

Public Comment Proposal

Update Data Collection to Align with U.S. Public Health Service Guideline, 2020

OPTN Ad Hoc Disease Transmission Advisory Committee

*Prepared by: Abigail Fox, M.P.A.
UNOS Policy and Community Relations Department*

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Public Comment Proposal

Update Data Collection to Align with U.S. Public Health Service Guideline, 2020

Data collection Impacted: DonorNet®, TIEDI DDR
Sponsoring Committee: Ad Hoc Disease Transmission Advisory
Public Comment Period: August 3, 2021 – September 30, 2021

Executive Summary

The 2020 U.S. Public Health Service (PHS) Guideline on “Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection” includes updated risk criteria for acute human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) disease transmission through solid organ transplantation.¹ PHS risk status is collected in UNetSM but there are no discrete fields to show which specific criteria the donor meets: information about the specific risk criteria could be written in several different text fields or added as an attachment to the donor record. Text fields in multiple places in UNetSM make it difficult and labor intensive to analyze trends with donors that meet the risk criteria identified in the 2020 PHS Guideline. The OPTN Ad Hoc Disease Transmission Advisory Committee (DTAC) proposes adding fields to the overall risk question in UNetSM systems DonorNet® and the Transplant Information Electronic Data Interchange® (TIEDI) Deceased Donor Registration (DDR) in order to better track donor risk criteria for HIV, HBV, and HCV.

This proposal aligns with the OPTN strategic goal of promoting transplant recipient safety: by collecting more granular data it will help identify potential impacts on recipient safety through trends in the transplantation of organs from donors with specific risk criteria. Collecting more granular data could inform future iterations of the PHS Guideline, with which OPTN policy must and does align. The 2020 PHS Guideline is “intended to increase the use of organs while continuing to maintain transplant recipient safety.”² If specific risk criteria data collection could help identify criterion that should be removed as risk factors, this could increase organ utilization since organs with risk designation have historically been underutilized.³ Adding fields to collect specific risk criteria will also support efficient donor evaluation because this information will be easier to find and review in DonorNet®. Finally, this proposal enables effective evaluation of the *Align OPTN Policy with the U.S. Public Health Service Guideline, 2020* policy changes approved by the Board of Directors in December 2020.⁴

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

² Ibid.

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

⁴ OPTN Briefing Paper, *Align OPTN Policy with U.S. Public Health Service Guideline*. https://optn.transplant.hrsa.gov/media/4225/bp_202012_align_2020_phs_guideline.pdf

Background

The 2020 PHS Guideline updated risk criteria for acute HIV, HBV, and HCV disease transmission through solid organ transplantation and removed the term “increased risk” for donors with risk criteria, among other changes.⁵ The opioid epidemic led to progressive increase in the proportion of donors labelled as increased risk under the 2013 PHS Guideline.⁶ An analysis performed by the CDC revealed that organs labelled as increased risk were underutilized.⁷ This information underscores the importance of tracking granular data regarding donors with risk criteria for acute HIV, HBV and HCV.

Prior to publication of the 2020 PHS Guideline, a 2018 study of PHS “increased risk” donors demonstrated the difficulty of collecting and analyzing donors with specific risk criteria using data gathered through UNetSM systems.⁸ The study was performed to identify donors based on risk factors for HIV, HBV, and HCV by taking a sample (10% or 290 donors) of all donors identified as “increased risk” in 2018. Sampling was used because of the difficulty of gathering the information from individual text fields (specifically: donor highlight, medical/social history and drug use), none of which are query-able. Analysis required manual review of individual records, which sometimes required interpretation of shorthand or ambiguous notes (e.g. ‘donor abused meth’ is unclear whether meth was injected with needles or not). This ambiguity indicated a limitation of the study in the potential for varying interpretation of records, and demonstrated the difficulty of analyzing information on PHS risk factors in UNetSM. The challenges related to shorthand, ambiguous notes, typos, and other errors made analysis through natural language processing prohibitively difficult as well.

The analysis served several purposes: it provided evidence that the term “increased risk” should be replaced and that specific risk criteria could be eliminated or revised. It also highlighted the need to continue to identify donors based on risk factors for HIV, HBV and HCV to inform the need for recipient testing post-transplant. Finally, the analysis provided evidence that the timeframe for review of risk criteria could be safely shortened to reflect the relevant window period of potentially missed infection. The results of this study informed the recommendations in the 2020 PHS Guideline, but also demonstrated the difficulty of querying the data effectively and the limitations of reviewing risk criteria in UNetSM without collecting the data in discrete fields.

