

**Aligning OPTN Policies with the 2013 PHS Guideline for Reducing Transmission of HIV,  
HBV, and HCV Through Solid Organ Transplantation webinar  
February 3, 2015: 2 – 3 p.m. (ET)**

**Questions and Answers**

**Follow-up testing of recipients post-transplant**

**1. What are the timeline recommendations for follow-up testing in transplant recipients of donors at increased risk for disease transmission?**

Policy does require post-transplant testing, but includes no time frame for completion. The DTAC was not comfortable developing prescriptive policy language that would enforce testing at specific times. There is limited data to support the time periods specified in the PHS Guideline for testing, and centers should have the flexibility to develop post-transplant testing protocols based upon their own philosophy. 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 their recipients' needs and program practices. Transplant hospitals are encouraged to consider the PHS Guideline (specifically recommendations 18, 19, and 20) when developing their protocols. 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.

**2. Do you think the FDA will eventually approve the use of NAT testing for recipients who have received an increased risk donor?**

In most transplant centers, FDA approved diagnostic NAT testing appropriate for follow up testing is available. Of note, -as serological responses in immunosuppressed patients may be inadequate- the PHS guidelines do recommend that NAT tests are included as part of the post-transplant testing protocol for recipients of increased risk donors (PHS guidelines Figure 6). While Policy 15.3.B, requires transplant hospitals to develop and implement a written protocol for post-transplant testing in recipients of increased risk donor organs for HIV, HCV, and HBV, the specific tests and timing of testing is not defined by policy.

**Living donors**

**1. Please address how the policy changes apply to living kidney and liver donors.**

The medical-social behavioral criteria questions included in the PHS Guideline also apply to living donors. These questions determine whether a donor is at increased risk for transmission of HIV, HBV, and HCV. Review the Frequently Asked Questions regarding the 2013 PHS Guideline located on the OPTN website under patient safety resources as a reference when determining increased risk. For a detailed list of changes, review the December 2014 policy notice located on the OPTN website under the Governance tab, as it outlines modifications relevant to living donors included in Policy 14.

**2. What questions should all living donors be asked to comply with OPTN policy?**

Questions regarding the medical-social behavioral criteria of living donors is included in the 2013 PHS Guideline. These questions determine whether a donor is at increased risk for transmission of HIV, HBV, and HCV. Review the Frequently Asked Questions regarding the 2013 PHS Guideline located on the OPTN website under patient safety resources.

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- 3. Does HCV and HIV antibody testing need to be done within 28 days of donation? For example, we currently complete serologies (HBV, HCV, HIV antibody) in a living donor evaluation a few months before donation and then NAT within 28 days of donation. Should BOTH serologies and NAT be done in pre-op within 2 months even if donor risk is low?**

**Can Centers choose how they test living donors before the 28 day pre-donation period?**

The PHS Guideline recommends that all living donors should be tested for HIV, HBV, and HCV as close as possible to the date of organ recovery, but at least within the 28-day time period prior to surgery. Current policy now requires that serology (antibody) testing be completed within this 28-day time period. The same will be true for the new NAT requirements when they are implemented this summer, regardless of whether a donor is considered to be at increased risk for disease transmission.

Prior to the 28 day pre-donation period, living donor recovery hospitals may complete testing as they choose for the purposes of donor evaluation and recipient matching.

- 4. Why can't NAT testing replace antibody testing within 28 days of transplant? Isn't NAT testing more sensitive? Do Centers still have to complete antibody and antigen testing if using NAT for HCV, HBV, and HIV results? Why repeat serologies at all?**

The 2013 PHS Guideline is clear in requiring serologies and NAT testing within 28 days. Some hospitals may do initial screening up to a year before the serologies expire (it's not a bad idea to repeat them) although it is not totally logical if the serologies were previously completed. Antibody tests ensure that you don't mistakenly get a negative NAT on an elite controller, or a patient on medications. Those on treatment for HIV are typically NAT/diagnostic quantitative PCR negative but seropositive. Donors can have a negative NAT and still have infection with HIV or viral hepatitis that can be transmitted to the recipient. There is a chance this is the ONLY test the donor commits to. The 28 day screening will pick up newly acquired disease in living donors. Presumably, a living donor who knew they had HIV and was on treatment would disclose that fact so the yield would be low and the donor would have already been screened by serology during the work up.

