

Updated August 23, 2023

## **FREQUENTLY ASKED QUESTIONS – PHS**

*Policy changes related to alignment with 2020 PHS Guidelines are being implemented on March 1, 2021\*. This document contains example questions and answers that help provide clarity to transplant programs or OPOs in anticipation of these policy changes.*

*\* All of the proposed changes are being implemented March 1, 2021 except for three elements that are either implemented June 1, 2021 or await OMB approval (date of implementation unknown at this time). See the Other – Timeline section of this document for an overview of the timeline of the different changes.*

### **Transplant Programs**

#### **Pre-transplant Testing**

Question: I tested my candidate for HBV, HCV, and HIV as part of their medical evaluation, do I have to repeat the tests?

Answer: The tests specifically should be

- a. HIV: CDC-recommended testing algorithm<sup>2</sup>
- b. HBV: total anti-HBc, anti-HBs, and HBsAg
- c. HCV: NAT and anti-HCV

Additionally, testing must occur during hospital admission for transplant but before transplant. If those are met, then you don't need to retest. If the criteria are not met, you do need to retest pre-transplant. Additional testing is required post-transplant.

Question: What should I do if the donor OR time gets pushed back and my testing specimens will be more than 96 hours old?

Answer: Policy requires the donor specimen should be collected within 96 hours prior to organ procurement; if the testing specimens are more than 96 hours, additional samples must be obtained and retesting must occur.

Question: What are acceptable types of nucleic acid testing (NAT)?

Answer: The following are acceptable for NAT:

- Nucleic acid amplification test (NAAT)
- Polymerase Chain Reaction (PCR)
- Strand Displacement Assay (SDA)
- Transcription Mediated Assay (TMA)

Question: If patient is waiting for transplant in the hospital to wait for transplant, can we draw labs on admission or do we have to wait until an offer becomes available?

Answer: You can draw labs on admission.

#### **Transplant Candidate Informed Consent & Risk Criteria**

Question: Are candidates still required to give informed consent for organs that meet the new risk criteria?

Answer: Candidates or their agents are not required to give specific informed consent for organs that meet the new risk criteria. Prior to transplant, candidates (or their agent) must be informed if an organ meets the new risk criteria for HIV, HBV, or HCV. Specific informed consent is required only if the donor organ tests positive (not just meets risk criteria) for HOPE Act (HIV positive), HBV positive (NAT or Surface Antigen), or HCV positive (NAT).

Question: I already told my patient when we put them on the waiting list they may get an “increased risk” organ offer do I need to tell them something different now?

Answer: Transplant programs should inform candidates who previously gave informed consent for “increased risk” organs (as defined in policy prior to March 1, 2021) of the fact that the risk criteria has changed. If they are offered an organ that meets the revised criteria for risk then the candidate or their agent will be informed of that fact.

Question: Can the discussion with the candidate informing them if an organ meets the new risk criteria be documented in the Electronic Medical Record (EMR) when the organ offer is made?

Answer: Yes, documentation can be in the EMR and can occur when the organ offer is made.

Question: If risk criteria are met, do patients need to be informed *that* risk criteria are present or *what* the specific risk criteria are?

Answer: Patients need to be informed *that* risk criteria are present. It is not a requirement that the risk criteria are specified. It is important to note that this is not a change from previous policy. Also, it is helpful for transplant programs to contextualize the discussion in accordance with the 2020 PHS Guideline:

- The risk for undetected HIV, HBV, or HCV infection is very low but not zero.
- Recipients will be tested for HIV, HBV, and HCV infections after transplantation and should transmission occur, effective therapies are available.
- Transplant candidates might have a higher chance of survival by accepting organs from donors with risk factors for HIV, HBV, and HCV infections compared with waiting for an organ from a donor without recognized risk factors.

Question: Who can have the discussion and document that the patient was informed that the donor meets the new risk criteria when the offer is made? Does it have to be the surgeon? Can it be an APP, fellow or transplant coordinator?

Answer: OPTN policy does not specify or require the discussion be had by a specific personnel member; transplant programs have discretion.

Question: Even though separate informed consent for donors with risk criteria isn't required anymore, can my transplant center still include informed consent as part of its protocol to make sure the information is being collected?

Answer: The OPTN policy changes in alignment with 2020 PHS Guideline describe the minimum requirement so individual transplant programs can have more specific requirements for informed consent than is required in OPTN policy.

Question: The new risk criteria are applicable within 30 days of recovery. The criteria regarding a child born to a mother positive for HIV/HBV/HCV would only be applicable to a child 30 days old or less, correct?

