

*OPTN/UNOS Ad Hoc Disease Transmission Advisory Committee*

# Improving Post-Transplant Communication of New Donor Information

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# Improving Post-Transplant Communication of New Donor Information

## Executive Summary

The Ad Hoc Disease Transmission Advisory Committee (DTAC) has been reviewing cases of potential donor-derived transmission events since 2006 to learn and the share lessons learned behind these transmissions and recommend processes to prevent unnecessary transmissions.

Communication delays or failures regarding new donor information learned post-transplant have led to transplant recipient morbidity and mortality. A statistically significant association between having a proven or probable donor-derived transmission event and the presence or absence of a communication gap was documented in a recent 2015 published article<sup>1</sup>.

Policy implemented in 2011 established reporting guidelines and patient safety contacts. Reporting behaviors since that implementation have demonstrated an increase in reporting, yet wide variation in reporting practices. Data analyzed suggest that some of these reporting behaviors have not led to overall system improvements.

Current policy requires OPOs to report results received post-transplant. However, OPO interpretations of what results must be reported to transplant hospital patient safety contacts and the OPTN vary greatly. An unintended consequence has been a shift away from focusing on recipient disease reports and spending more time on donor cultures with wide variations in types of disease reporting and, in some areas, over-reporting of results with little benefit to the system goal. Over-reporting may lead to reporting fatigue or desensitization, thus taking away from the critical and important intent of the system. Communication delays or failures in the current process can also lead to negative consequences for patients.

This proposal adds clarity and essential details to the current reporting policy. Specifying what conditions must be reported and how they must be reported should add more reliability and consistency to the process. This proposed policy will aim to reduce unnecessary reporting to both the OPTN and transplant hospital patient safety contacts. By triaging reporting requirements, fatigue from over-reporting should be reduced and help focus time and energy on reporting and following relevant and critical results.

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<sup>1</sup> R Miller et al, "Communication Gaps Associated with Donor-Derived Infections," *American Journal of Transplantation* 15 (2015): 259-264.

# Improving Post-Transplant Communication of New Donor Information

*Affected Policies:* Policies 2.9 Required Deceased Donor Infectious Disease Testing, 2.11.C Required Information for Deceased Heart Donors, 2.13 Post Procurement Follow Up and Reporting, 15.4 Reporting of Potential and Proven Disease Transmissions, 15.5 Requirements for Post-Transplant Discovery of Donor Disease or Malignancy, 15.6 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors

*Sponsoring Committee:* Ad Hoc Disease Transmission Advisory Committee

*Public Comment Period:* January 25, 2016 – March 25, 2016

## What problem will this proposal solve?

Careful review of potential donor-derived disease transmission events (PDDTE) by both the Ad Hoc Disease Transmission Advisory Committee (DTAC) and UNOS staff have highlighted instances in which communication delays or failures regarding new donor information learned post-transplant led to transplant recipient morbidity or mortality. A recent 2015 published article documented a significant association with communication gaps and donor-derived transmission events. It found both a higher chance of an event when communication gaps were present as well as a reduced chance of an event with effective communication of results<sup>2</sup>.

DTAC has been reviewing PDDTE since 2006 with the aim of improving the reporting system and reducing preventable transmissions. Each case is reviewed and classified according to **Table 1** below.

**Table 1: PDDTE Classifications and Definitions**

Classification	Definition
Proven	Donor plus one recipient
Probable	One or more recipients with suggestive data
Possible	Evidence to suggest but not prove transmission
Intervention without Documented Transmission (IWDT)	No transmission because antimicrobials were used (or for RCC, affected KI discarded or tumor excised)
Unlikely	Limited evidence to suggest transmission could have occurred, but no transmission documented
Excluded	No evidence of transmission

*Modified from Ison et al. Am J Transplant. 2009; 9: 1929-1935.*

In 2011, revised policy added reporting requirements and a requirement to have a 24/7 patient safety contact to handle reports (Policy 15.1: *Patient Safety Contact*). Data between 2011 and 2015 as shown in Table 3 (page 11) show significant increases in reporting since that change, yet some of the increased reporting has not led to gains in prevention as evidenced by a significant number of reports not reviewed

<sup>2</sup> R Miller et al, 259.

by DTAC. The manpower required by OPOs, transplant hospitals, and UNOS staff to report and follow-up as is occurring currently may not be the best use of limited resources. In addition, reporting practices vary greatly by region and Donation Service Area (DSA).

Reports from transplant patient safety contacts indicate that significant time and energy are being spent on reports that are known not to have an impact on recipients or transplant community knowledge. This may be causing reporting fatigue or desensitization, thus taking away from the focus on reporting and following relevant results.

DTAC believes that part of these issues are due to varying interpretation of current policy. This proposal will refocus efforts on reporting and investigating cases that are most likely to be donor-derived transmission events and improve the process to better outcomes for all recipients. Revamping the policy will provide an opportunity for OPOs and transplant hospitals to re-examine and update protocols, highlight effective practices, and provide training and education as recommended by quality improvement efforts.

## Why should you support this proposal?

This proposal seeks to improve communication regarding new information critical to recipient care, enhance recipient safety, and help to prevent or quickly treat donor-derived disease transmission. The proposal provides greater specifics for what test results must be reported to transplant hospital patient safety contacts and the OPTN to improve reporting of relevant test results and reduce unnecessary reporting.