- 5. Do the 28-day testing requirements apply only to increased risk living donors?**

No, the PHS Guideline recommends all living donor testing for HIV, HBV, and HCV be completed within 28 days of organ recovery, regardless of whether a donor is considered to be at increased risk for transmission of HIV, HBV, and HCV.

- 6. Does the serology draw for living donors have to be archived for ten years like deceased donors?**

No. Policy requires only deceased donor sample archiving because.

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- 7. For PHS increased risk behaviors when screening living donors: does a “yes” on any of those behaviors preclude someone from being a living donor? Or is it up to the transplant center to determine actual level of risk and whether or not someone should proceed as a living donor?**

Policy does not prohibit increased risk individuals as defined by the PHS Guideline from living donation. Living donor transplant hospitals make the determination on whether they choose to proceed during the evaluation process. Additionally, a potential recipient of an increased risk organ of any type requires informed consent. If the living donor is uncomfortable with this information being shared, he or she may withdraw from the donor evaluation process.

- 8. For us, the difficult part in adhering to these requirements are that we do not know the protocol from UNOS for "increased risk" - for example, what are criteria for "high risk" HIV or "high risk" as travel to endemic area - where are the protocols and criteria outlined.**

The eleven criteria to identify increased risk are set in the [PHS Guideline](#), which is a reference document to this webinar. You may access this list on page 128 of the Guideline. They appear as bullet points.

Risk related to seasonal or endemic disease are covered in a [guidance document](#) from the DTAC that is available on the OPTN website under the Resources tab when you click on living donation.

- 9. Does the PHS questionnaire on living donors need to be repeated within 28 days of surgery?**

Policy does not require that the questionnaire be repeated within 28 days of organ recovery, but best practice encourages communication with living donors regarding risk factors, especially if these factors were noted upon the initial questionnaire.

**Testing requirements**

- 1. When will the NAT testing requirement be effective?**

The DTAC recognizes that OPOs and living donor recovery hospitals may need time to establish laboratory relationships to allow for NAT testing for all donors. Additionally, there are currently no data collection fields to capture NAT results for donors. NAT requirements will not be implemented until programming to add these fields is completed in UNet<sup>SM</sup>. This is anticipated for completion mid to late summer 2015. Members will be notified as the date approaches via UNet<sup>SM</sup> Systems Notices.

- 2. My OPO uses triplex NAT testing. What should I do if I receive a positive result for a donor?**

Many OPOs are using a triplex test, which includes NAT results for HIV, HBV, and HCV in one test. The critical reason to sub-test is that if the triplex is picking up HIV, then currently all transplants from that point forward are not allowed. When a triplex test is positive, it does not distinguish which virus or viruses are present in the donor. As testing technology

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continues to improve, this may no longer be the case. Currently, however, additional confirmatory testing must be run to determine which virus is present in the donor recognized by the triplex NAT. In these cases, individual confirmatory testing should be run according to test manufacturer or FDA recommendations to make this determination. Specific instructions on how to proceed with varying results from varying manufacturers is beyond the purview of the OPTN. OPOs should work with their testing laboratories to develop a process for handling these positive results.

- 3. Please provide guidance on the types of specimens that need to be archived to comply with serology and NAT testing storage requirements during the 10 year period.**

The type of samples needed will depend on the type of testing technology used. As test manufacturers continue to innovate and the FDA approves new platforms, the samples needed may change. This is why the DTAC did not make specific requirements in policy. Current best practice, as shared by Lisa Stocks, includes archiving 2ml each of serum and plasma. This will allow for completion of most tests.

- 3. As an OPO, I am unsure how to comply with the new requirement that blood be stored for NAT testing for ten years. We currently only store serum, though we do perform pre-recovery NAT testing on all deceased donors. Our testing lab director indicates that the test kit we use for NAT can only be used on blood stored for up to 30 days. If stored longer, it cannot reliably be used in the test kit. Can you offer guidance on how the OPTN expects us to comply with this policy? Are there other test kits that can use blood stored for longer time periods?**

The [PHS Guideline](#) suggests that the OPO collect two blood specimens for archiving, when possible. Further, it suggests that if it is only feasible to collect one specimen, a plasma specimen collected in EDTA, rather than a serum specimen, is optimal.