⁵ JM Jones, I Kracalik, ME Levi, et al, “Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020,” *Morbidity and Mortality Weekly Report*, 69, (No. RR-4), June 26, 2020, 1-16, <http://dx.doi.org/10.15585/mmwr.rr6904a1>.

⁶ Ibid.

⁷ WE Abara, MG Collier, A Moorman, et al., “Trends in Deceased Solid Organ Donor Characteristics and Hepatitis B, C, and HIV Screening Results – United States, 2010-2017,” *Morbidity and Mortality Weekly Report*, 68(3), January 25, 2019, 61-66, <http://dx.doi.org/10.15585/mmwr.mm6803a2>.

⁸ M Michaels, “PHS IRD Discussion.” Presentation to U.S. Department of Health and Human Services (HHS) Advisory Committee on Blood and Tissue Safety and Availability (ACBTSA), April 3, 2019

The 2020 PHS Guideline removed the following risk criteria as no longer applicable for assessing potential disease transmission from donors to recipients:

1. Woman who has had sex with a man who has had sex with another man
2. Newly diagnosed or treated syphilis, gonorrhea, chlamydia, or genital ulcers
3. Hemodialysis
4. Hemodiluted blood specimen used for donor HIV, HBV, and HCV testing
5. Child (aged ≤18 months) born to a mother at increased risk for HIV, HBV, or HCV infection
6. Child breastfed by a mother at increased risk for HIV infection

. The remaining and current risk criteria for HIV, HBV or HCV identified in the 2020 PHS Guideline are:

1. Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV, or HCV infection
2. Man who has had sex with another man
3. Sex in exchange for money or drugs
4. Sex with a person who had sex in exchange for money or drugs
5. Drug injection for nonmedical reasons
6. Sex with a person who injected drugs for nonmedical reasons
7. Incarceration (confinement in jail, prison, or juvenile correction facility) for 72 or more consecutive hours
8. Child breastfed by a mother with HIV infection
9. Child born to a mother with HIV, HBV, or HCV infection
10. Unknown medical or social history

In August 2020, the DTAC sponsored a public comment proposal to align OPTN policy with the 2020 PHS Guideline.⁹ The *Align OPTN Policy with U.S. Public Health Service Guideline, 2020* project brought the OPTN into compliance with its requirements in NOTA but did not include collecting individual risk criteria within its scope. However, work on updating the PHS Guideline and aligning OPTN policies highlighted the need for better data collection. The policy evaluation plan of the proposal to align OPTN policies with the 2020 PHS Guideline focused on monitoring by risk status instead of by individual criterion because of the challenges in ascertaining individual risk criterion met in UNetSM.¹⁰ During a February 2021 teleconference, the DTAC affirmed the need to consider more granular data collection in DonorNet® related to HIV, HBV, and HCV risk criteria.¹¹

As a data collection project, the Data Advisory Committee (DAC) was updated on the new project and expressed support for the effort of the DTAC to collect more granular risk criteria data.¹² As the project developed, the DTAC reviewed the DAC Checklist to ensure that collecting the data would be appropriate and in line with OPTN Principles of Data Collection that were approved by the OPTN Board of Directors in December 2006. Through review of the Checklist, the DTAC affirmed in reviewing the

⁹OPTN Public Comment Proposal, *Align OPTN Policy with U.S. Public Health Service Guideline*.
https://optn.transplant.hrsa.gov/media/3933/align_policy_with_phc_guideline_2020_pc.pdf

¹⁰OPTN Briefing Paper, *Align OPTN Policy with U.S. Public Health Service Guideline*.
https://optn.transplant.hrsa.gov/media/4225/bp_202012_align_2020_phc_guideline.pdf

¹¹ OPTN DTAC Meeting Summary, February 22, 2021. Available at
https://optn.transplant.hrsa.gov/media/4511/2021_02_22_dtac-full-cmte_mtg-summary.pdf

¹² OPTN DAC Meeting Summary, March 8, 2021. Available at
https://optn.transplant.hrsa.gov/media/4497/20210308_dac_meeting_summary.pdf

Checklist that collecting the data in discrete fields would be beneficial without producing an undue burden on members, and the change is sufficiently clear and precise.¹³

