing that includes results for both HIV and hepatitis. A laboratory representative in the group noted that many labs are phasing out singlet tests in favor of these duplex and triplex tests.

In some ways, that may make this a moot point. It can be seen as a concession from the PHS, which may have offered the combination test as an option for antibody testing while remaining in compliance with policy modifications proposed by the DTAC during fall 2013 public comment.

The Joint Subcommittee's ultimate recommendation was to allow fourth generation HIV antigen/antibody combination test or NAT for all increased risk donors.

See Policies 2.9 (Required Disease Donor Infectious Disease Testing) and 14.4.B (Living Kidney Donor Medical Evaluation Requirements) for proposed modifications related to this recommendation. The Committee proposed earlier modifications to clarify current deceased donor testing requirements and add the option of using HIV antigen/antibody combination test as part of donor evaluation during the fall 2013 public comment period. These modifications will be considered by the Board in June 2014, but are included in the proposed policy language at the end of this document to provide continuity in evaluating these changes.

Recommendation 8: (All potential organ donors (living or deceased) should be tested for both anti-HCV and for HCV RNA by NAT. Donor blood specimens should be obtained before procurement. Ab test results should be made available before transplantation. (Note: Optimally, all NAT results for deceased donors should be available before the transplant occurs; however, if having NAT results before transplantation is not feasible, test results can be useful to guide recipient treatment.)

Joint Subcommittee members remained divided in their opinions on how to address this recommendation. Part of the tension related to this issue is that this recommendation may lead to donors being lost. Many OPOs will use a triplex test that combines HIV, HBV, and HCV NAT if all donors are required to receive HCV NAT. This could be expected to result in process errors (false positives) that lead to discard of donor organs. It was noted, however, that not all OPOs use the triplex test kit. One member suggested that roughly 20-30% of OPOs use separate NAT results, but others on the Joint Subcommittee with laboratory background noted that the singlet assays are expected to be phased out as new triplex tests receive FDA clearance. It was recognized that at least one of the new triplex tests does provide individual results per virus, versus one positive result for all that would then require additional discriminatory testing to determine which virus is positive.

It was noted as important to consider whether an OPO or living donor recovery center will want HCV NAT results from the inadvertent addition of NAT results received as part of the triplex test. The yield of completing this test in standard criteria donors must be considered. Research has

already been done in this area by Ellingson et al². Duplex assay results expect roughly one in 5,000 adult deceased donors with negative/NAT positive result. This suggests a relatively low yield for requiring NAT for all potential donors regardless of standard or increased risk status. A pediatric representative on the call noted that this does not take into account the risk of pediatric false positives and the impact on pediatric donors if testing all potential donors. Most children would not be considered at increased risk for transmission of disease.

One must also take into account the differences between deceased and living donors. The majority of OPOs are using FDA-approved NAT for deceased donors. A limited survey of living donor centers indicated that most are capturing quantitative viral load testing. A requirement for FDA- approved, cleared or licensed NAT testing will be a bigger burden for living donor programs, but it was acknowledged that they do have more time to meet this requirement. Currently, the FDA requirement is not included in living donor policy. This document appears to attempt to align deceased and living donor testing requirements, but the Joint Subcommittee acknowledges that these are two very different populations.

Only one OPO has reported logistical issues in getting NAT results pre-transplant. Otherwise, all remaining OPOs appear to have access to NAT for, at minimum, increased risk donors.

Ultimately, the full Joint Subcommittee was supportive of HCV NAT for increased risk donors, but consensus could not be reached on requiring this test for all donors- as recommended by the PHS. An OPO representative noted concerns regarding donor case times while awaiting NAT results. This will certainly have an impact on overall time from consent to OR. Members noted that a donor classification is only as good as the history collected during medical-social evaluation. Trying to predict whether or not to use this test based upon the increased risk label is challenging, and there is no data to definitively back up either decision.

The DTAC specifically discussed this recommendation on its December 19, 2013, conference call. Interpretation of the Final Rule led to the inclusion of HCV NAT for all donors, living and deceased, to follow the PHS Guideline recommendation. The Committee requests careful consideration and feedback regarding this new requirement, recognizing its potential impact on the number of donors being classified as at increased risk for potential transmission of HCV if false positive NAT results arise during testing. It seeks specific feedback regarding a number of questions related to the specific inclusion of HCV NAT, as listed in the final bullet of the At-A-Glance box that precedes this proposal.

See Policies 2.9 (Required Disease Donor Infectious Disease Testing) and 14.4.B (Living Kidney Donor Medical Evaluation Requirements) for proposed modifications related to this recommendation.

Recommendation 10: *(An informed consent process discussion between the transplant candidate, or medical decision maker, and the listing clinician should start before the patient is placed on the transplant wait list.)*

² Ellingson, K., Seem, D., Nowicki, M., Strong, D. M., Kuehnert, M. J. and for the Organ Procurement Organization Nucleic Acid Testing Yield Project Team (2011), Estimated Risk of Human Immunodeficiency Virus and Hepatitis C Virus Infection among Potential Organ Donors from 17 Organ Procurement Organizations in the United States. American Journal of Transplantation, 11: 1201–1208. doi: 10.1111/j.1600-6143.2011.03518.x

The Joint Subcommittee and DTAC believed that time requirements for the informed consent process should not be proscribed in policy language, but that guidance may be helpful to the community as questions regarding best practices do frequently arise. This may be an opportunity for collaboration with the professional societies.

Recommendation 17: *(Pre-transplant testing of transplant candidates for HBV or HCV should be conducted when the donor (living or deceased) is known to be infected with HBV or HCV.)*

The Joint Subcommittee believed this practice would add nothing but complexity to the pre-transplant process at the hospital. If this were a research study, such information would be appropriate and helpful, but it adds nothing to test every recipient as a baseline at time of transplant in general practice. It was noted as burdensome with no benefit. The only question to be answered here is whether the recipient became positive between his last test and his day of transplant. Genotyping and sequencing can always be completed if potential donor-derived infection is suspected. While such a practice would make CDC and DTAC investigations easier, it is not a practical recommendation for all transplant candidates/recipients based upon the extremely low number of proven or probable donor-derived disease transmission events reviewed by the DTAC.