Information from one of the large contract labs used by some OPOs indicates that properly processed (separation within 24 hours of draw) and stored plasma (at -80°C and not freeze/thawed cryoviral) serum/ samples have a long lifespan for NAT. Samples collected as far back as the 1970s that have been stored in this manner have been used in research. OPOs are encouraged to communicate with their testing laboratories and specimen storage provider regarding this new requirement.

- 4. Does viral load testing meet the NAT requirement? If a quantitative HIV, HCV, or HBV is completed, will this eliminate NAT testing?**

“NAT” refers to a test that detects nucleic acid (DNA or RNA) rather than antibody (serological test). The policy language approved by the Board allows for the use of screening or diagnostic NAT for deceased donors and is silent on type of NAT for living donors. “Viral load diagnostic testing” is a type of NAT commonly performed in hospital laboratories. The test result is quantitative, reflecting the number of copies of the virus in the tested compartment. While screening NAT is ideal for deceased donors, viral load testing would meet the testing requirement in policy for both deceased and living donors. Please

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check with your testing lab if you have concerns regarding whether a particular test is a “NAT” test.

- 5. If we use HIV Ag/Ab combination testing for all donors (living and deceased) as part of the required testing, then wouldn't that be sufficient HIV testing for any donor that is considered increased risk?**

Yes. Because the HIV Ag/Ab combination test is an alternative to HIV Ab screening, and also an alternative to HIV NAT for increased risk donor testing, this particular test may be used to meet both HIV testing requirements. It is important to note, however, that the window period for recognizing infection is slightly shorter when using NAT.

- 6. Will a field be added for HIV Ag/Ab combo testing along with the NAT field additions?**

Yes. The HIV Ag/Ab combination test will also be added for OPOs to display results. This and the NAT additions are scheduled for implementation this summer.

- 7. What does NAT reduce the infectious window period to?**

The table<sup>1</sup> below estimates window period length for different testing methods:

	<b>Standard Serology</b>	<b>Enhanced Serology (4<sup>th</sup> gen or combination tests)</b>	<b>NAT</b>
<b>HIV</b>	17-22 days	~7-16 days	5-6 days
<b>HCV</b>	~70 days	~40-50 days	3-5 days
<b>HBV</b>	35-44 days	Not applicable	20-22 days

- 8. Did I hear correctly that NAT results will be required before a match run can be executed?**

No. The PHS Guideline notes that optimally, all NAT results for deceased donors should be available before transplant occurs; however, if having NAT results before transplantation is not feasible, test results can be useful to guide recipient treatment. In order to avoid scenarios where antibody screening completed pre-transplant was negative and positive NAT results are discovered post-transplant, OPOs are encouraged to work with their testing laboratories to determine if these results can be obtained prior to organ allocation and transplant. Current policy is silent on a timing requirement, based upon the PHS Guideline.

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<sup>1</sup> 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

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- 9. Will “unknown” remain an option to check in DonorNet® in order to run a match run when results are not known. This will be important for expedited placement.**

Yes. OPOs will still be able to execute match runs with results not done or pending for a donor. The DTAC did release a public comment proposal in January 2015 that recommends requirements to re-execute the match run when positive results are received in this scenario.

- 10. Per OPTN Policy 2.5: hemodilution assessment on deceased donor, will any hemodiluted sample result in a donor that is increased risk? If a qualified sample is used for all Hepatitis, HIV and NAT but a non-qualified sample is used for RPR, CMV, etc., is donor increased risk?**

No, such a donor would not be increased risk as the hepatitis and HIV tests were performed on a qualified specimen. However, accepting centers should be informed of testing that was performed on non-qualified specimens. The PHS Guideline indicates that 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. If a hemodiluted specimen is used to test for these three viruses, the donor must be considered as at increased risk for transmission of these diseases. Policy 2.5 indicates that a donor testing completed using a hemodiluted sample must be treated as presenting increased risk as defined by the PHS Guideline.

- 11. Is it mandatory to have NAT results entered in Donor Highlights or is it ok that full serology results (including NAT) are attached to DonorNet®?**

Until the NAT data collection fields are added to DonorNet®, using the Donor Highlights field to convey this information is a best practice.

