

*Briefing to the OPTN Board of Directors on*

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

*OPTN Ad Hoc Disease Transmission Advisory Committee*

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# 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 – Sept 30, 2021  
*Board of Directors Meeting:* December 6, 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.<sup>1</sup> PHS risk status is collected in UNet<sup>SM</sup> but there are no discrete fields to show which specific criteria the donor meets. Information about the specific risk criteria may be written in several different text fields or added as an attachment to the donor record. Text fields in multiple places in UNet<sup>SM</sup> 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 the UNet<sup>SM</sup> 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 that meet specific risk criteria. 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 (Board) in December 2020.<sup>2</sup> Collecting more granular data could inform future iterations of the PHS Guideline. The 2020 PHS Guideline is “intended to increase the use of organs while continuing to maintain transplant recipient safety.”<sup>3</sup> 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.<sup>4</sup> 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®.

<sup>1</sup> 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>.

<sup>2</sup> 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](https://optn.transplant.hrsa.gov/media/4225/bp_202012_align_2020_phs_guideline.pdf)

<sup>3</sup> *Ibid.*

<sup>4</sup> 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>.

## 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<sup>®</sup>, or added in other text fields in DonorNet<sup>®</sup>. There is a “yes-no” question regarding whether the donor meets risk criteria in UNet<sup>SM</sup>, but specific criteria are not collected as discrete fields (see pages 4-5 for the current risk criteria). Text fields in multiple places in UNet<sup>SM</sup> 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.<sup>5</sup> 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.<sup>6</sup> The 2020 PHS Guideline is “intended to increase the use of organs while continuing to maintain transplant recipient safety.”<sup>7</sup> 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 historically been underutilized.<sup>8</sup> The proposed changes could also support more efficient donor evaluation as this information is currently difficult to find in DonorNet<sup>®</sup> and may be unclear or require interpretation.

## 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.<sup>9</sup> The opioid epidemic led to progressive increase in the proportion of donors labelled as increased risk under the 2013 PHS Guideline.<sup>10</sup> Different analyses including one performed by the CDC revealed that organs labelled as increased risk were underutilized.<sup>11</sup> This information underscores the importance of tracking granular data regarding donors with risk criteria for acute HIV, HBV and HCV.

<sup>5</sup> MG Bowring, CM Holscher, S Zhou, et al. Turn down for what? Patient outcomes associated with declining increased infectious risk kidneys. *Am J Transplant* 2018;18:617–24; KP Croome, DD Lee, S Pungpapong, AP Keaveny, CB Taner. 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.

<sup>6</sup> 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](https://optn.transplant.hrsa.gov/media/4225/bp_202012_align_2020_phs_guideline.pdf).

<sup>7</sup> 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>.

<sup>8</sup> 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>.

<sup>9</sup> 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>.

<sup>10</sup> Ibid.

<sup>11</sup> WE Abara, MG Collier, A Moorman, et al., “Trends in Deceased Solid Organ Donor Characteristics and Hepatitis B, C, and HIV

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 UNet<sup>SM</sup> systems.<sup>12</sup> The study was performed to identify donors based on risk factors for HIV, HBV, and HCV by taking a sample (10% or 290) 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). Analysis required manual review of individual records, which sometimes required interpretation of shorthand or ambiguous notes (e.g. ‘donor abused meth’ is unclear whether methamphetamine 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 UNet<sup>SM</sup>. 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 UNet<sup>SM</sup> without collecting the data in discrete fields.

The 2020 PHS Guideline removed the following risk criteria as no longer applicable for assessing potential HIV, HBV and HCV 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

Another change with the 2020 PHS Guideline and OPTN policy is that donors are evaluated for risk within the previous 30 days instead of the year prior to organ procurement. The remaining and current risk criteria identified in the 2020 PHS Guideline are below. It is important to note that a donor is identified as having risk for HIV, HBV and HCV if at least one criterion is met, but donors may meet multiple criteria.

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

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>; ML Volk, AR Wilk, C Wolfe, DR Kaul, “The “PHS Increased Risk” Label is Associated with Nonutilization of Hundreds of Organs per Year.” *Transplantation*, 101(7), July 2017, 1666-1669.