Recommendations 18, 19, and 20

Post-transplant HBV testing of recipients should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HBV infection, (2) screening specimens are hemodiluted, (3) the medical/behavioral history is unavailable, or (4) the donor is infected with HBV. Recipient testing should be performed sometime between one and three months post-transplant to include HBV NAT and HBsAg, and at 12 months post-transplant to include antibody to hepatitis B surface antigen (anti-HBs), anti-HBc, and either HBV NAT or HBsAg (unless infection was documented pre-transplant).

Post-transplant HIV testing of recipients should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HIV infection, (2) screening specimens are hemodiluted, or (3) the medical/behavioral history is unavailable. Recipient testing should be performed sometime between one and three months post-transplant to include HIV NAT or an HIV Ag/Ab combination assay (unless infection was documented pre-transplant). NAT or an Ag/Ab combination assay for HIV detection is important as infected recipients may remain Ab-negative due to immunosuppression.

Post-transplant HCV testing of recipients should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HCV infection, (2) screening specimens are hemodiluted, (3) the medical/behavioral history is unavailable, or (4) the donor is infected with HCV. Recipient testing should be performed sometime between one and three months post-transplant to include HCV NAT (unless infection was documented pre-transplant). NAT is important for HCV detection as infected recipients may remain Ab-negative due to immunosuppression.)

The DTAC supported the Joint Subcommittee's suggestion that it was not comfortable developing prescriptive policy language that would enforce testing at specific times. There is no data to support these time periods for testing, and centers should have the flexibility to develop post-transplant testing protocols based upon their own philosophy. Existing policy does require testing, but includes no time frame for completion. Requiring programs to have a process or protocol on record and to follow this process allows centers to work with infectious disease staff at their institution to develop protocols based upon what best suits their recipients' needs and

their program practices. From a monitoring perspective, site surveyors will verify that each program has internal policy or protocol in place, and that this policy is being consistently followed for its recipients.

See proposed modifications related to these recommendations in Policy 15.3.B (Deceased Donors at Increased Risk for Transmission of Blood-borne Pathogens), as noted at the end of this proposal.

Recommendation 21: *(For deceased donors, the OPO should consider collecting two blood specimens, when possible, for HIV, HBV, and HCV real-time testing (i.e., prior to organ recovery) an ethylenediaminetetraacetic acid (EDTA) plasma specimen or serum specimen for serologic assays and a separate EDTA plasma specimen for NAT. Additionally, the OPO should consider collecting two blood specimens for archiving, when possible. If it is only feasible to collect one specimen, a plasma specimen collected in EDTA, rather than a serum specimen, is optimal.)*

The Joint Subcommittee and full DTAC recognized that deceased donor specimen storage is already required in policy, but agreed that this recommendation is too detailed for the purpose policy. The Joint Subcommittee did not support including language to require specific types of tubes for storage. The group was more supportive of general language referencing “specimens appropriate for antibody and nucleic acid testing.” Having such specific language in place would require additional public comment in order to update based upon changes in evolving laboratory practice.

Proposed modifications related to this recommendation are captured in Policy 2.2 (OPO Responsibilities, as noted at the end of this proposal.

Recommendation 23: *(For living donors, transplant candidates, and recipients, two blood specimens should be collected when HIV, HBV, or HCV testing is planned an EDTA plasma specimen or serum specimen for serologic assays and a separate EDTA plasma specimen for NAT.)*

Joint Subcommittee members noted confusion regarding this recommendation. This language is very similar to recommendations 21 and 22 (which recommends storage of deceased donor specimens for at least ten years), which outlines recommendations for the collection and storage of deceased donor samples for later infectious disease testing. It appears to indicate storage of specimens for candidates, recipients and living donors without specifically stating such a recommendations. It is unclear what transplant centers would do with the tubes collected otherwise. The Joint Subcommittee felt strongly that collection and storage of samples from living donors, candidates and recipients would be extremely costly to maintain (storage space, appropriate refrigeration equipment to keep samples at viable temperatures, monitoring of this equipment, etc) and carry limited value overall. Additionally, there is often pre-transplant blood used for crossmatching stored in center histocompatibility labs.

The DTAC’s review of reported potential donor-derived disease transmission events indicates that less than 1% of all transplants result in proven or probable donor-derived disease transmission. Members agreed that the number of potential donor-derived disease transmission events reported and reviewed as compared to the total number of transplant completed each year do not justify the expense related to this recommendation. Therefore, the overall cost would outweigh the limited benefit if storage is truly desired by the PHS for living donors, candidates, and recipients.

Recommendation 25: *(All stored blood vessel conduits from a donor found to be infected with HIV, HBV, or HCV should be quarantined immediately and not released for clinical use unless the HBV or HCV infected vessel conduits are needed for the initial transplant procedure in the recipient.)*

The current policy addresses this recommendation, but Joint Subcommittee members recognized that passage of the Hope Act³ will necessitate updates to Policy 16.7B. This will be addressed as part of a larger policy updated related to the use of HIV positive organs in HIV positive recipients. As currently written, Hepatitis B core antibody positive vessels may be stored and used at a later date.

The group did suggest that the PHS recommendation language should be incorporated to note that “all recovered blood vessel conduits” would avoid misunderstanding. This, however, is outside of the purview of this group.

Another member questioned whether general “infected with HIV, HBV, or HCV” appropriate or whether it should be broken down specifically by type of test that is positive. Another member noted that while this may be important in considering use, but perhaps should not appear in policy language. The Joint Subcommittee and DTAC overwhelmingly agreed to include the following language in current policy 16.7B as a housekeeping effort, assuming that NAT is ultimately included in deceased and living donor testing.

Criteria for Identifying Increased Risk for recent HIV, HBV, and HCV infection. The Committee also considered concerns raised by several OPOs upon implementation of the 2013 PHS Guideline’s criteria for recognizing potential donors at increased risk for disease transmission. The last of the eleven medical-social criteria applies only to define whether a donor is at increased risk for recent HCV infection: *People who have been on hemodialysis in the preceding 12 months.*

While the Committee appreciates the risk of potential HCV transmission in donors who have received dialysis as a maintenance treatment in a dialysis center, it is concerned regarding those potential donors who may only receive hemodialysis or continuous veno-venous hemofiltration (CVVH) in the ICU to treat acute renal failure as part of their terminal hospital stay. The risks for HCV transmission in this setting would be negligible, with no known disease transmission events related to transmission specifically by CVVH published in the literature.