- 12. If the NAT and serology results are different, which one should be used for a match run?**

Ultimately both are required. If either are HIV positive (and the determination is that these are not false positive results), then donation cannot move forward. If either the HBV or HCV tests are positive, these need to be communicated as part of the match run. The current data collection fields are meant to capture only donor serology results. Programming is underway to add NAT data collection fields. To be compliant with current policy, OPOs should enter serology results in the appropriate field. While policy does not specifically dictate that NAT must be entered into the Donor Highlights field, it is helpful to transplant hospitals considering offers to have this information specifically called out here if results are positive. If a donor tests Ab negative, but NAT positive and the Ab result is entered into DonorNet®, there would be no way for a hospital to recognize this when glancing at DonorNet® without opening attachments.

- 13. Clarification needed: OPTN policy does not mention NAT testing currently?!**

NAT is not currently referenced in OPTN policy available on the OPTN’s website because these requirements have not yet been implemented. The upcoming requirements are available for review in the [Policy Notice](#) that outlines policy changes approved by the Board during its November 2014 meeting. The NAT requirements will not be implemented until

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programming to add data fields to collect this information and candidate screening options is complete. This is expected this summer. Members will be notified through Systems Notices regarding the upcoming changes. In the interim, please work within your institution to prepare for these changes.

**Informed Consent**

**1. What must be included in the disclosure of increased risk to the potential recipient? Must the center share specific diseases or behaviors the candidate is at increased risk of acquiring?**

There is both a minimum objective requirement for consent that OPTN dictates, and a very subjective part of the discussion that happens between every potential recipient and their center, depending on the individual's disease and circumstance. Policy requires that, prior to transplant, a transplant hospital must obtain informed consent. It does not include specific requirements as to how this conversation must be conducted, or who must have the discussion with the candidate. The only requirement is that risks must be explained and informed consent received prior to transplant and that this must be documented in the candidate's medical record. When drafting this language, the DTAC was sensitive to transplant professionals' medical judgment on how to have these conversations based upon each individual candidate's health literacy and specific situation.

**2. Explain the elements required by the OPTN as part of the recipient PHS informed consent for transplant.**

The informed consent requirements in OPTN policy cover:

- Donor medical conditions (known pre-transplant) that may be transmissible to recipient
- Increased risk donors (per PHS Guideline)
- Hemodiluted specimens used for donor testing
- Explanation of general risks ( a donor cannot be tested for anything and everything and some transmissible diseases or malignancies may be identified in the organ donor after transplant)

Programming is currently underway that will allow OPOs to clearly note which tests were completed using a hemodiluted specimen in DonorNet<sup>®</sup>. If any testing for HIV, HBV, or HCV is completed using a hemodiluted specimen, the donor should be treated as presenting increased risk for transmission of these viruses. OPOs are required to report information as outlined in Policy 2.5 any time a hemodiluted specimen is used for testing.

**3. Is the OPO required to have signed documentation from a transplant surgeon that they have alerted their recipients of the increased risk?**

OPTN Policy does not require the OPO to maintain signed documentation from a transplant surgeon that the recipient has been made aware of increased risk status.

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**4. How much information should be given to the recipient and documented in the recipient's chart about the donor's PHS status, taking HIPAA into consideration?**

The only information required to be provided to the recipient and documented in the medical record is that the donor met PHS increased risk criteria. Disclosure of details related to why the donor met PHS increased risk criteria is left to the discretion of the transplant hospital.

**Increased Risk Criteria**

**1. Clarify whether hemodialysis performed during a current admission will make a donor at increased risk.**

The 2013 PHS Guideline indicates that potential organ donors who have received hemodialysis at any point in the preceding 12 months be classified as an increased risk donor due to potential for HCV infection only. This has been a topic of some confusion since the release of the Guideline, and has led to discussion between the Committee and CDC representatives. The increased risk of HCV from hemodialysis is due to the fact that hemodialysis machines are used by multiple patients. Those who have **ever** used hemodialysis, regardless of the length of time, are at increased risk for new hepatitis C infection until 12 months have passed since their last dialysis treatment. This would include a single dialysis treatment at the time of terminal hospitalization.