<sup>12</sup> 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

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.<sup>13</sup> 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 UNet<sup>SM</sup>.<sup>14</sup> During a February 2021 teleconference, the DTAC affirmed the need to consider more granular data collection in DonorNet<sup>®</sup> related to HIV, HBV, and HCV risk criteria.<sup>15</sup>

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.<sup>16</sup> The DTAC reviewed the Data Element Standard of Review 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. The DTAC affirmed in reviewing the 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.<sup>17</sup>

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.<sup>18</sup> The 2018 PHS study discussed above demonstrates the difficulty of collecting and analyzing donors with specific risk criteria using data gathered through UNet<sup>SM</sup> 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."<sup>19</sup>

<sup>13</sup>OPTN Public Comment Proposal, *Align OPTN Policy with U.S. Public Health Service Guideline*.

[https://optn.transplant.hrsa.gov/media/3933/align\\_policy\\_with\\_phs\\_guideline\\_2020\\_pc.pdf](https://optn.transplant.hrsa.gov/media/3933/align_policy_with_phs_guideline_2020_pc.pdf)

<sup>14</sup>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](https://optn.transplant.hrsa.gov/media/4225/bp_202012_align_2020_phs_guideline.pdf)

<sup>15</sup> 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](https://optn.transplant.hrsa.gov/media/4511/2021_02_22_dtac-full-cmte_mtg-summary.pdf)

<sup>16</sup> OPTN DAC Meeting Summary, March 8, 2021. Available at

[https://optn.transplant.hrsa.gov/media/4497/20210308\\_dac\\_meeting\\_summary.pdf](https://optn.transplant.hrsa.gov/media/4497/20210308_dac_meeting_summary.pdf)

<sup>17</sup> 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](https://optn.transplant.hrsa.gov/media/4705/2021_05_24_dtac-full-cmte-mtg-summary.pdf)

<sup>18</sup> OPTN DAC Meeting Summary, March 8, 2021. Available at

[https://optn.transplant.hrsa.gov/media/4497/20210308\\_dac\\_meeting\\_summary.pdf](https://optn.transplant.hrsa.gov/media/4497/20210308_dac_meeting_summary.pdf)

<sup>19</sup> 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](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>.

## Proposal for Board Consideration

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<sup>®</sup> (including the mobile application) and the DDR in TIEDI. The fields would include “yes” and “no” response options for all ten risk criteria, and additionally “not applicable” for the two pediatric criteria. In order to send out electronic offers, OPOs must currently respond whether the donor meets 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<sup>®</sup> 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<sup>®</sup> record is locked (except for cultures or attachments) no more than 5 business days after the procurement date, in accordance with the policy-required timeframe for organ disposition submission.

The DTAC concluded from public comment feedback and the general support received that sending the proposal to the Board with minimal changes would be appropriate.<sup>20</sup> The only change to the proposal was in response to OPO Committee feedback and removes the “unknown” response option, leaving only “yes,” “no” and “not applicable” (for pediatric risk criteria) as potential responses for specific risk criteria. The justification for that change is described in the following section.

### “Unknown” Option

In response to public comment feedback, the DTAC removed “unknown” as a response option, leaving only “yes,” “no” and “not applicable” (for pediatric risk criteria) as potential responses for specific risk criteria. One of the ten risk criterion is itself “unknown medical or social history” of the donor, which can still be utilized if information on the donor’s history is lacking. This project seeks better alignment with the U-DRAI, integration with EMRs (electronic medical records), increased efficiency and system integration. Keeping the “unknown” option could negatively impact that alignment because this is not how OPOs conduct donor screening currently using the U-DRAI, which requires “yes” or “no” and does not include “unknown” as an option. Having “unknown” as a response option for each of the risk criteria could cause unnecessary and painful follow up questions with the donor family member to clarify risk because of the misalignment with the U-DRAI. The OPTN OPO Committee emphasized in its review of this proposal the importance of collecting this data as simply as possible and noted the potential conflict with the U-DRAI.