In some hospitals, dialysis machinery used for patients requiring treatment only as part of a terminal hospitalization (as a potential organ donor) may also be used for patients receiving chronic maintenance dialysis on a routine basis, potentially raising the risk of HCV exposure. CVVH uses different machinery and disposable tubing, and is not expected to present the same risks for HCV exposure.

The Committee is concerned that OPOs may not be aware of the distinction between CVVH and dialysis during evaluation and may potentially identify these patients as at increased risk for disease transmission. This could be very misleading to transplant hospitals, candidates and

³ To review full text of the Hope Act, please visit the following link: <http://www.gpo.gov/fdsys/pkg/BILLS-113s330rfh/pdf/BILLS-113s330rfh.pdf>

their family members considering these organ offers. The Committee requests specific feedback regarding this issue, as noted in the questions included in the At-A-Glance box that precedes this proposal.

Supporting Evidence and/or Modeling

The Joint Subcommittee reviewed the supporting documentation used to develop the PHS Guideline, a number of journal articles as it considered the various tests recommended by the PHS for donor, candidates, and recipients. It also sought feedback from subject matter experts in laboratory practice and testing from inside and outside of the committees represented on the Joint Subcommittee.

The Joint Subcommittee also reviewed unpublished data, including aggregate statistics from DTAC potential donor-derived disease transmission event reporting and personal communications regarding the topic of testing to learn more about false positive and false negative testing results. Additionally, package inserts for various serologic and NAT products were reviewed and compared for data regarding false positive and false negative results.

A number of Joint Subcommittee members also shared feedback from the 2008 NAT consensus conference in Chicago and the Living Donor Consensus Conference in 2011 in Washington D.C.

Publications considered during discussion of these testing recommendations included:

- Blumberg, E. A., Ison, M. G., Pruett, T. L., Segev, D. L. and on behalf of the Optimal Testing of the Live Organ Donor Consensus Conference Participants (2013), **Optimal Testing of the Live Organ Donor for Blood-Borne Viral Pathogens: The Report of a Consensus Conference**. American Journal of Transplantation, 13: 1405–1415. doi: 10.1111/ajt.12205
- Branson BM, Stekler JD. **Detection of Acute HIV Infection: We Can't Close the Window**. The Journal of Infectious Diseases (Impact Factor: 5.85). 12/2011; 205(4):521-4. DOI:10.1093/infdis/jir793
- Chavez P, Wesolowski L, Patel P, Delaney K, Owen SM. **Evaluation of the Performance of the Abbott ARCHITECHT HIV Ag/Ab Combo Assay**. Journal of Clinical Virology, 2011 Dec; 52 Suppl 1:S51-5. doi: 10.1016/j.jcv.2011.09.010. Epub 2011 Oct 7.
- Chinchilla-Reyes C, Sampaio M, Mone TD, Stocks L, Taguibao R, Niles P, Johnson M, Nowicki M. **Seven years experience with multiplex TMA-based assay for HIV and HCV screening among organ and tissue donors - definitive report**. 2013 American Transplant Congress. Oral Presentation
- Ellingson K, Seem D, Nowicki M, Strong DM, Kuehnert MJ, and for the Organ Procurement Organization Nucleic Acid Testing Yield Project Team (2011), **Estimated Risk of Human Immunodeficiency Virus and Hepatitis C Virus Infection among Potential Organ Donors from 17 Organ Procurement Organizations in the United States**. American Journal of Transplantation, 11: 1201–1208. doi: 10.1111/j.1600-6143.2011.03518.x
- Humar, A., Morris, M., Blumberg, E., Freeman, R., Preiksaitis, J., Kiberd, B., Schweitzer, E., Ganz, S., Caliendo, A., Orlowski, J. P., Wilson, B., Kotton, C., Michaels, M., Kleinman, S., Geier, S., Murphy, B., Green, M., Levi, M., Knoll, G., Segev, D., Brubaker, S., Hasz, R., Lebovitz, D. J., Mulligan, D., O'Connor, K., Pruett, T., Mozes, M., Lee, I.,

Delmonico, F. and Fischer, S. (2010), **Nucleic Acid Testing (NAT) of Organ Donors: Is the 'Best' Test the Right Test? A Consensus Conference Report**. American Journal of Transplantation, 10: 889–899. doi: 10.1111/j.1600-6143.2009.02992.x

- Rosenberg NE, Kamanga G, Phiri S, Nsona D, Pettifor A, Rutstein SE, Kamwendo D, Hoffman IF, Keating M, Brown LB, Ndalama B, Fiscus SA, Congdon S, Cohen MS, Miller WC. **Detection of Acute HIV Infection: A Field Evaluation of the Determine® HIV-1/2 Ag/Ab Combo Test**. Journal of Infectious Disease. 2012 Feb 15;205(4):528-34. doi: 10.1093/infdis/jir789. Epub 2011 Dec 29.
- Theodoropoulos N, Jaramillo A, Ladner DP, Ison MG. **Deceased organ donor screening for HIV, hepatitis B, and hepatitis C viruses: a survey of organ procurement organization practices**. American Journal of Transplantation. 2013 Aug;13(8):2186-90. doi: 10.1111/ajt.12260. Epub 2013 May 24.
- ARCHITECT HIV Ag/Ab Combo Reagent Insert
- ARCHITECT HIV Ag/Ab Combo PMA Summary of Safety and Effectiveness Data

Even after careful consideration of the testing recommendations, literature, and shared experiences from laboratorians, infectious disease specialists, and OPO personnel, clear consensus could not be reached regarding an HCV NAT requirement for all potential organ donors.

Expected Impact on Living Donors or Living Donation

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

Expected Impact on Specific Patient Populations

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

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

It is anticipated that by modifying and creating new policies to be consistent with the PHS Guideline (as required by the Final Rule), OPOs and transplant centers will have a straightforward and consistent interpretation of deceased and living donor testing requirements as well as those for candidates and recipients. This is expected to result in improved patient safety.