Conversely, continuous veno-venous hemofiltration (CVVH) which is individually used and not machinery shared by multiple patients, will not put a donor at increased risk of HCV infection. The same is true for peritoneal dialysis, which does not use shared machinery and therefore will also not result in classification as an increased risk donor. For this reason, if it is known that a donor has had dialysis in the past 12 months, care should be taken by the OPO or living donor recovery hospital to determine which type of dialysis was used in order to avoid misclassification of donor risk.

You may wish to review the DTAC's recorded town related to application of the PHS increased risk criteria. This is available on the OPTN website. Additionally a frequently asked questions document covering similar topics is posted on the OPTN website as a professional resource to the transplant community.

It should also be noted that donors whose only increased risk factor is hemodialysis are at risk only for HCV infection, and not HIV or HBV. For this reason, these donors are not required to have HIV NAT as recommended in the PHS Guideline and proposed for



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deceased donors in *Policy 2.9 (Required Deceased Donor Infectious Disease Testing)* and for living donors in *Table 14.2 (Requirements for Living Kidney Donor Medical Evaluations)*, and this is a post-public comment modification clearly outlined in the language presented to the Board for consideration.

The increased risk designation applies specifically to HIV, hepatitis C and hepatitis B. However transplant centers should recognize that any infectious disease testing might have an increased false negative rate if the sample is not qualified.

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**Other**

**1. Can you give guidance for OPOs who use 'OPO increased risk' that do not meet the PHS increased risk criteria?**

Some OPOs chose to create their own “high risk” or “increased risk” criteria prior to the release of the 2013 PHS Guideline. The previous Guideline was specific to HIV only, and was sometimes difficult to define when interviewing donor historians. The DTAC believes that the new 2013 PHS Guideline is much more specific and now covers Hepatitis B and Hepatitis C in addition to HIV. The DTAC cannot provide guidance here, as it can only speak to the use of the specific PHS increased risk criteria, as required by OPTN policy.

**2. Have centers evaluated which educational methods for recipients and live donors is most effective?**

Not that we are aware of.

**5. Where can you find guidance on what should be documented in Donor Highlights (in DonorNet®)?**

The OPTN has not developed a guidance document on this topic. This area is frequently used to call out or explain donor information critical to considering an offer. Currently, it also serves as a place to list NAT results- though this will no longer be necessary once programming is complete to add these data collection fields. A suggestion might be to pose this question on the AOPO list serve for further suggestions from OPO colleagues.

**6. Why are OPOs still required to test for HTLV and why is this no longer a requirement for living donors?**

The HTLV donor screening requirement was removed (for all donors) from policy in 2009. A small number of OPOs still test for HTLV regularly. The data collection field remains in DonorNet®, but it is optional. HTLV is extremely rare in the United States, and an analysis of HTLV testing demonstrated that the vast majority of initial positive results did not reflect true HTLV-1 infection. Testing could be considered, however, in donors at high risk for HTLV-1 infection.

**7. Will there be guidance on the volume of serum or plasma that must be maintained for archiving?**

Lisa Stocks shared her OPO’s practice for preferred volume of samples for the purposes of archiving. She suggested that OPOs work with their testing laboratories to determine volumes necessary to complete testing in order to develop a standard. There are no current plans within the OPTN to develop guidance in this area.

**8. Will the vessel label be updated to include NAT results?**

Yes. Staff is coordinating updates for labels and TransNet<sup>SM</sup> to reflect NAT and HIV Ag/Ab combination results.

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- 9. Is the language willing to donate required instead of willing to move forward with evaluation for living donor consenting?**

**Is only one living donor consent required with the language "willing to donate" for evaluation and OR instead of one consent for evaluation and one for OR.**

Policy 14.3: *Informed Consent Requirements*, Table 14.1: *Requirements for Living Donor Informed Consent* includes language to require a donor's signature on a document that confirms he or she is willing to donate.

The informed consent policy was historically separated into two sections. It is now combined into one policy. The center is still required to obtain surgical consent for the nephrectomy per the transplant hospital's policy.

- 10. What medical personnel is included in the "must" be told group in relation to HIV test results?**

The change to Policy 2.7.B was a housekeeping edit to remove the term should from policy. This section of policy may be somewhat out of date, as it was originally intended to prevent unnecessary sharing of HIV positive status for donors when HIV was more of a taboo in the early 1990s.