The proposal aligns with the OPTN Principle of Data Collection to ensure patient safety when no alternative sources of data exist by better tracking trends with specific donor risk criterion, such as the impact of a risk factor becoming more prevalent in the donor population and the associated outcomes for recipients who accepted organs from donors with that particular risk factor.¹⁴ The 2018 PHS study discussed above demonstrates the difficulty of collecting and analyzing donors with specific risk criteria using data gathered through UNetSM systems without available alternative data. Adding the specific risk criteria also supports effective monitoring/review of the project to align OPTN policy with the 2020 PHS Guideline, which is "intended to increase the use of organs while continuing to maintain transplant recipient safety."¹⁵

Purpose

Current data collection on transplant donor risk factors for HIV, HBV and HCV as defined by the 2020 PHS Guideline is not granular. Information about specific risk criteria may be included as part of the medical history upload on the Universal Donor Risk Assessment Index (U-DRAI) and attached via DonorNet®, or added in other text fields in DonorNet®. There is a "yes-no" question regarding whether the donor meets risk criteria in UNetSM, but specific criteria are not collected as discrete fields. Text fields in multiple places in UNetSM make it very difficult and labor intensive to parse out donors with specific risk criteria; this limits the ability to identify trends with specific donor risk criteria.

There is an association identified between candidates declining organs with risk criteria and greater risk of waitlist mortality.¹⁶ Collecting better data on the specific risk criteria that donors meet may help evaluate the connection between risk criterion and risk of transmission, helping to ensure patient safety and informing future iterations of the PHS Guideline and OPTN policy. Addressing this problem also supports effective monitoring/review of the project to align OPTN policy with the 2020 PHS Guideline.¹⁷ The 2020 PHS Guideline is "intended to increase the use of organs while continuing to maintain transplant recipient safety."¹⁸ If specific risk criteria data collection help identify criterion that should be removed as risk factors, this could increase organ utilization since organs with risk designation have

¹³ OPTN DTAC meeting summary, May 24, 2021. Available at https://optn.transplant.hrsa.gov/media/4705/2021_05_24_dtac-full-cmte-mtg-summary.pdf

¹⁴ OPTN DAC Meeting Summary, March 8, 2021. Available at https://optn.transplant.hrsa.gov/media/4497/20210308_dac_meeting_summary.pdf.

¹⁵ OPTN Briefing Paper, *Align OPTN Policy with U.S. Public Health Service Guideline*. https://optn.transplant.hrsa.gov/media/4225/bp_202012_align_2020_phs_guideline.pdf

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

¹⁶ Bowring MG, Holscher CM, Zhou S, et al. Turn down for what? Patient outcomes associated with declining increased infectious risk kidneys. *Am J Transplant* 2018;18:617–24.

Croome KP, Lee DD, Pungpapong S, Keaveny AP, Taner CB. What are the outcomes of declining a Public Health Service increased risk liver donor for patients on the liver transplant waiting list? *Liver Transpl* 2018;24:497–504.

¹⁷ OPTN Briefing Paper, *Align OPTN Policy with U.S. Public Health Service Guideline*.

https://optn.transplant.hrsa.gov/media/4225/bp_202012_align_2020_phs_guideline.pdf

¹⁸ M Jones, I Kracalik, ME Levi, et al, "Assessing Solid Organ Donors and Monitoring Transplant Recipients for Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Infection — U.S. Public Health Service Guideline, 2020," Morbidity and Mortality Weekly Report, 69, (No. RR-4), June 26, 2020, 1-16, <http://dx.doi.org/10.15585/mmwr.rr6904a1>.

historically been underutilized.¹⁹ The proposed changes could also support more efficient donor evaluation as this information is currently difficult to find in DonorNet® and may be unclear or require interpretation.

Overview of Proposal

The DTAC proposes collecting the specific risk criteria defined in the 2020 PHS Guideline for potential HIV, HBV, and HCV transmission in addition to the “overall risk” question present in both DonorNet® and the DDR. The fields would include “yes,” “no,” and “unknown” response options. In order to send out electronic offers, OPOs must currently respond to the “overall risk” question “yes” or “no.” The proposed change would provide a list of fields for the OPO to indicate which specific criteria the donor meets in addition to the “overall risk” question. In order for the “overall risk” question to be “yes” the person answering the questions in DonorNet® would then need to answer “yes” to at least one of the ten risk criteria questions. Any updates to information on specific risk criteria could be added to the DDR since the DonorNet® record is locked (except for cultures or attachments) no more than 5 business days after the procurement date, when the donor organ disposition is to be submitted by.