The DTAC's proposal will address three of the OPTN/UNOS Strategic Plan Goals:

- Promote safe, high quality care for transplant candidates and recipients by improved identification of potential infection in deceased and living donors.
- Achieve the best use of donated organ by clearly identifying donor testing requirements to help transplant centers better identify donor risk/quality versus benefit to their recipient(s).
- Maximize the number of transplants through careful screening of deceased and living donors and clear requirements for communicating these results.

The Committee's goals for these policy modifications meet provisions of the Final Rule as outlined in §121.6(a)⁴.

Plan for Evaluating the Proposal

This proposal is designed to enhance patient safety for all recipients of both living and deceased donor organs by better identifying donors at increased risk for transmission for HIV, HBV, and HCV, and modifying the donor testing requirements for these same viruses. The evaluation of this proposal will monitor the number of HIV, HCV, HBV potential disease transmissions reported to the DTAC that are classified as a proven or probable transmission event.

The analysis will be initiated one year after policy implementation and will include providing the number of HIV, HCV, and HBV cases reviewed by the DTAC, the number of cases classified as a proven or probable transmission, and the number and outcome of affected recipients.

Due to the very small number of cases expected, the analysis will be updated every six months for three years after implementation.

Additional Data Collection

Implementation of the full proposal will require the collection three new data elements and label changes to existing tabs or fields to accommodate the addition of molecular testing in addition to serology testing. The OPO community is eager for the addition of these fields. Currently, there is no place to enter NAT results and confusion on how to proceed with data entry when required serology testing and NAT results do not agree.

- 1) Three new fields (HIV NAT, HCV NAT, and HBV NAT) will be added to the "Serologies" tab in DonorNet[®]. Additionally, this tab label will need to be changed to "Viral Detection" because NAT is not a serology test. Similar changes will be made to update the DonorNet[®] mobile application.

(Please note: Corresponding fields to collect this information on the Deceased Donor Registration (DDR) form in Tiedi have already been approved by the Board of Directors as part of the 2010 forms review project. Additionally, a field to collect HIV antigen/antibody combination test results in these same sections was included in the DTAC's Fall 2013 public comment proposal.)

Data Collection Principle = Ensure patient safety when no alternative sources of data exist

- 2) Two of the fields (HBV NAT and HCV NAT) will be added as screening criteria prior to running a match for all organs. The screening criteria are applicable to both deceased donors and living donors.

⁴ To view the full text of the Final Rule, please visit the following link: http://optn.transplant.hrsa.gov/policiesAndBylaws/final_rule.asp

Data Collection Principle = Ensure patient safety when no alternative sources of data exist

- 3) In Tiedi[®], three new fields (HIV NAT, HCV NAT, HBV NAT) will be added to the Transplant Recipient Registration (TRR) form in the “Clinical Information: Pre-transplant” section. *(Please note: Adding a new field to the TRR requires Office of Management and Budget (OMB) approval. This new field cannot be added until approval is obtained, usually when current forms expire. Current forms expire in March 2015)*

Data Collection Principle = Ensure patient safety when no alternative sources of data exist

- 4) Three new fields (HIV NAT, HCV NAT, HBV NAT) will be added under the header “Serologies” tab under “Donor Summary” on the Kidney Paired Donation (KPD) form.

Data Collection Principle = Ensure patient safety when no alternative sources of data exist

Expected Implementation Plan

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in November 2014 and, if approved, new policy requirements will become effective on February 1, 2015.

DonorNet[®] and Tiedi[®] will be reprogrammed to add new fields to collect response on whether HIV, HBV, or HCV NAT was completed for both deceased donors and transplant recipients. Additionally, new waiting list screening criteria will be added to allow centers to indicate if they would accept an HCV or HBV NAT positive organ. This proposal will require additional programming to collect these new data elements. If programming is not complete prior to policy implementation, NAT results must be reported in the Donor Highlights field in DonoNet[®] until these fields are made available for entry.

OPOs will need to:

- Familiarize themselves with the new policy requirements
- Coordinate with laboratories used for donor testing to determine whether HCV NAT is available for all deceased donors
- Coordinate with laboratories used for donor testing to determine whether combination HIV Ag/Ab testing or HIV NAT is available for donors meeting increased risk criteria.
- Note any donor for whom there is no medical-social history as carrying increased risk of transmitting HIV, HBV, and HCV.
- Update internal policies and procedures to address any changes made based upon these policy modifications and update any internal documents or processes accordingly.
- Educate staff impacted by these changes (e.g., medical directors, laboratory directors, procurement coordinators, data entry coordinators, etc.).

Living donor recovery hospitals will need to:

- Familiarize themselves with the new policy requirements

- Coordinate with laboratories used for donor testing to determine whether HCV NAT is available for all living donors
- Coordinate with laboratories used for donor testing to determine whether combination HIV Ag/Ab testing or HIV NAT is available for living donors meeting increased risk criteria.
- Update internal policies and procedures to address any changes made based upon these policy modifications and update any internal documents or processes accordingly.
- Educate staff impacted by these changes (e.g., medical directors, laboratory directors, procurement coordinators, data entry coordinators, etc.).

Transplant hospitals will need to:

- Familiarize themselves with the new policy requirements
- Review modifications to informed consent policy language, including the development of a plan for post-transplant testing of recipients receiving organs from increased risk donors (deceased and living)
- Update internal policies and procedures to address any changes made based upon these policy modifications and update any internal documents or processes accordingly.
- Educate staff impacted by these changes (e.g., medical directors, laboratory directors, procurement coordinators, data entry coordinators, etc.).

Communication and Education Plan

Upon Board approval, several communications channels will be used to inform transplant and donation professionals about the changes to testing requirements. Since this change affects the testing for all donors, extensive notification will be required in addition to any UNetSM training or special education sessions.

The first notification of this change will be sent to members through the policy notice in December 2014, 30 days after approval by the Board. A link to the policy notice will be included in the December Transplant Pro e-newsletter.