The issues targeted in the proposal are based on multiple years of Committee experience, OPTN data analysis, and peer-reviewed published literature. The recommendations for policy change and other actions resulted from a Failure Modes and Effects Analysis (FMEA). FMEA is a widely accepted methodology used to improve process. The efforts to develop this proposal involved multiple committees including the Organ Procurement Organization (OPO), Transplant Administrators (TAC), and Transplant Coordinators (TCC) Committees, as well as other external stakeholders including the Association of Organ Procurement Organizations (AOPO).

This proposal will provide much needed guidance to OPOs regarding reporting. OPOs will need to report specified positive results to recipient transplant program patient safety contacts and/or the OPTN IPS. The Centers for Disease Control and Prevention (CDC) and DTAC collaborated to develop a list of special pathogens that will be maintained and provided outside of policy (**see Appendix A**). This list is similar to the CDC nationally notifiable list<sup>3</sup> but is tailored to be relevant to transplant. When donors are found to have evidence or suspicion of these diseases both the OPTN and transplant patient safety contacts will be notified. The CDC also reviews all incoming reports. This allows the OPTN to involve the CDC who in turn can provide medical guidance as appropriate to help prevent recipient disease. The OPTN will continue to receive reports on diagnoses or findings highly suggestive of malignancy. Other **positive** relevant results as specified in the proposed policy will be reported only to the transplant hospital patient safety contact. By specifying results that must be reported and triaging them to the appropriate parties, OPOs will have a more structured and standardized guidelines for reporting thus reducing the reporting of results that are not relevant to a particular centers recipient.

The proposal also addresses an emerging issue with toxoplasmosis infections that have been found to negatively impact non-thoracic recipients. Under the current policy, toxoplasmosis results are often not obtained and communicated to all programs. The new proposed requirement will help address an identified communication gap and reduce potential morbidity and mortality in recipients.

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<sup>3</sup> <https://wwwn.cdc.gov/nndss/conditions/notifiable/2016/>

Although much of the policy language changes are directed to OPO reporting, the Committee wants to stress that; overall, these changes will put the priority on reporting and following sick recipients as the system should focus on recipient disease not donor culture results. Transplant hospitals currently have, and will continue to have, requirements to report sick recipients for whom donor-derived disease is suspected. Living donor recovery hospitals currently have, and will continue to have, responsibility to report living donor findings that could result in donor-derived transmissions, such as post-recovery conditions and malignancies. The Committee urges all transplant hospitals and living donor recovery hospitals to review and, if needed, amend their reporting policies and protocols to identify and report possible donor-derived disease transmissions. The OPTN is fortunate to have the assistance of the CDC and DTAC to promote optimal recipient outcomes through timely and conscientious reporting.

### How was this proposal developed?

Potential donor-derived disease transmission events sometimes occur due to inadequate communication of donor information between OPO and transplant centers. These communication failures continue to pose patient safety risks. Policy to standardize the process for OPOs to communicate with transplant hospitals has helped, but still needs greater clarity. Delays in communicating post-transplant donor testing information can result in delays in detecting and treating potential recipient symptoms.

A joint DTAC-OPO effort was launched to build consensus on a plan to address these concerns. In January 2014, it was determined that an FMEA was needed to map out the process used by OPOs receiving post-transplant information and the pathway for communicating this information to transplant centers. Failure Modes and Effects Analysis (FMEA) is a risk assessment technique to identify and rank potential target steps in the process needing improvement. The FMEA exercise is used in many industries such as aerospace and aviation as well as health care to identify areas of risk. Healthcare FMEA as a quality improvement process has been found to be a valid tool for proactive analysis in hospitals as it facilitates a very thorough analysis of vulnerabilities (i.e., failure modes) before adverse events occur. It has been established as a tool valuable for identifying the multifactorial nature of most errors and the potential risk for errors although time-consuming. The process has also been found to minimize group biases by using multidisciplinary teams and to promote teamwork through the systematic step-by-step process used to complete the FMEA.<sup>4</sup> The FMEA process would highlight potential failure points throughout the process and provide evidence for policy development meant to enhance patient safety.