Answer: Yes

### **Recipient Testing & Vaccination**

Question: Who has to do post-transplant testing for HIV, HBV and HCV?

Answer: For all candidates, except candidates known to be infected with HIV, HBV or HCV, universal post-transplant testing policies apply March 1, 2021 and after. These candidates must receive HIV, HBV, and HCV NAT post-transplant testing within 4-8 weeks (28-56 days) post-transplant; liver recipients of transplants performed on March 1, 2021 and after must receive HBV NAT at 11-13 months (335-395 days) post-transplant.

Question: I have a recipient who received an increased risk organ (as defined in policy prior to March 1, 2021) in January 2021, how should I handle the post-transplant follow up now that the policy has changed?

Answer: Since your recipient was transplanted before the March 1, 2021 implementation date, the requirement for universal post-transplant nucleic acid testing (NAT) for Human Immunodeficiency Virus (HIV), Hepatitis B Virus (HBV), and Hepatitis C Virus (HCV) does not yet apply. Policy that applies prior to March 1, 2021 indicates that you follow your transplant program's protocol for HIV, HBV and HCV testing since your recipient received an "increased risk" organ (as defined in policy prior to March 1, 2021). Testing for HIV, HBV, and HCV by NAT is the recommended way to detect potential donor-derived infection.

Question: If a patient is hospitalized for the evaluation and inpatient until the transplant, does the viral testing need to be redone once the organ offer is received?

Answer: No, the requirement is that the testing be done after admission but prior to anastomosis of the first organ, and if the candidate is hospitalized for that period there is not a time limit. However, as a best practice it's always good to consult with the infectious disease team at your hospital and if there is any concern for potential viral exposure it's appropriate if not specifically required by the new policy to retest a candidate to ensure they receive early interventions if infected.

Question: What if a family does not want to give a child the Hepatitis B vaccine for personal reasons?

Upon OMB approval and notice to members, OPTN policy will not require HBV vaccination, but policy will require documentation of whether or not a candidate was vaccinated, and if they weren't, why not.

Those reasons don't have to be medical, we know that those reasons can be personal. The conversation must be documented per OPTN policy requirements.

Question: The TRF form is being updated to include a viral detection section at 6 months and 1 year. Do we need to order these NAT tests at 6 months and 1 year on all recipients to complete the viral detection section on the TRF form?

Answer: The tests must be completed 4-8 weeks' post-transplant and documented on the 6-month TRF. Liver recipients must also receive HBV testing at 11-13 months post-transplant.

Question: On the PHS 2020 guideline, it said post-transplant testing within 4-6 weeks. So is OPTN policy going to be 4-8 weeks?

Answer: OPTN policy was developed to include an additional two weeks to better coincide with post-transplant follow up.

Question: What about patients who have been on the waiting list for several years? Do we have to backtrack and ask about vaccination?

Answer: Yes, upon OMB approval, implementation and notice to members, the requirement to have a conversation and document will apply to all patients on the list.

Question: For recipients, is documentation of positive Hepatitis B Surface Antibody acceptable for Vaccination need assessment? What if recipient is negative, will we be required to give Hepatitis B Vaccination?

Answer: The transplant program is required to have a conversation with the patient about vaccination status and document, if appropriate, the reason not vaccinated. The Hepatitis B Vaccination is not required. What is required is the conversation and the documentation.

### **Living Donor Recovery Hospitals**

Question: Before this policy change, the time interval for reviewing risk for living donors was within the previous year. Now that time interval is shortened to 30 days. If a donor is evaluated and completes the risk assessment which is then reviewed by social work and psychology, but then doesn't donate for several months, does the specific risk assessment have to be updated prior to donation?

Answer: No, because the time interval refers to the 30 days prior to the risk assessment. If the donor is evaluated and completes the assessment of risk criteria for the previous 30 days, the requirement for the specific risk assessment is already met and does not need to be updated prior to donation. The 2020 PHS Guideline specifies that "living potential donors who have past or ongoing risk for acquiring HIV, HBV, or HCV infection should receive individualized counseling on specific strategies to prevent exposure to these viruses during the period before surgery."

Question: Who will store the lab samples for living donors, since that's a new change to keep them for 10 years? What are the specimen storage requirements?

Answer: The revised PHS Guideline advises that OPO and living donor recovery hospitals store donor blood specimens for at least ten years. Two specimens (one for NAT and one for serology) should be collected within 24 hours before organ procurement/recovery. Living donor recovery hospitals must arrange for additional storage for living donor specimens. This will require additional storage space, development of storage protocols, and updates to living donor informed consent protocol. Additional time is needed for living donor recovery hospitals to create storage agreements, so this component will be implemented on June 1, 2021 instead of March 1, 2021 to allow transplant programs that perform living donor recoveries to get ready for this new requirement.