The new requirements will be covered in the article about Board actions in the November-December 2014 Update.

We will further communicate the new information with articles that will appear in the Transplant Pro e-Newsletter and we will link readers to the relevant policy. System notices will be sent to DonorNet[®] users to provide advance notice of the change at time of implementation of related system programming.

We will also publicize all educational activities via Transplant Pro as they become available.

Table 2, below, outlines the proposed communication and education activities.

Table 2: Communication Activities

Communication Activities			
Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice (summary of all policy changes approved by the board in a PDF format)	Transplant community	Electronic – Included in the monthly Transplant Pro e-newsletter sent on the 3 rd Thursday of each month	December 2014 (or 30 days after board approves the change)
System Notice	UNet SM users	Through UNet SM	January & February 2015
News items on the Transplant Pro website and in the monthly e-newsletter.	OPOs, transplant centers, labs	http://transplantpro.org	January & February 2015
Update Magazine (November-December 2014 issue)	OPOs, transplant centers, labs	Print and online	December 2014

Additional member education is under consideration by the Instructional Innovations department. This may include and podcast or webinar to provide targeted education related to changes in testing requirements associated with this policy proposal.

Compliance Monitoring

This section will describe proposed changes to the routine monitoring of members' compliance based on the proposed changes.

Policy 2.2 OPO Responsibilities - No changes to monitoring method

Policy 2.3 Evaluating and Screening Potential Deceased Doors - No changes to monitoring method

Policy 2.4 d Deceased Donor Medical and Behavioral History - No changes to monitoring method

Policy 2.7 HIV Screening of Potential Deceased Donors – The monitoring plan will be updated as follows:

Upon site review of member OPOs, UNOS will review a sample of deceased donor records for documentation:

- That HIV testing was completed with a FDA licensed, approved or cleared HIV (anti HIV) donor screening test, or a FDA licensed HIV antigen/antibody (Ag/Ab) combination test.

Policy 2.8 Required Deceased Donor General Risk Assessment – No changes to monitoring method

Policy 2.9 Required Deceased Donor Infectious Disease Testing

Upon site review of member OPOs, UNOS will review a sample of deceased donor records for documentation of completion of the following tests for infectious disease:

- HIV antibody (Anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
- Hepatitis B surface antigen (HBsAg) **screening** test
- Hepatitis B core antibody (anti-HBc) **screening** test
- Hepatitis C antibody **screening** test (anti-HCV)
- HCV ribonucleic acid (RNA) by nucleic acid testing (NAT)
- Syphilis screening or diagnostic test

If a deceased donor is identified as increased risk for HIV infection per the PHS Guideline, UNOS will look for documentation of completion of:

- HIV ribonucleic acid (RNS) by NAT or HIV antigen/antibody (Ag/Ab)

UNOS will also look for documentation of which test was used (the manufacturer name and name of test kit or assay used).

Policy 2.10 Required Deceased Donor Information – No monitoring planned

Policy 14.4.B Living Kidney Donor Medical Evaluation Requirements - The monitoring plan will be updated as follows:

Upon site review of member recovery hospitals, UNOS will review a sample of living donor records for documentation of results for:

- HIV antibody (Anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
 - HCV ribonucleic acid (RNA) by nucleic acid testing (NAT)
- If a living donor is identified as increased risk for HIV infection per the PHS Guideline, Surveyors will look for documentation of completion of:
- HIV ribonucleic acid (RNS) by NAT or HIV antigen/antibody (Ag/Ab)

Policy 15.3 Informed Consent of Transmissible Disease Risk -The monitoring plan will be updated as follows:

Upon site review of member transplant hospitals, UNOS will review a sample of recipient records for documentation of specific informed consent before transplant if either:

- The donor meets any of the criteria for increased risk of transmitting HIV, HBV, or HCV, as specified in the U.S. Public Health Service (PHS) Guideline
- A hemodiluted specimen is used for donor HIV, HBV or HCV screening

Policy 15.3.B Donors at Increased Risk for Transmission of Blood-borne Pathogens – the monitoring plan will be updated as follows:

Upon site review of member transplant hospitals, UNOS will review internal policies, protocols or procedures to verify:

- A written protocol for post-transplant testing for HIV, HCV and HBV, as appropriate, based on the recipient's pre-transplant status

Policy 16.7.B Vessel Storage - the monitoring plan will be updated as follows:

Upon site review of member transplant hospitals, UNOS will review internal policies, procedures and/or protocols and/or interview key clinical personnel to verify that they address that:

- HCV antibody positive or HCV NAT positive extra vessels are NOT stored for later use
- HBV surface antigen positive (HbsAg) or HBV NAT positive extra vessels are NOT stored for later use

Policy or Bylaw Proposal

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

2.2 OPO Responsibilities

The host OPO is responsible for *all* of the following:

1. Identifying potential deceased donors.
2. Providing evidence of authorization for donation.
3. Evaluating deceased donors.
4. Maintaining documentation used to exclude any patient from the imminent neurological death data definition or the eligible data definition.
5. Verifying that death is pronounced according to applicable laws.
6. Establishing and then implementing a plan to address organ donation for diverse cultures and ethnic populations.
7. Clinical management of the deceased donor.
8. Assuring that the necessary tissue-typing material is procured, divided, and packaged.
9. Assessing deceased donor organ quality.
10. Preserving, packaging, and transporting the organs.
11. Reporting to the OPTN Contractor all deceased donor information required for organ placement, including the donor's human leukocyte antigen (HLA) type.
12. Executing the match run and using the resulting match for each deceased donor organ allocation.
13. Documenting and maintaining complete deceased donor information for seven years for all organs procured.
14. Ensuring that written documentation of the deceased donor evaluation, donor management, authorization for donation, death pronouncement, and organ procurement quality accompanies the organ as described in *Policy 16: Organ and Vessel Packaging, Labeling, Shipping, and Storage*.
15. Maintaining samples appropriate for serologic and nucleic acid testing (NAT), as available, ~~serum sample~~ for each deceased donor for at least 10 years after the date of organ transplant and ensuring the ~~serum~~ sample is available for retrospective testing. The host OPO must document the type of sample in the deceased donor medical record and, if possible, should use qualified specimens.