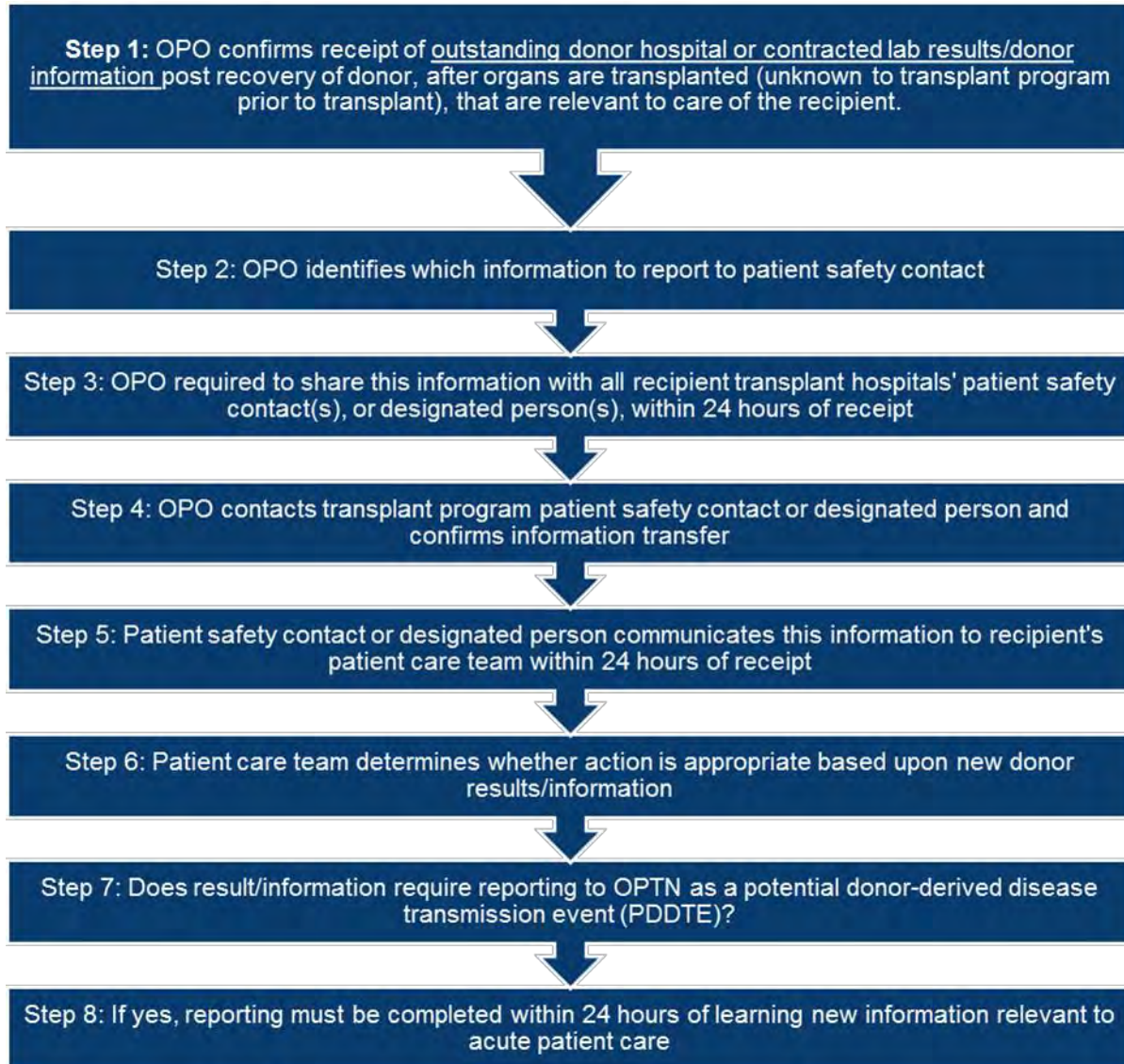
The FMEA was conducted with representatives from the DTAC, OPO, TCC, and TAC to identify latent patient safety risks associated with how new donor information received post-transplant is reported to recipient transplant centers. The FMEA was facilitated by a human factors and quality improvement expert.

Committee members participated in a series of sessions to conduct the FMEA. A process map consisting of eight major steps was developed (See **Figure 1**). It started with the OPO confirming receipt of outstanding donor hospital or contracted lab results or donor information obtained post recovery after donor organs were transplanted (Step 1) and ended at completing the Potential Donor Derived Transmission Event (PDDTE) report to the OPTN within 24 hours (Step 8). The process map was reviewed and developed through consensus with representation from OPOs and transplant hospitals.

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<sup>4</sup> Ronda G. Hughes "Tools and Strategies for Quality Improvement and Patient Safety" in: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 44. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK2682/>

**Figure 1: PDDTE FMEA Process Map**



Reviewing the process map and reflecting on their individual organizational specific work processes, DTAC members identified 28 potential failure modes across all process steps. Each failure mode was prioritized by aggregating members' rankings of severity to patient safety, likelihood of occurring, and ability of current controls (e.g. standardized protocols for communicating PDDTE information) to detect and mitigate risk for each failure mode. Finally, a structured communication process known as the Delphi<sup>5</sup> approach was used to review risk priority ratings, discuss outliers, and come to a final risk priority ranking for all failure modes. Recommendations were developed for addressing and mitigating the 16 highest priority failure modes.

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<sup>5</sup>Southard, Peter; Kumar, Sameer; and Southard, Cheryl A., "A Modified Delphi Methodology to Conduct an Failure Modes Effects Analysis: a Patient-centric Effort in a Clinical Medical Laboratory" (2011). Operations and Supply Chain Management Faculty Publications. Paper 1. <http://ir.stthomas.edu/ocbopmtpub/1>.

Seventeen recommendations were identified to mitigate the highest priority failure modes. Recommendations included a range of approaches such as revising current policy and employing resilient strategies to allow individual organizations to identify their own protocols. Given the wide variability in OPO and transplant processes for communicating and processing donor information post-transplant, it was recommended that considerable attention and resources be directed at guidance and training. The guidance and training would be focused on enabling individual organizations to apply quality improvement and human factors methods to improve their own system of care processes and ensure high reliability levels of patient safety. The guidance and education will be incorporated into the policy implementation plan. The Committee is also working with OPO and transplant program stakeholders to identify and disseminate effective practices.

The FMEA results also guided this proposal and helped to focus on improving communication issues. **Table 2** below summarizes the FMEA identified fail points and recommendations. The recommendations that are addressed through this policy proposal are noted in bold. Those in italics are being addressed through non-policy education efforts or the pilot being developed by the UNOS Customer Council to improve reporting through DonorNet®.