Question: With the new policy of storing living donor blood specimens—what type and number of specimens should be stored?

Answer: The PHS guideline recommended storage of two specimens, serum for serologic assays and a plasma specimen for NAT testing. They recommended that priority would be an EDTA plasma specimen for NAT testing. OPTN policy does not specify the number and type of specimen.

Question: I'm concerned about the impact of the new living donor blood specimen storage requirement. Why was this change made?

Answer: The requirement is included in policy changes to ensure OPTN policies are consistent with CDC recommendations outlined in the 2020 PHS Guideline, which specifies 10-year blood specimen storage for both living and deceased donors. Given community concerns, the Ad Hoc Disease Transmission Advisory Committee (DTAC) is not only considering the impact of this change starting with its 6-month post-implementation evaluation, but is proactively requesting a data analysis on use of deceased donor post-transplant blood specimens to assess possible disease transmission stratified by years from transplant that the specimens were reviewed. These data will help inform monitoring and any potential request to revisit or change the Guideline.

Question: Does the requirement of living donor specimen storage for 10 years apply to domino donors?

Answer: No because according to Policy 14.9: "Although domino donors and non-domino therapeutic donors are considered living donors, the requirements in Policy 14: Living Donation are limited only to Policies 14.9.A through 14.9 E." – and the specimen storage requirement will be added to Policy 14.8, outside of the applicable policies.

Question: Can or will the living donor blood specimen be used to test for diagnosis of possible metabolic disease or genetic disease that has occurred in the recipient?

Answer: The specimen is only able to be used for evaluation of suspected donor-derived disease in the recipient. The specimen would not be able to be used for any reason other than this evaluation. The requirement stems from a patient safety concern, given that DTAC has found

cases of donor-derived transmission for less common pathogens that are not traditionally screened for pre-transplant many years down the road.

Question: For kidney exchanges is it the recovering hospital responsible for the donor blood storage?

Answer: Yes

Question: Do we destroy the samples after 10 years?

Answer: Programs must follow local and federal guidelines on specimen storage. Policy and PHS Guideline don't specify.

### OPOs

Question: I am inquiring with a question regarding the upcoming PHS changes. If we are currently in the process of a donor on 3/1/2021, do we need to re-screen the patient for "risk criteria for HIV/HBV/HCV"? Or would we following the current policy for active donors, and donors that we authorize after midnight on 3/1/2021 would follow the new changes?

Answer: The policy implementation is expected to be released at 8:30 am EST. We recommend following what will be the active policy at time of procurement. Member compliance will not be assessed based on date/time that the risk assessment was done, so if donor evaluations cross over the policy timeline either risk assessment would be acceptable.

Question: Changes to Policy 2.9 require that donor samples for HIV, HBV, and HCV testing must be obtained within 96 hours prior to organ procurement. How is the time of organ procurement being measured - the OR date in DonorNet, or when a donor enters the OR as per the OPO's EMR?

- Answer: Site survey would be going off the OR date in DonorNet, specifically the field label is "recovery date" in the donor organ disposition (below), so the monitoring descriptions provided in the briefing paper and the Evaluation Plan preview describe 4 days before the recovery date.

Question: For donors referred and evaluated before March 1 that were deemed "PHS Increased Risk" using the 2013 PHS Guideline, how should extra vessels labeling be handled, considering that updating the TransNet<sup>SM</sup> app will update the labels to reflect the 2020 PHS Guideline?

Answer: This is for situations in which OPOs have donors that were referred and evaluated prior to the March 1<sup>st</sup> implementation date and deemed quote-unquote "Increased Risk" using the 2013 PHS Guidelines. As the donor was already referred and labeled prior to the March 1<sup>st</sup>

implementation date, but all new labels must go into effect beginning starting March 1<sup>st</sup>, the OPO may choose to use the new extra vessels labels (which specify “HIV, HBV, HCV Criteria” instead of “increased risk”) to represent the donor risk status (as met by the 2013 PHS Guidelines).

Specifically, for OPOS with a case “in flight” on your mobile device, we recommend you first WiFi transfer that case up to UNOS servers, install the new TransNet application version, and the WiFi transfer the case back down. Previously entered responses for “PHS Risk” and ‘anti-HBc’ will transition to the new labels of ‘HIV, HBV, HCV Criteria’ and ‘Total anti-HBc’ respectively. Ensure that data entered for these questions is still accurate and proceed with the case.