2.3 Evaluating and Screening Potential Deceased Donors

The host OPO must perform *all* of the following and report the resulting information to all receiving OPOs or transplant hospitals:

1. Attempt to obtain the deceased donor's medical and behavioral history from one or more individuals familiar with the donor according to *Policy 2.4: Deceased Donor Medical and Behavioral History*.
2. Review the deceased donor's medical record.
3. Complete a physical examination of the deceased donor, including the donor's vital signs.
4. Document in the deceased donor medical record if any of this information is not available and the reason it is not available.

2.4 Deceased Donor Medical and Behavioral History

The host OPO will attempt to obtain a history on each potential deceased donor to screen for medical conditions that may affect the decision to use the donated organ. If a medical-behavioral history cannot be obtained or risk factors cannot be determined, the donor must be identified as at increased risk for transmission of HIV, hepatitis B, and hepatitis C per the PHS Guideline. The host OPO must communicate this information to all transplant programs receiving organs from the deceased donor.

The medical and behavioral history for each potential deceased donor should include *all* of the following:

1. Any testing and laboratory results used to identify the presence of transmissible diseases or malignancies, treated and untreated, or any other known condition that may be transmitted by the deceased donor organ and may reasonably impact the recipient.
2. Whether the potential deceased donor has factors associated with an increased risk for disease transmission, including blood-borne pathogens HIV, Hepatitis B, and Hepatitis C. If the deceased donor meets the criteria for increased risk for disease transmission set forth in the current U.S. Public Health Service (PHS Guideline), the host OPO must communicate this information to all transplant programs receiving organs from the deceased donor.
3. Whether the potential deceased donor has a history of prior exposure or treatment with non recombinant Human Pituitary Derived Growth Hormone (HPDGH). If so, the potential deceased donor has an increased risk of prion disease and the host OPO must communicate this information to all transplant programs receiving organs from the donor.

Modifications recommended for Policies 2.2.3.2 and 2.2.4 and its subsections (now numbered 2.7, 2.9, and 2.10) as part of the DTAC's Fall 2013 public comment proposal are included alongside modifications specific to this proposal to provide the reviewer continuity in considering these changes. The Fall 2013 proposal language was not in the new plain language format approved by the Board of Directors in November 2013.

2.7 HIV Screening of Potential Deceased Donors

~~The host OPO must screen all potential deceased donors for anti-HIV-1 and anti-HIV-2 using an FDA-licensed, serological screening test.~~ Members may not participate in the recovery or transplantation of organs from deceased donors known to be infected with HIV. Members may only recover organs if the laboratory data, medical history, and behavioral history indicate that the donor is not HIV infected.

The host OPO must accurately document HIV test results for every deceased donor. All deceased donors must be tested for HIV as outlined in Policy 2.9, #3.

~~If a potential deceased organ donor with a negative HIV test that was completed on a qualified (non-hemodiluted) blood sample receives subsequent transfusions of blood that have not been tested for HIV, the donor must be re-tested for HIV. The Host OPO must document the result of this re-testing.~~

Retesting the potential deceased donor for HIV is not necessary if *all* the following are true:

- ~~1. The sample is qualified.~~
- ~~2. The HIV screening test completed by the host OPO is negative.~~
- ~~3. Blood for subsequent transfusions has been tested and found to be HIV negative.~~

~~If the~~The host OPO performs multiple HIV tests, it must report the results of all HIV tests it performs directly to all receiving OPOs and transplant programs.

2.7.A Exceptions to HIV Screening Requirement

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

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

1. Provide all available deceased donor medical and social history to the transplant program.
2. Treat the deceased donor as having an increased risk for disease transmission based on current U.S. PHS Guideline.

In this case the receiving transplant hospital must:

- Obtain and document informed authorization from the potential transplant recipient or the recipient's authorized agent before transplantation.

2.7.B Informing Personnel

The host OPO ~~should~~ must only inform health care personnel caring for potential deceased donors or deceased donors who test positive for HIV only when it is necessary for making medical decisions.

2.8 Required Deceased Donor Information-General Risk Assessments

~~The host OPO is responsible for evaluating all deceased donors.~~

~~In addition to the medical Laboratory testing must occur in an appropriately accredited laboratory using FDA licensed, approved, or cleared serological screening tests. If a required screening test is not commercially available before transplant, then the host OPO may use an FDA licensed, approved, or cleared diagnostic test for all tests except Anti-HIV.~~

~~The host OPO must document in the deceased donor record the tests that were used and must report the results of all tests performed to all receiving transplant programs and OPOs.~~

~~All of the following information is~~ general laboratory tests are required for each potential deceased organ donor:

1. ~~Age~~
2. ~~Sex~~
3. ~~Diagnosis (or cause of brain death)~~
4. 1. Blood type determination and reporting as outlined in *Policy 2.6 above*, including sub-typing for

- blood type A donors
5. ~~_____~~ FDA licensed anti-HIV 1 and anti-HIV 2 serological testing as outlined in *Policy 2.7* above
 6. ~~_____~~ Hepatitis serological testing; including hepatitis B surface antigen, hepatitis B core antibody, and Anti-HCV
 7. ~~_____~~ Venereal disease research laboratory (VDRL) or rapid plasma regain (RPR) testing. (FDA-approved diagnostic tests are acceptable.)
 8. ~~_____~~ Anti-cytomegalovirus (CMV) assay
 9. ~~_____~~ Epstein-barr virus (EBV) serological testing
 10. ~~2.~~ Arterial blood gas results
 11. ~~3.~~ Blood and urine cultures
 12. ~~4.~~ Chest x-ray
 13. ~~5.~~ Complete blood count (CBC)
 14. ~~6.~~ Electrolytes
 15. ~~7.~~ Serum glucose
 16. ~~8.~~ Urinalysis within 24 hours prior to cross clamp

2.9 Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that infectious disease testing is completed as follows:

1. In CLIA-certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS).
2. If a donor screening test cannot be performed or is not available, the use of an FDA licensed, approved, or cleared diagnostic test is acceptable. Minimum testing for HIV must be completed using only the testing methods listed in (3) below.