Inclusion in DonorNet® and the DDR

The DTAC agreed that the new fields should be included in both DonorNet® and the DDR.²⁰ DonorNet® is used for donor evaluation in real time, but the DDR is more commonly used for analysis and monitoring purposes. Committee members agreed that the individual risk criteria need to be displayed in DonorNet®, not just the DDR, so that it’s able to be accessed by transplant programs for real-time donor evaluation. The answers provided in DonorNet® would cascade to the DDR, which could be used for analysis and post-implementation monitoring purposes.

Overall Risk Question

The DTAC reviewed the language of the “overall risk” question, which is currently in both DonorNet® and the DDR: “According to the OPTN policy in effect on the day of referral, does the donor have risk factors for blood-borne diseases transmission.” The question was formulated to be generalized to avoid the need for updating any time the PHS Guideline or OPTN policies changed. The DTAC agreed that the current overall risk question is appropriate and does not need changing. The community is already familiar with the language, and there is no reason for it to change just because the specific risk criteria are being added as new fields.

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

²⁰ OPTN DTAC Meeting Summary, April 26, 2021. Available at https://optn.transplant.hrsa.gov/media/4612/2021_04_26_dtac-full-cmte-mtg-summary.pdf

Pediatric Fields

The DTAC discussed the potential for displaying the pediatric risk criteria, breastfed by a mother with HIV infection and born to a mother with HIV, HBV, or HCV infection, for only pediatric donors.²¹ The OPO representatives on the committee felt that it would be more consistent to include all 10 risk criteria in DonorNet®, and that including the two additional pediatric boxes does not represent a significant difference in level of effort. For clarity and accuracy of data, committee members agreed that “not applicable” should be an option for the two pediatric-specific risk criteria, in addition to the option of “unknown.”

“Unknown” Option

The person entering the data in DonorNet® or the DDR could enter “unknown” if it is not known whether the donor has a specific risk behavior. The DTAC considered whether entering all “unknown” answers should validate (affirm) the overall risk criteria question, but agreed that only “yes” answers should confirm risk factors present for the donor.²² There is already a risk factor specifically for “unknown medical or social history” that can provide an affirmative validation for the overall risk question.

NOTA and Final Rule Analysis

The Committee submits this data collection proposal under the authority of NOTA, which requires the OPTN to collect, analyze, and publish data concerning organ donation and transplants,²³ and the OPTN Final Rule, which requires the OPTN to “(ii) Maintain records of all transplant candidates, all organ donors and all transplant recipients; [and] (iii) Operate, maintain, receive, publish, and transmit such records and information electronically...”²⁴ and requires OPOs and transplant hospitals “as specified from time to time by the Secretary, to submit to the OPTN...information regarding transplantation candidates, transplant recipients, [and] donors of organs...”²⁵ NOTA also requires the OPTN to develop “Criteria, standards, and regulations with respect to organs infected with HIV,”²⁶ and the Final Rule further requires the OPTN to develop “[p]olicies, consistent with recommendations of the Centers for Disease Control and Prevention, for the testing of organ donors and follow-up of transplant recipients to prevent the spread of infectious diseases.”²⁷

This proposal collects specific risk criteria data on both the DDR and in DonorNet® on organ donors, consistent with the recommendations of CDC, identified in the 2020 PHS Guideline as potential indicators of infectious disease, namely, HIV, HBV, and HCV.

This proposal will improve the OPTN’s maintenance of records of organ donors with regard to risk of transmission of infectious disease.

²¹ OPTN DTAC Meeting Summary, April 26, 2021. Available at https://optn.transplant.hrsa.gov/media/4612/2021_04_26_dtac-full-cmte-mtg-summary.pdf

²² Ibid.

²³ 42 U.S.C. §274(b)(2)(I)

²⁴ 42 C.F.R. §121.11(a)(1)(ii)-(iii)

²⁵ 42 C.F.R. §121.11(b)(2)

²⁶ 42 U.S.C. §274f-5

²⁷ 42 C.F.R. §121.4(a)(2)

Implementation Considerations

Member and OPTN Operations

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

OPOs already collect this information but in various spots in DonorNet® and the DDR so collecting this information in discrete fields could provide efficiency for OPOs.

