

**OPTN Ad Hoc Disease Transmission Advisory Committee
PHS Revisions Workgroup
Meeting Summary
July 14, 2020
Conference Call**

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Introduction

The PHS Revisions Workgroup met via Citrix GoToMeeting teleconference on 07/14/2020 to discuss the following agenda items:

1. Living Donor Specimen Storage
2. Hepatitis B (HBV) Vaccination
3. Policy Language Review
4. Programming Implications
5. Public Comment Feedback Questions

The following is a summary of the Workgroup's discussions.

1. Living Donor Specimen Storage

The Workgroup discussed the living donor specimen storage portion of the [2020 US Public Health Service Guidelines](#).

Summary of discussion:

Concerns raised

- 10 years' storage for living donor specimens doesn't seem to fit with HIV/HBV/HCV
 - 1-2 years' storage fits much more closely with HIV/HBV/HCV
 - The concept of 10 years' storage makes sense, just not in relation with the three pathogens being addressed in the US PHS guideline
 - It's much easier to put a more restrictive policy out to public comment and then relax it than it is to do the opposite
- This should be discussed specifically with the Living Donor Committee

CDC input

- This proposal was written with more than just HIV/HBV/HCV in mind, especially since there are other pathogens that could potentially take much longer to detect
- Living donor follow-up can occasionally be difficult, and the conditions that you test them in years later aren't the same as the conditions at time of transplant

Proposed changes to policy

- Going to public comment with 10 years' proposed living donor specimen storage, and asking the transplant community if they felt that was an appropriate length of time

2. Hepatitis B (HBV) Vaccination

The Workgroup discussed the HBV vaccination portion of the [2020 US Public Health Service Guidelines](#).

Summary of discussion:

Concerns raised

- The OPTN may not have the purview to require this
- Concern raised about the wording “initiate” in the proposed policy language- the workgroup is allowing that other providers could give the vaccination; it’s not required to be given by the transplant program

CDC input

- Guidance is that transplant candidates are vaccinated, not candidates or recipients. We would prefer this be given prior to transplant, but we understand that there are outlying situations that need to be written into policy

Proposed changes to policy

- Change language from transplant programs “initiating vaccination” to “ensuring vaccination”, to account for the fact that other providers could be administering the series

Next steps:

UNOS legal will continue to review with HRSA to determine if the OPTN has the legal authority to require a candidate vaccination.

3. Policy Language Review

UNOS staff presented draft policy language to the workgroup for review.

Summary of discussion:

Concerns raised

- One workgroup member brought up a concern about triplex HIV/HBV/HCV NAT testing and the potential for an indiscriminate positive result causing issues with allocation for HOPE Act donors
 - This issue is outside of the scope of this proposal
- Discussed vessel labels to make sure there would be an option for “testing not done” so that OPOs would not be required to perform all types of testing listed as an option for the labels

Proposed changes to policy language

- Add a definition for HIV

Next steps:

UNOS staff will take the updated policy language to a meeting of the full OPTN Ad Hoc Disease Transmission Advisory Committee to vote on sending the language to Public Comment this summer.

4. Programming Implications

UNOS staff presented on the potential impact on programming changes and data collection based on the current proposal.

Summary of discussion:

Concerns raised

- The OPTN does not currently collect a date/time for candidate specimens tested pre-transplant, or for recipient specimens tested post-transplant
- The OPTN does not currently collected a time for donor infectious disease testing, only a date

Proposed changes to programming

- Child fields for individual risk factors in UNet where there is currently the parent field asking if a donor has risk factors for HIV, HBV, or HCV as defined by the PHS Guideline
- Update kidney minimum acceptance criteria so it no longer references the outdated PHS Guideline
- Add a parent field for candidate HBV vaccination, as well as ask for a reason why if it was not completed
- Fields for post-transplant HIV/HBV/HCV testing fields for all organ recipients, as this data is currently only collected when donors have risk factors as defined in the 2013 PHS Guideline

Next steps:

UNOS staff will discuss the proposed changes with Data Governance and IT, and incorporate needed changes into the Public Comment document.

5. Public Comment Feedback Questions

Workgroup members discussed key questions to ask for Public Comment feedback.

Proposed questions:

- What is the appropriate length of time to require living donor specimens be stored by recovery hospitals? Why?
- Is HBV vaccination a feasible requirement for transplant candidates? What do you see as the logistical challenges if this were to be a requirement?
- What is the projected impact of removal of informed consent?

Next steps:

UNOS staff will incorporate key questions into the Public Comment document.