The host OPO must document in the donor record which test was used to assess the potential donor and must also provide this information to the receiving transplant hospital before transplant.

3. FDA licensed, approved, or cleared infectious disease testing for all potential deceased organ donors, as listed below:
 - HIV antibody (anti-HIV) donor screening test or HIV antigen/antibody (Ag/Ab) combination test
 - Hepatitis B surface antigen (HBsAg) and Hepatitis B core antibody (anti-HBc) screening tests
 - Hepatitis C antibody screening test (anti-HCV)
 - HCV ribonucleic acid (RNA) by screening nucleic acid testing (NAT)
 - Syphilis screening or diagnostic test
 - Epstein-Barr Virus (EBV) antibody (anti-EBV) screening or diagnostic test
 - Cytomegalovirus (CMV) antibody (anti-CMV) screening or diagnostic test

If a deceased donor is identified as being at increased risk for HIV infection according to the PHS Guideline criteria, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test.

If a Host OPO completes any testing in addition to what is required for a potential donor, the results of these tests must be reported to all recipient transplant hospitals as soon as possible, but no later than 24 hours after receiving the test result.

2.10 Required Deceased Donor Information

All the following information is required for each potential deceased donor:

1. Age
2. Sex
3. Diagnosis (or cause of brain death)

Policies 2.10 (Required Deceased Donor Information) through 2.13 (Donation after Circulatory

14.4.B Living Kidney Donor Medical Evaluation Requirements

A medical evaluation of the potential living kidney donor must be performed by the recovery hospital and by a physician or surgeon experienced in living donation. The goals of the medical evaluation are *all* of the following:

1. To assess the immunologic compatibility of the living donor to the recipient
2. To assess the general health and surgical risk of donation to the living donor including screening for conditions that may predict future complications from having only one kidney
3. To determine if there are diseases present that may be transmitted from the living donor to the recipient
4. To assess the anatomy and function of the living donor's kidneys

Documentation of the medical evaluation must be maintained in the donor medical record.

The medical evaluation must include *all* of the components in *Table 14-2* below.

Table 14-2: Requirements for Living Kidney Donor Medical Evaluations

This evaluation must be completed:	Including evaluation for and assessment of this information:
A general living donor history	<ol style="list-style-type: none"> 1. A personal history of significant medical conditions which include but are not limited to: <ol 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 2. History of infections 3. A kidney-specific personal history including: <ol style="list-style-type: none"> a. Genetic renal diseases b. Kidney disease, proteinuria, hematuria c. Kidney injury d. Diabetes including gestational diabetes e. Nephrolithiasis f. Recurrent urinary tract infections 4. Active and past medications with special consideration for known nephrotoxic medications 5. Allergies 6. An evaluation for coronary artery disease
General family history	The living donor's family history of coronary heart disease and cancer
Kidney-specific family history	The living donor's family history of: <ul style="list-style-type: none"> • Kidney disease • Diabetes • Hypertension • Kidney Cancer
Social history	The living donor's history of: <ul style="list-style-type: none"> • Occupation, employment status, health insurance status, living arrangements, and social support • Smoking, alcohol and drug use and abuse • Criteria to assess increased risk for disease transmission as defined by the PHS Guideline • Psychiatric illness, depression, suicide attempts

This evaluation must be completed:	Including evaluation for and assessment of this information:
Physical Exam	<p>A physical exam of the living donor including:</p> <ul style="list-style-type: none"> • Height • Weight • BMI • Examination of all major organ systems • Blood pressure taken on at least two different occasions or 24-hour or overnight blood pressure monitoring
General laboratory and imaging tests	<ul style="list-style-type: none"> • Complete blood count (CBC) with platelet count • Blood type and screen • 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)
Other metabolic testing	<ul style="list-style-type: none"> • Fasting blood glucose • Fasting lipid profile (cholesterol, triglycerides, HDL cholesterol, and LDL cholesterol) • Glucose tolerance test or glycosylated hemoglobin in first degree relatives of diabetics and in high risk individuals
Kidney-specific tests	<ul style="list-style-type: none"> • Urinalysis or urine microscopy • Urine culture if clinically indicated • Measurement of urinary protein and albumin excretion • Measurement of glomerular filtration rate by isotopic methods or a creatinine clearance calculated from a 24-hour urine collection • Hospitals must develop and comply with a protocol for polycystic kidney disease or other inherited renal disease as indicated by family history • Patients with a history of nephrolithiasis or nephrolithiasis (>3mm) identified on radiographic imaging must have a 24-hour urine stone panel measuring: <ul style="list-style-type: none"> ○ Calcium ○ Oxalate ○ Uric acid ○ Citric acid ○ Creatinine ○ Sodium

This evaluation must be completed:	Including evaluation for and assessment of this information:
Anatomic assessment	<p>An assessment to determine:</p> <ul style="list-style-type: none"> • Whether the kidneys are of equal size • If the kidneys have masses, cysts, or stones • If the kidneys have other anatomical defects • Which kidney is more anatomically suited for transplant. <p>The choice of test for radiologic imaging may be determined based on the local radiological expertise and surgical preference, and may include CT angiogram or MR angiogram.</p>
Transmissible disease screening	<p>Infectious disease 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 3. HIV 1,2 (Human Immunodeficiency Virus) antibody testing <u>or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery</u> 4. HepBsAg (Hepatitis B surface antigen) <u>as close as possible, but within 28 days prior to organ recovery</u> 5. HepBcAB (Hepatitis B core antibody) <u>as close as possible, but within 28 days prior to organ recovery</u> 6. HepBsAB (Hepatitis B surface antibody) <u>as close as possible, but within 28 days prior to organ recovery</u> 7. HCV (Hepatitis C Virus) antibody testing <u>as close as possible, but within 28 days prior to organ recovery</u> 8. <u>HCV ribonucleic acid (RNA) by NAT as close as possible, but within 28 days prior to organ recovery</u> 9. RPR (Rapid Plasma Reagin test for syphilis) <p><u>If a living donor is identified as being at increased risk for HIV infection according to the PHS Guideline, testing must also include HIV ribonucleic acid (RNA) by NAT or HIV antigen/antibody (Ag/Ab) combination test as close as possible, but within 28 days prior to organ recovery .</u></p> <p>Living donor recovery hospitals must determine if the potential donor is at increased risk for tuberculosis (TB) and if so testing must include screening for latent TB using either intradermal PPD or Interferon Gamma Release Assay (IGRA).</p>
Endemic transmissible diseases	<p>For the following infectious diseases, recovery hospitals must determine if the potential donor is from an endemic area, and if so must test for:</p> <ul style="list-style-type: none"> • Strongyloides • Trypanosoma cruzi • West Nile