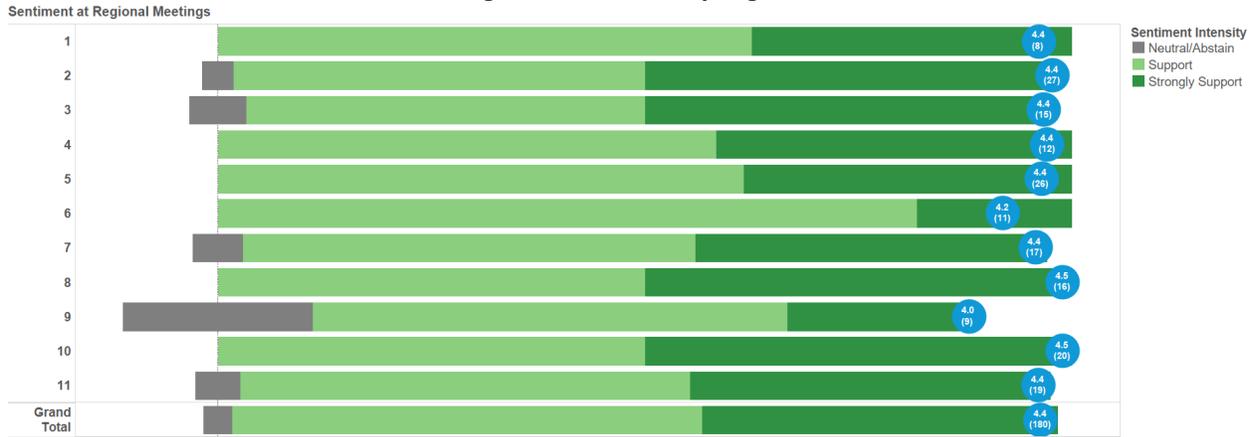
## Overall Sentiment from Public Comment

No individual or organization expressed opposition to this proposal. The proposal was supported by all 11 regions, six societies (ANNA, AOPO, ASHI, ASTS, AST, NATCO) and three OPTN committees (OPO, Transplant Administrators, Data Advisory) that reviewed the proposal. There were no concerns or suggestions for modifications from the public. Figures 2 and 3 summarize public comment feedback by region and member type, demonstrating the widespread support the proposal enjoyed across the country and by different type of OPTN member.

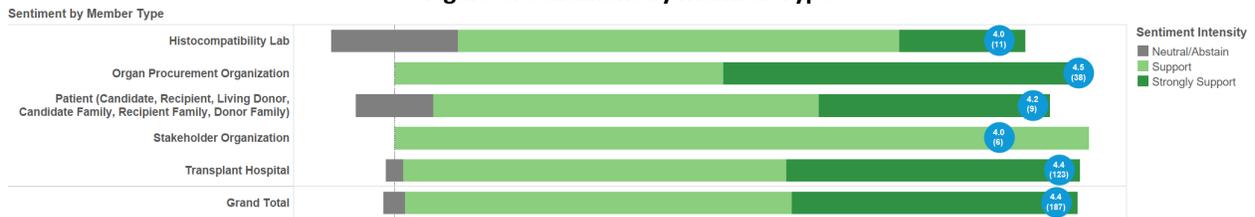
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<sup>20</sup> OPTN DTAC meeting summary, September 28, 2021. OPTN DTAC meeting summary, October 5, 2021.

**Figure 2: Sentiment by Region**



**Figure 3: Sentiment by Member Type**



Below is a summary of public comment feedback and a review of DTAC’s responses.

Public comment feedback highlighted that the proposed changes were straightforward (Transplant Administrators Committee) and avoid discrepancies and duplication of effort (Data Advisory Committee). NATCO and ASTS highlighted that this proposal supports better tracking of data and analysis of trends. ASHI and AOPO highlighted that this proposal should increase efficiency and standardize documentation. Several comments also discussed the benefit of a better safety net helping organs be used for the best recipient, and the potential benefit of efficiency on organ utilization.

The OPO Committee supported the effort to better collect this data, noting that it could provide significant value. The OPO Committee recommended having the risk criteria response options mirror those in the U-DRAI donor risk assessment interview, which allow only “yes” or “no” responses. The OPO Committee’s feedback on the seamless integration with the U-DRAI was reviewed and considered by the DTAC, which agreed to remove the “unknown” option to encourage consistency with the U-DRAI and better integration with EMRs (see Proposal for Board Consideration – Unknown Option section, above). This would provide added efficiency, while still accomplishing the benefit of adding context to the donor’s potential risk for HIV, HBV or HCV.

There was one comment that more generally considered the impact of the *Align OPTN Policy with the U.S. Public Health Service Guideline, 2020* policy that was passed by the OPTN Board in December 2020. The comment expressed concern about blood volume requirements for pediatric patients and the potential financial burden associated with the effort to align OPTN policy with the 2020 PHS Guideline. The DTAC considered in its review that this comment was out of scope of the current proposal, but

noted that the pediatric blood volume issue is being addressed in a joint project with the OPTN Pediatric Committee that will result in a proposal for January 2022 public comment.