Operations affecting Transplant Hospitals

This proposal is not anticipated to affect the operations of transplant hospitals.

Operations affecting the OPTN

This proposal would require programming changes in UNetSM; specifically, DonorNet® and the Transplant Information Electronic Data Interchange® (TIEDI) Deceased Donor Registration (DDR) form. DonorNet® alignment will include updating the mobile DonorNet® application to display the new fields. This proposal requires the submission of official OPTN data that are not presently collected by the OPTN. The OPTN Contractor has agreed that data collected pursuant to the OPTN's regulatory requirements in §121.11 of the OPTN Final Rule will be collected through OMB approved data collection forms. Therefore, after OPTN Board approval, the forms will be submitted for OMB approval under the Paperwork Reduction Act of 1995. This will require a revision of the OMB-approved data collection instruments, which may impact the implementation timeline.

Projected Fiscal Impact

This proposal is projected to have a fiscal impact on the OPTN but it is not anticipated to have any fiscal impact on organ procurement organizations (OPOs), transplant hospitals, or histocompatibility laboratories. While OPOs will be required to report additional information, there is no anticipated fiscal impact because PHS risk factors are already collected, and reporting this information is not expected to significantly alter existing processes or workflows.

This fiscal analysis is performed by the Fiscal Impact Group (FIG). The purpose of FIG is to gather fiscal impact information to allow the OPTN Board of Directors to consider high level, direct financial implications on OPTN members as part of their decision-making process. FIG members represent transplant programs, OPOs, and histocompatibility laboratories.²⁸

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

²⁸ OPTN Transplant Administrators Committee Meeting Summary. May 26, 2021. Available at https://optn.transplant.hrsa.gov/media/4658/20210526_tac_meeting-summary.pdf

Projected Impact on Organ Procurement Organizations

This proposal is not anticipated to have any fiscal impact on OPOs. OPOs are collecting this information already so should not impact workflows or add burden; can also update records in DDR later.

Projected Impact on Transplant Hospitals

This proposal is not anticipated to have any fiscal impact on transplant hospitals.

Projected Impact on the OPTN

This proposal would require a medium size effort to implement programming changes. Additional hours relate to monitoring, compliance, and communication to members.

Post-implementation Monitoring

Member Compliance

At OPOs, site surveyors will review a sample of deceased donor records to verify that the OPO has accurately reported any identified risk criteria for acute HIV, HBV, or HCV infection according to the 2020 PHS Guideline in UNetSM.

Policy Evaluation

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

The following questions, and any others subsequently requested by the Committee, will guide the evaluation of the proposal after implementation. These questions address the success of the proposal by better tracking donor risk criteria trends that may impact recipient safety and supporting a replete evaluation of the policies implemented in alignment with the 2020 PHS Guideline:

- Has the number/proportion of deceased donors with risk factors for HIV, HBV, and HCV changed?
- What proportion of deceased donors with risk factors for HIV, HBV, and HCV fall within each of the risk criteria?
Have organ utilization rates for deceased donors with risk factors for HIV, HBV and HCV changed?

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

- The number/percent of deceased donors with risk factors for HIV, HBV and HCV, overall and by organ (pre- vs post-implementation).
- The number/percent of deceased donors with risk factors for HIV, HBV and HCV meeting each individual risk criteria, overall and by organ (post-implementation only).
- Organ utilization rates for deceased donors with risk factors for HIV, HBV and HCV by organ (pre- vs post-implementation).

Conclusion

Lack of discrete data fields in UNetSM impacts the ability to assess specific HIV, HBV and HCV risk criteria for potential transmission to transplant recipients and leads to inefficiency in donor evaluation. The DTAC proposes adding fields to the “overall risk” question in DonorNet® and DDR to collect better data on risk criteria for potential disease transmission of acute HIV, HBV and HCV for donor assessment and analysis of the impact of the risk criteria.

Appendix A: Proposed Data Fields

DonorNet® addition

ADD: individual risk criteria as fields to “overall risk” question

- Options for “yes,” “no,” and “unknown,” for all risk criteria; “not applicable” for two pediatric risk criteria
- Fields use text of 10 risk criteria (see page 4-5 of the proposal)

DDR addition

ADD: individual risk criteria as fields to “overall risk” question

- Options for “yes,” “no,” and “unknown,” for all risk criteria; “not applicable” for two pediatric risk criteria
- Fields use text of 10 risk criteria (see page 4-5 of the proposal)