**Table 2: PDDTE FMEA Failure Modes, Rankings, and Recommended Actions**

Process Step/ Failure Mode	Priority Score	Priority Rank	Recommended Action(s)
1d. OPO does not get all of the valid information	448	11	<ul style="list-style-type: none"> <li>● <b>OPOs must develop a protocol for tracking and collecting all pending results</b></li> <li>● <b>OPOs must post information to DonorNet® for transplant center review</b></li> <li>● <i>Conduct review of best practices and disseminate</i></li> </ul>
1e. OPO does not follow up on all labs (e.g. pending cultures, donor hospital cultures drawn prior to OPO assuming care of the donor)	464	10	<ul style="list-style-type: none"> <li>● See 1d above</li> </ul>
2a. Incomplete information is reported	448	11	<ul style="list-style-type: none"> <li>● <b>Develop decision support tool to triage information reporting</b></li> <li>● Ensure staff making decisions to send information have adequate expertise and training.</li> <li>● <b>Post negatives to DonorNet® and then call positives using "on call" features within DonorNet®. Features allow for email or text rather than phone.</b></li> </ul>
2b. OPO fails to appropriately identify information to report to patient safety contact	296	19	<ul style="list-style-type: none"> <li>● See 2a above</li> </ul>
3a. Failure to notify all recipient centers when multiple organ donor	448	11	<ul style="list-style-type: none"> <li>● <i>On call coordinator or other suitable role should be assigned as a backup if the PSC cannot be reached. This may be the local OPO for imports.</i></li> <li>● <i>Have updated information readily available on transplant center website listing all recipient centers</i></li> </ul>
3c. Fail to get in contact with PSC or PSC not available	504	4	<ul style="list-style-type: none"> <li>● <i>Develop checklist tool to confirm attempts to contact PSC</i></li> <li>● <i>Ensure multiple contact points for PSC (See 3a above)</i></li> </ul>
4a. Delay in information reaching patient safety contact	576	3	<ul style="list-style-type: none"> <li>● <b>Require OPOs to have a protocol</b></li> </ul>
4b. Failure to confirm information transfer	432	15	<ul style="list-style-type: none"> <li>● See 4a above</li> </ul>
5a. Delay in information reaching patient care team in a timely manner	504	4	<ul style="list-style-type: none"> <li>● <i>Require programs to have a plan/protocol for how the PSC will address this as an option for addressing this issue.</i></li> </ul>

Process Step/ Failure Mode	Priority Score	Priority Rank	Recommended Action(s)
5b. PSC not able to communicate within 24 hours of receipt	504	4	<ul style="list-style-type: none"> <li>● See 5a above</li> </ul>
5c. Incomplete or missing lab results information	504	4	<ul style="list-style-type: none"> <li>● <i>Training could be included within guidance on who is most appropriate to retrieve and communicate this information as part of a TX center's plan</i></li> </ul>
5d. PSC does not retrieve information in a timely manner from when they have been delivered through fax, email, or other means.	441	14	<ul style="list-style-type: none"> <li>● <i>Provide education through guidance document to share best practice</i></li> <li>● <i>Develop protocol to standardize handoff of information</i></li> </ul>
6c. Appropriate staff members are not notified.	486	9	<ul style="list-style-type: none"> <li>● <i>Education on best practices</i></li> <li>● <i>Cover in policy-mandated plan</i></li> </ul>
7b. Failure to report potential donor-derived disease transmission event (PDDTE) from transplant hospital	504	4	<ul style="list-style-type: none"> <li>● <b>Ongoing educational effort to optimize reporting and minimize burden to members (reducing potential over reporting) (Note: Will be done as part of policy implementation)</b></li> </ul>

The DTAC has presented several ideas to stakeholders to help address the identified issues. Some of the ideas that are contained within this proposal were presented to AOPO and OPO leadership to obtain stakeholder feedback. Feedback on the ideas presented included:

- 1.) Stratify OPO to transplant hospital communication by urgency of results learned post-procurement
  - All information should be easily available to all accepting centers
  - Urgent information requires higher level of communication
- 2.) Clarify policy language regarding reporting to DTAC via patient safety portal
  - Focus on recipient disease
  - Clarify specific items to be reported for donor
- 3.) Remove broad language in Policy 2.13.A that currently reads:

“The host OPO must report to the OPTN Contractor’s Patient Safety Portal any new disease or malignancy in the deceased donor that may be transmitted to transplant recipients.”

  - This is expected to reduce OPO or transplant hospital burden related to unnecessary reporting or “noise” that may desensitize members receiving this information
- 4.) Create a table to provide direction on “triaging” testing/culture follow up to transplant hospitals, including:
  - When it is necessary to communicate with the Patient Safety Contact for specific positive results as listed
  - When should positive donor results should be reported to the OPTN Improving Patient Safety Portal (IPS) if there are no recipients showing signs of potential transmission

In addition to the FMEA, the DTAC reviewed historical reporting trends and gathered feedback from important stakeholders to develop the proposal requirements.



## How well does this proposal address the problem statement?

OPTN/UNOS policy and the DTAC PDDTE review exist to prevent unnecessary transmissions from donor organs and to minimize morbidity and mortality when transmissions do occur. A 2015 article documented some of the issues surrounding PDDTE. The findings acknowledge challenges inherent in this task: “The detection and management of potential donor derived infections is challenging, in part due to complexity in communications among diverse labs, OPOs, and recipient transplant hospitals.” This research conducted an analysis of communication delays or errors occurring in the reporting and management of donor-derived infections to determine if they were associated with preventable adverse events in recipients. “All reported potential donor-derived transmission events reviewed by DTAC from January 2008 to June 2010 were evaluated for communication gaps between the donor center, OPO and transplant centers. The impact on recipient outcomes was then determined. Fifty-six infection events (IEs) involving 168 recipients were evaluated. Eighteen IEs involving 48 recipients were associated with communication gaps. Twelve of these resulted in adverse effects in 69% of recipients (20/29), including six deaths. When IEs and test results were reported without delay, then appropriate interventions were taken, subsequently minimizing or averting recipient infection for 23 IEs involving 72 recipients.”<sup>6</sup>

The research found:

...a significant association between having a proven/probable transmission or not, and the presence or absence of a communication gap present ( $\chi^2_{2/1} = 13.13, p = 0.0003$ ). The odds of a communication gap are 3.54 times higher (95% CI [1.76, 7.16]) for those with a proven/probable transmission than those without. Equivalently, recipients with a proven/probable infection transmission event were significantly more likely to have a communication gap surrounding the transmission event than those recipients whose exposure to a potential IE was without a communication gap. The relative risk of developing a proven or probable infection transmission event was 2.36 (95% CI [1.48–3.78]) for these recipients...