## Compliance Analysis

### NOTA and OPTN Final Rule

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,<sup>21</sup> 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...”<sup>22</sup> 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...”<sup>23</sup> NOTA also requires the OPTN to develop “Criteria, standards, and regulations with respect to organs infected with HIV,”<sup>24</sup> 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.”<sup>25</sup>

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.

### OPTN Strategic Plan

1. *Increase the number of transplants:* 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.<sup>26</sup> 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® and the DonorNet® mobile application. Efficient donor evaluation supports more efficient organ placement which then supports utilization efforts. This data collection also 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.<sup>27</sup>

<sup>21</sup> 42 U.S.C. §274(b)(2)(I)

<sup>22</sup> 42 C.F.R. §121.11(a)(1)(ii)-(iii)

<sup>23</sup> 42 C.F.R. §121.11(b)(2)

<sup>24</sup> 42 U.S.C. §274f-5

<sup>25</sup> 42 C.F.R. §121.4(a)(2)

<sup>26</sup> 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>.

<sup>27</sup> 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](https://optn.transplant.hrsa.gov/media/4225/bp_202012_align_2020_phs_guideline.pdf)

2. *Promote living donor and transplant recipient safety:* By collecting more granular data this proposal will help identify potential impacts on recipient safety through trends in the transplantation of organs from donors that meet 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."<sup>28</sup>

## 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 will use discrete data fields to report specific risk criteria. OPOs already collect the information as part of the donor assessment.

#### *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 UNet<sup>SM</sup>; specifically, DonorNet<sup>®</sup> and the Transplant Information Electronic Data Interchange<sup>®</sup> (TIEDI) Deceased Donor Registration (DDR) form. DonorNet<sup>®</sup> alignment will include updating the mobile DonorNet<sup>®</sup> 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.

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.<sup>29</sup>

<sup>28</sup> Ibid.

<sup>29</sup> OPTN Transplant Administrators Committee Meeting Summary. May 26, 2021. Available at [https://optn.transplant.hrsa.gov/media/4658/20210526\\_tac\\_meeting-summary.pdf](https://optn.transplant.hrsa.gov/media/4658/20210526_tac_meeting-summary.pdf)

## *Projected Impact on Histocompatibility Laboratories*

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

## *Projected Impact on Organ Procurement Organizations*

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.

## *Projected Impact on Transplant Hospitals*

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

## *Projected Impact on the OPTN*

Policy and Community Relations (PCR) and Information Technology (IT) staff supported a joint effort to propose creating 10 individual risk data elements in DonorNet® and the TIEDI DDR to align with the 2020 Public Health Service (PHS) Guidelines. The proposal supports adding these data elements to better track donor risk criteria for human immunodeficiency virus (HIV), hepatitis B virus (HBV), and hepatitis C virus (HCV) transmission.

A large IT implementation effort, estimated at 896 hours, will be required in order to provide a standardized field for real time donor evaluation, as well as provide discrete data for donor analysis and future evaluation of the PHS guideline. Research does not anticipate any significant implementation hours necessary for this project beyond the time needed to prepare and present a 1-year post-implementation monitoring report.

No one department will require greater than 40 ongoing hours to continue to support this project, with an estimated total of 90 ongoing hours between all departments.

## **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 UNet<sup>SM</sup>.

### **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 UNet<sup>SM</sup> 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<sup>®</sup> 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.

## Proposed Data Fields

1 **DonorNet® addition**

2

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

4 - Options for “yes” and “no,” for all risk criteria; “not applicable” for two pediatric risk  
5 criteria

6 - Fields use text of 10 risk criteria:

7 1. Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a  
8 person known or suspected to have HIV, HBV, or HCV infection

9 2. Man who has had sex with another man

10 3. Sex in exchange for money or drugs

11 4. Sex with a person who had sex in exchange for money or drugs

12 5. Drug injection for nonmedical reasons

13 6. Sex with a person who injected drugs for nonmedical reasons

14 7. Incarceration (confinement in jail, prison, or juvenile correction facility) for 72 or  
15 more consecutive hours

16 8. Child breastfed by a mother with HIV infection

17 9. Child born to a mother with HIV, HBV, or HCV infection

18 10. Unknown medical or social history

19 -

20 **DDR addition**

21

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

23 - Options for “yes” and “no” for all risk criteria; “not applicable” for two pediatric risk  
24 criteria

25 - Fields use text of 10 risk criteria (see list above)

26

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