It is the OPO’s responsibility to communicate to the accepting transplant hospital if the OPO evaluated the donor using the 2013 PHS Guidelines.

Question: Is PHS implementation expected to impact OPO EMRs and their interfacing with DonorNet in light of the requirement for HIV, HBV, and HCV testing to be within 96 hours of procurement?

Answer: This should not change how the EMRs interact with the UNOS system. Members are still able to upload changed infectious disease results as necessary.

Question: Do I still have to perform a hemodilution assessment and report the hemodilution status in UNet<sup>SM</sup>?

Answer: Hemodilution is only removed from the PHS Guideline list for assessing risk criteria, it is not completely removed from policy. So, yes you still have to perform a hemodilution assessment and report the status in UNet because it is still required by *Policy 2.5: Hemodilution Assessment*.

Question: If a deceased donor serology is reactive for Hepatitis B or C and the specimen is now greater than 96 hours do we still need to obtain a new specimen less than 96 hours?

Answer: You only need to obtain a new specimen for tests those that were non-reactive.

Question: How will the OPO be letting transplant programs know about risk criteria? Will there be a field in UNet with the organ offer that indicates if risk criteria are present in the donor?

Answer: There is a field in DonorNet that currently lets the OPO indicate risk assessment. While the language will change to reflect the removal of “increased risk,” instead referring to “donors with risk criteria,” the field itself will still be there.

Question: I heard mentioned that deceased donor testing should occur within 24 hours of procurement. Isn't it 96 hours?

Answer: 24 hours before organ procurement is the timeframe for collection of deceased and living donor specimen for 10-year storage. 96 hours is the timeframe for specimen collection before procurement for deceased donor testing.

Question: If the time of procurement falls outside of the 96 hours, can the sample that needs to be re-sent count as the archive sample that needs to be collected within 24 hours prior to procurement?

Answer: If the resent sample is within 24 hours prior to procurement, and sufficient volume is collected, then policy does not preclude some of the specimen being used for donor testing and some being used for 10-year storage.

Question: Does the blood sent with organs need to be drawn within 24 hours as well?

Answer: No because the 24-hour requirement refers to collection of donor specimen for 10-year storage.

### Other - Timeline

Question: I'm confused about the effective date of implementation. When are the PHS policy changes being implemented?

Answer: The below table highlights changes with specific time requirements stratified by implementation date.

<b>Highlighted PHS Policy Changes by Implementation Date</b>			
<b>Implementation date</b>	<b>Member Impacted</b>	<b>Specific Change</b>	<b>Time Requirements</b>
March 1, 2021	OPOs, Tx programs	Use updated PHS risk criteria for risk assessment of all living and deceased donors	30 days before... OPOs: procurement Tx programs: living donor evaluation
March 1, 2021	Transplant programs	Specific informed consent for candidates receiving organs with risk criteria no longer required, but candidate must be informed and that documented in the medical record	Still applies after the organ offer (can be in the same conversation as the organ offer) but before transplant
March 1, 2021	OPOs	Obtain deceased donor specimen for infectious disease test collection	Within 96 hours before organ procurement
March 1, 2021	Tx programs	Pre-transplant testing for HIV, HBV and HCV infections for all candidates, regardless of donor risk criteria	During hospital admission for transplant but before transplant
March 1, 2021	Tx programs	Universal post-transplant testing of NAT HIV, HBV, and HCV for all candidates except those known to have HIV, HBV or HCV will not have to be retested for known infection	4-8 weeks (28-56 days) post-transplant (all recipients)  for liver recipients, additional HBV 11-13 months (335-395 days) post-transplant



June 1, 2021	Tx programs	Living donor blood specimen collection for storage – consent for specimen storage as part of informed consent discussion	Must be collected within 24 hours of organ recovery  Must be stored for 10 years post-transplant
TBD (needs OMB approval)	Tx programs	For all transplant candidates, assess need for HBV vaccine and document status, reason not vaccinated if applicable	During candidate medical evaluation

The only policy changes that **do not** go into effect March 1, 2021 are:

- *Policy 14.8.B: Living Donor Specimen Collection and Storage.* The requirement that living donor blood specimen to be stored for 10 years that can be used for NAT or serology testing if future disease investigation needed (June 1, 2021)
- *Policy 14.3: Informed Consent Requirements.* Consent must be obtained for blood specimen storage as part of overall living donor consent (June 1, 2021)
- *Policy 15.2: Potential Candidate Screening Requirements.* Added requirements about candidate HBV vaccination assessment and documentation (implementation upon OMB approval and notice to members)