...The types of communication delays and errors were reviewed. It was found that gaps occurred at several points in the communication process. In some events, more than one communication gap occurred. In five IEs, the transplant hospital delayed contacting the OPO or the OPTN with a suspected donor-derived infection (range 22–56 days). In four IEs, the laboratory failed to relay donor results (including autopsy results) to the OPO and/or transplant hospital. Other communication gaps included an OPO delay in contacting the OPTN or transplant centers (three IEs), clerical errors in the reporting donor viral serologies (three IEs), and incomplete communication of test results by the OPO to transplant centers (three IEs).

The majority of communication gaps occurred within 2 months of transplantation and involved bacterial pathogens. This is likely the result of OPTN policy requiring routine pre-procurement donor bacterial cultures and the ease of linking subsequent recipient infections to these donor cultures, rather than any characteristics inherent to bacterial pathogens. These communication gaps contributed to adverse outcomes among affected transplant recipients, in some cases even leading to potentially preventable recipient deaths. Conversely, effective communication was associated with minimized or averted infection in transplant recipients through the implementation of preventive or preemptive treatment strategies.<sup>7</sup>

The article notes that improving communication at all levels in the transplant process has been an area of focus in the transplant community, informed by lessons learned by DTAC’s ongoing review of reports of potential donor-derived disease transmissions. In 2011, the OPTN/UNOS implemented policy changes regarding communication, largely focusing on the procedures for OPOs and transplant centers to report and share donor-related information with relevant groups. This included policy requiring the identification

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<sup>6</sup> R Miller et al, 259.

<sup>7</sup> R Miller et al., 261-263.

of specific individuals responsible for communication on a 24-hour per day basis at all transplant hospitals and OPOs. The article also noted that further refinements of the process are currently being explored by the OPTN/UNOS as resources available vary tremendously and it mentioned the FMEA being used as evidence in this proposal as an effort to address these issues. It called out other organizations, including the Council of State and Territorial Epidemiologists, Centers for Disease Control and Prevention, and World Health Organization, as being involved with broader efforts to improve these communication deficiencies. The authors recommended that educational efforts continue by all groups, targeting transplant and non-transplant healthcare providers, to increase awareness of potential donor-derived events, utilize the existing reporting process, and understand the channels of communication to obtain timely, clinically relevant information for patient management.<sup>8</sup>

This article detailed in peer-reviewed and published literature both the positive impact of effective communication as well as the adverse outcomes that can occur with communication gaps regarding infectious disease results in organ transplantation.

Communication patterns of PDDTE widely vary and have changed significantly since the 2011 policy changes. Data from DTAC reviewed cases would suggest that these policy changes contributed to heightened reporting (See **Table 3**). Reporting to the OPTN has significantly increased over the years. In the early years of reporting, the sentiment was “when in doubt, report”. Between 2011 and 2014, the number of reports to the OPTN/UNOS doubled. Due to the increasing number of reports and the lack of potential PDDTE, not all reports are reviewed by the DTAC. DTAC leadership excludes a case from full committee review if it is evident that it is a donor culture reported without possible impact on a specific organ recipient. The number of reports not chosen for review by DTAC has more than tripled since 2011. Only 70% of reports made in 2015 were reviewed for PDDTE. In addition, of the reports reviewed by DTAC, approximately 60% are classified as excluded. These data point to possible over-reporting without notable benefit.

**Table 3: Historical Trends of PDDTE Reporting to the OPTN**

	2011	2012	2013	2014	2015
<b>Reports made to OPTN</b>	217	235	391	458	406
<b>Reports chosen for DTAC review</b>	181	198	284	278	290
<b>Reports not reviewed</b>	36	37	107	180	117
<b>% Reviewed</b>	83.4%	84.3%	72.6%	60.7%	71.3%
<b>Donors transmitting proven/probable</b>	31	33	32	35	N/A <sup>9</sup>
<b>Intervention without documented transmission (IWDT)</b>	34	23	73	63	N/A
<b>Unlikely/Excluded</b>	98	128	152	166	N/A
<b>Possible</b>	18	14	27	14	N/A
<b>Donors transmitting proven/probable</b>	17.1%	16.7%	11.3%	12.6%	
<b>IWDT</b>	18.8%	11.6%	25.7%	22.7%	
<b>Unlikely/Excluded</b>	54.1%	64.6%	53.5%	59.7%	
<b>Possible</b>	9.9%	7.1%	9.5%	5.0%	

Many of these reports involve positive donor cultures with no sick recipients. The community has commented anecdotally that part of this reporting behavior may be due to fears of being cited for not