This evaluation must be completed:	Including evaluation for and assessment of this information:
Cancer screening	<p>Recovery hospitals must develop and comply with protocols consistent with the American Cancer Society (ACS) to screen for:</p> <ul style="list-style-type: none"> • Cervical cancer • Breast cancer • Prostate cancer • Colon cancer • Skin cancer • Lung cancer
Exclusion criteria	<p>Kidney recovery hospitals may exclude a donor with any condition that, in the hospital's medical judgment, causes the donor to be unsuitable for organ donation.</p> <p>Kidney recovery hospitals must exclude all donors who meet <i>any</i> of the following exclusion criteria:</p> <ul style="list-style-type: none"> • Is both less than 18 years old and mentally incapable of making an informed decision • Uncontrollable hypertension or history of hypertension with evidence of end stage organ damage • HIV • Diabetes • Active malignancy, or incompletely treated malignancy • High suspicion of donor coercion • High suspicion of illegal financial exchange between donor and recipient • Evidence of acute symptomatic infection (until resolved) • Diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality

15.3 Informed Consent of Transmissible Disease Risk

Transplant programs must obtain specific informed consent before transplant of any organ when, ~~in the transplant program's medical judgment,~~ in the transplant program's medical judgment, any of the following occurs:

- The ~~deceased~~ donor has a known medical condition that may, in the transplant program's medical judgment, be transmissible to the recipient, with the exception of HIV, which must be handled according to *Policy 2.7: HIV Screening of Potential Deceased Donors*.
- The ~~deceased~~ donor meets any of the guidelines criteria for an increased risk of transmitting HIV, hepatitis B, or hepatitis C transmissible disease as specified in the *U.S. Public Health Services (PHS) Guideline*.
- When a hemodiluted specimen is used for ~~deceased~~ donor HIV, hepatitis B, or hepatitis C screening, according to *Policy 2.5: Hemodilution Assessment*.

Transplant programs must also inform potential candidates of the general risks of potential transmission of malignancies and disease from organ donors, including *all* of the following information:

1. Deceased donors are evaluated and screened as outlined in *Policy 2.3: Evaluating and Screening Potential Deceased Donors*.
2. Living Donors are ~~only~~ required to undergo screening for the diseases listed in *Policy 14.4: Medical Evaluation Requirements for Living Donor*.
3. That there is no comprehensive way to screen ~~potential~~ deceased and living donors for all transmissible diseases.
4. That transmissible diseases and malignancies may be identified after transplant.

The transplant program must do *both* of the following:

1. Explain these risks and obtain informed consent from the potential candidate or candidate's agent before transplant.
2. Document consent in the potential candidate's medical record.

15.3.A Deceased Donors with Additional Risk Identified Pre-transplant

If additional ~~deceased~~ donor disease or malignancy transmission risk is identified pre-transplant, the transplant program must do *all* of the following:

1. Explain the risks and obtain informed consent from the potential transplant recipient or the potential recipient's agent before transplant.
2. Document this consent in the potential recipient's medical record.
3. Follow any recipient of the deceased donor organs for the development of potential donor-derived disease after transplantation.

15.3.B Deceased Donors at Increased Risk for Transmission of Blood-borne Pathogens

If a ~~deceased~~ donor is found to have an increased risk for transmitting blood borne pathogens, HIV, hepatitis B, and hepatitis C, the transplant program must offer recipients of the donor organs *all* of the following in addition to routine post-transplant care:

1. Additional post-transplant testing for HIV, hepatitis C, and hepatitis B as appropriate based on the recipient's pre-transplant status. Every transplant program must develop and implement a written protocol for post-transplant testing for these diseases (unless infection in the recipient was documented pre-transplant).
2. Treatment of or prophylaxis for the transmissible disease, when available.
3. Routine post-transplant follow up care.

16.7 Vessel Recovery, Transplant, and Storage

16.7.A Deceased Donor Vessel Recovery and Transplant Use

To recover and use vessels in an organ transplant, the deceased donor authorization forms must include language indicating that the vessels will be used for transplant. The vessels can only be used for transplant or modification of an organ transplant.

Transplant hospitals may share vessels. If sharing occurs between transplant hospitals, the receiving transplant hospital must submit a detailed explanation to the OPTN Contractor that justifies why the sharing occurred. The Membership and Professional Standards Committee (MPSC) will review the explanation. If the receiving transplant hospital later disposes of any vessels, it must notify the OPTN Contractor.

16.7.B Vessel Storage

Transplant hospitals may not store for later use any hepatitis C antibody positive (HCV), HCV

NAT positive, hepatitis B surface antigen positive (HBsAg), or hepatitis B NAT positive extra vessels. If the transplant hospital stores vessels and later uses the vessels for the intended recipient or another recipient, it must notify the OPTN Contractor.

The Transplant hospital must designate a person to do *all* of the following:

1. Monitor and maintain all records relating to the use and management of vessels
2. Monitor the refrigerator where the vessels are stored
3. Destroy expired vessels
4. Notify the OPTN

Additionally, the transplant hospitals must do *all* of the following:

1. Store vessels in a Food and Drug Administration (FDA) approved preservation solution
2. Package and label vessels as required by *Policy 16.4: Packaging and Labeling*
3. Store vessels in a secured refrigerator with a temperature monitor and maintain the temperature no colder than 2 degrees Celsius and no warmer than 8 degrees Celsius
4. Monitor vessels daily with documented security and temperature checks
5. Destroy unused vessels within 14 days after the recovery date
6. Maintain a log of stored vessels
7. Have accessible at all times the vessel deceased donor information for the transplant surgeon prior to using the vessels in any recipient other than the originally intended recipient