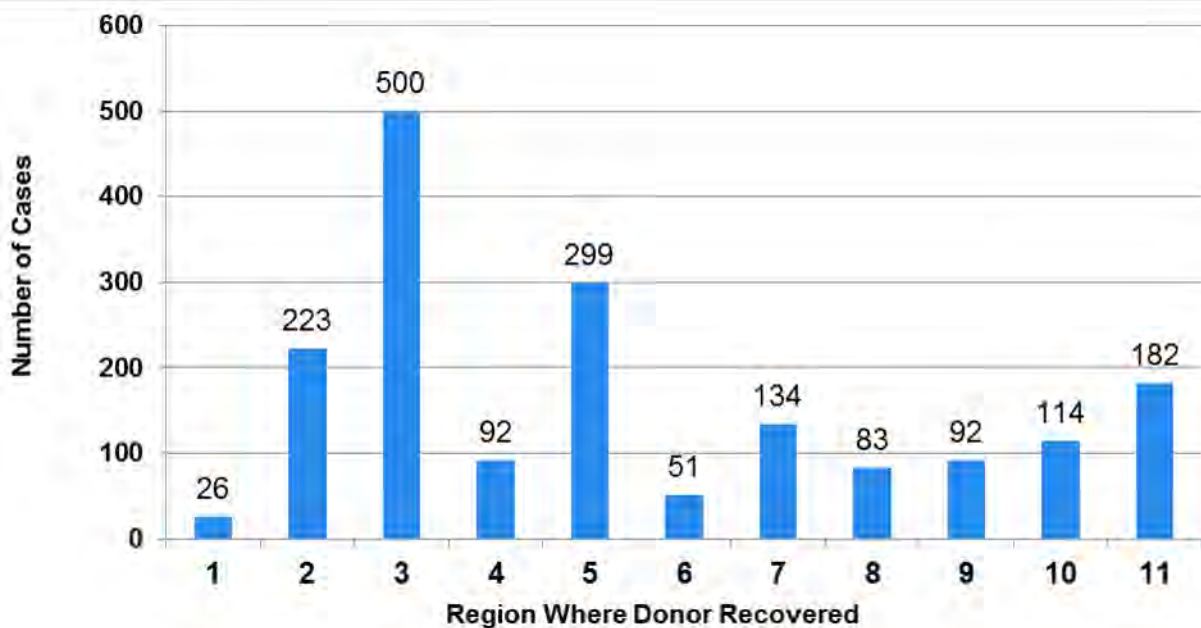
<sup>8</sup> Ibid.

<sup>9</sup> Analysis of all 2015 cases has not yet been completed.

reporting all potential PDDTE, including items such as positive sputum cultures in kidney-only recipients, due to policy language interpretation. Over-reporting may also be leading to desensitization. Although data are not officially tracked, many patient safety contacts and transplant representatives have commented on the magnitude of reports received without notable benefit for some types of clinically irrelevant reports. This may not be the most effective use of system resources and is not the purpose of reporting mechanisms.

Data tracked by DTAC showing reporting by region and DSA further exemplify the likely differing interpretation of policy versus actual variation in rates of donor-derived transmissions. Between 2006 and 2014, there were 1,796 cases reported to the OPTN through the IPS. Cases received vary dramatically by region (**Figure 2**).

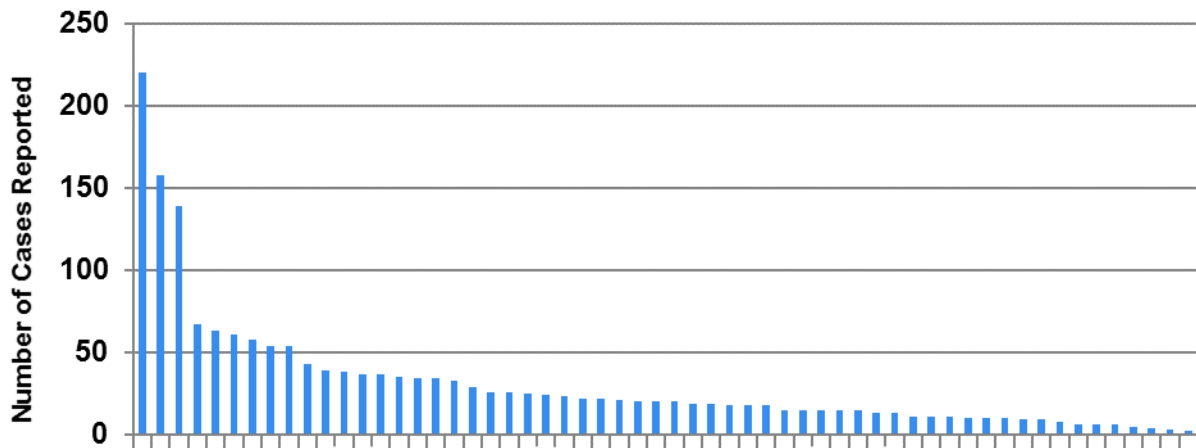
**Figure 2. Total Deceased Donor Cases Reported to OPTN by Region of Donor Recovery, 2006-2014**



This variation is consistent with the latest single year data. In 2014, there were 172 reports from region 3 where the overall highest number of reports have historically originated and five reports from region 1 where the lowest number of reports have historically originated. Regions 2 and 5 had 62 and 50 cases, respectively. The four regions with the smallest number of cases were regions 1 (n =5), 6 (n =9), 10 (n =11), and 7 (n =16).

Variation by DSA is evident as well in **Figure 3**. All DSAs had at least two cases reported from 2006-2014. The greatest number of reported cases from a single DSA was 220, followed by 158 and 139 for two other DSAs. The range of reports spans from two to 220.

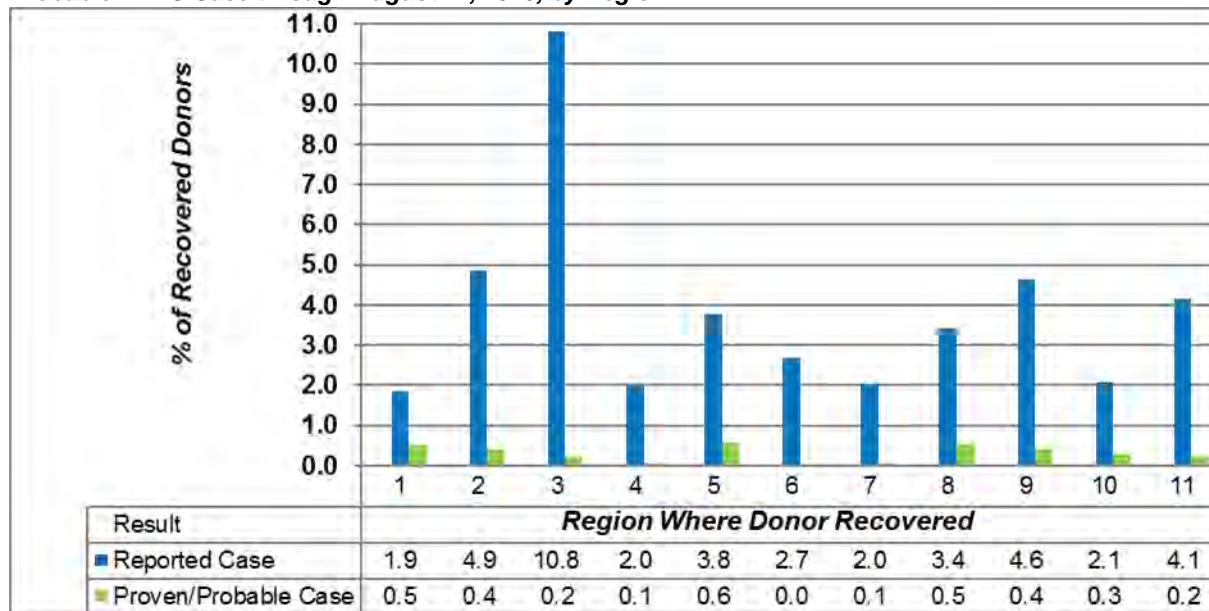
**Figure 3. Deceased Donor DTAC Cases Reported by the Recovering DSA 2006-2014**



The latest data for 2014 show these trends to be continuing. Eight of the 58 DSAs did not have any cases reported during 2014. The highest number of reported cases in a single DSA was 129, followed by 53. For the DSA with 129 cases, this represented 79% of the donors they recovered during the year.

The raw numbers and trends are not dependent on recovery patterns or regional disease patterns. The variation by percentage of recovered donors is displayed below in **Figure 4**. The percent of donors recovered with a proven or probable transmission does not appear to correlate with the number or percentage of reports.

**Figure 4. Percent of Deceased Donors Recovered in 2013-2014 Resulting in a Reported Case and a Proven or Probable DTAC Case through August 21, 2015, by Region**



This latest figure portrays cases as a percentage of all deceased donors recovered, but limits the percentage calculation to cases classified as proven or probable by the DTAC. By doing this, it weeds out those types of cases that perhaps did not need to be reported. It also gets to the charge of the Committee in determining the rate of disease transmission in solid organ transplantation. It is important to note that by limiting the analysis to proven and probable cases, the variation in actual number of such cases during

the period is minimal. These figures do not account for the Intervention without documented transmission (IWDT) cases as these may represent prevented proven or probable cases.

The number of proven/probable cases from deceased donors recovered in 2013-14 by region ranged from zero to 15 cases. All the percentages are below 0.6% of deceased donors recovered during the period with a high of just under 0.6% in region 5 and a low of 0% in region 6.

While the previous data support the need to provide greater clarity for reporting to reduce unnecessary reporting and promote consistent and efficient communication, this proposal also addresses one area where under-reporting has had adverse outcomes. Several DTAC members reviewed 14 PDDTE of toxoplasmosis reports received from January 2008 through September 2015. Proven or probable donor derived toxoplasmosis developed in 11 organ recipients from 10 donors not known to be toxoplasmosis positive at time of transplant. In four reports, toxoplasmosis was detected in the donor because of OPO or recipient center donor testing; these resulted in no transmission events. Transmissions were reported in six heart recipients as well as five non-heart recipients (including liver, kidney, and lung recipients). Five out of eleven (45%) recipients died of their infection. Communication issues contributed to poor outcomes in three of the infections in non-cardiac recipients.

While the potential for this infection in heart recipients is well appreciated, the data cited above (not yet published) suggests that this infection can be lethal in non-cardiac recipients as well. Current policy requires either OPO testing or sending a tube of blood with the heart for testing. This proposal will require transplant hospitals that perform toxoplasmosis testing to report all results (including negative results) back to the host OPO for rapid and complete dissemination to all recipient programs. The DTAC is currently working with the Thoracic and OPO committees to discuss this as well as other potential solutions. The adverse outcomes affecting both cardiac and non-cardiac recipients, in part due to lack of policy requirements and communication issues, support this new requirement for transplant hospitals.

The quantitative data from historical OPTN/UNOS reports and DTAC reviews support the changes in this proposal. The proposal specifies the types of positive reports that must be reported to the transplant hospital patient safety contact and/or the OPTN/UNOS within 24 hours after receipt. The more detailed policy should reduce variation and improve efficient communications.

The strengths of this proposal include the use of data and incorporating FMEA recommendations as well as stakeholder input in its development. Educational efforts as recommended by the FMEA are also underway. The weakness of the proposal may be that it does not completely address issues with the patient safety contact. There is, however, a UNOS Customer Innovations pilot being developed that would further refine post-transplant reporting and employ a triaged contact system according to result types similar to that used for organ notifications. This effort is not dependent on this policy passing but will augment the overall effort to improve communication of results received post-procurement or post-transplant.

### Was this proposal changed in response to public comment?

This proposal was well received and supported within the transplant community.

All eleven regions approved the proposal. Every region unanimously voted in favor except in region 2 where there was only one “no” vote. The Kidney, Living Donor, Membership and Professional Standards, OPO, Operations and Safety, Thoracic, Transplant Administrators, Transplant Coordinators, and Vascularized Composite Allograft (VCA) Committees all expressed support for the proposal. In addition, the American Society of Transplantation (AST), American Society for Transplant Surgeons (ASTS), American Society for Histocompatibility and Immunogenetics (ASHI), and NATCO all commented in support of the proposal. AOPO did not formally comment but has been a collaborator in the development of the proposal.

Several themes that emerged during public comment and the DTAC made several post-public comment changes in response to comments.

1. Toxoplasmosis testing for all deceased donors

The DTAC sought specific public comment regarding toxoplasmosis testing on all deceased donors due to recent data showing morbidity and mortality in non-cardiac transplant recipients from this disease. The transplant community overall supported toxoplasmosis testing for all deceased donors. The DTAC has changed this proposal to require toxoplasmosis testing for all deceased donors.

Several commenters asked about testing when no specific tests have been approved, licensed, or cleared by the US Food and Drug Administration (FDA) specifically for donor screening. The FDA was consulted and responded that they had no concerns with this requirement. They provided a list of cleared FDA tests that can be used.

Some members in one region expressed concern about the cost of testing and another region commented that it might add roughly \$25,000 per year but that the cost could be absorbed. Multiple OPOs also indicated that they were already conducting toxoplasmosis testing in all donors.

The ASTS, ASHI, International Society for Heart and Lung Transplantation (ISHLT), and NATCO all supported routine toxoplasmosis testing. The AST requested more evidence to expand toxoplasmosis testing beyond donors involving heart allocation. The DTAC has an abstract being presented at the upcoming 2016 American Transplant Congress on a retrospective review of proven and probable toxoplasmosis reports from January 2008 through September 2015. The data show proven or probable transmissions in 11 recipients. Nearly half (45%) were in non-heart recipients (heart recipients = 6; non-heart recipients = 5). Five of the 11 recipients died. To exclude non-cardiac cases would miss an opportunity to prevent morbidity and mortality.

The MPSC, OPO, Operations and Safety, Thoracic, and VCA committees all expressed support for toxoplasmosis testing in all deceased donors.

Several commenters explained that the current system for either testing or sending a tube of blood to the transplant hospital for testing was problematic due to lost tubes, laboratories not accepting the specimens, and gaps in communicating results to all transplant hospitals.

2. VCA specific requirements

The DTAC sought specific feedback on the need for VCA specific requirements. In response to comments from the VCA Committee and the AST, the DTAC and VCA Committees will be forming a work group to explore specific testing and reporting needs regarding VCA donors.

The proposal was amended to require 24 hour reporting of positive results for genitourinary cultures, respiratory samples (bacterial or *Candida species*) to transplant programs receiving lungs or head and neck VCAs, and urine cultures (bacterial or *Candida species*) to transplant programs receiving kidneys or genitourinary VCAs.

3. Specific requirements for reporting positive results

In response to comments to concerns of potential over reporting regarding negative histopathology results, the DTAC amended this requirement to include only relevant findings.

In response to concern for including positive tissue cultures and the possibility of confusion with tissue recovery, the DTAC amended the language to exclude a specific statement on positive tissue cultures as the organ transplantation needs are actually covered in the requirement to report positive serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi.

The DTAC also clarified language regarding reporting of bacterial, mycobacterial, and fungal results including requirements for reporting *Candida species*.

Other themes emerged for which the DTAC did not make specific changes.

1. Patient safety contacts

The DTAC acknowledges issues with the patient safety contact system as identified in the FMEA and public comments. The DTAC agrees that improvements can be made in this area. Standardization where feasible would improve the quality of communication processes including more agile processes for identifying and contacting patient safety contacts. The DTAC has not addressed this issue in the proposal because there is a pilot UNOS Customer Innovation project that should help with this issue and provide increased abilities to identify, amend, and contact designated patient safety contacts.

2. Information transfer and confirmation of receipt of information

The DTAC agrees that standardization of information transfer and documented receipt of information would improve the quality of communication processes. The DTAC has not addressed this issue in the proposal because there is a pilot UNOS Customer Innovation project that should help address this issue and provide more standardized processes including documentation of communication.

3. Active seeking and posting of negative results by OPOs

The DTAC discussed comments requesting that OPOs actively seek results. The proposed language does require OPOs to have a protocol to obtain and report all results. Due to the variability in result reporting timeframes, a specific time period was not proposed. OPOs, however, should develop their protocols to include a specific process to obtain all results within a timely period. This will be highlighted in educational efforts.

4. Duplicative reporting

Some commenters asked for ways to receive feedback on cases or have search abilities to identify previously reported cases in order to avoid unnecessary duplicative reporting. The DTAC did not change the current policy that requires both OPOs and transplant hospitals to report to avoid the greater harm and potential for missing reports.

## Which populations are impacted by this proposal?

This proposal will impact all OPOs and transplant programs. It will specifically impact those staff responsible for reporting and follow up of potential donor derived transmissions including the patient safety contacts. The policy will provide more clarity and therefore should reduce workload overall and allow for emphasis on critical and relevant results.

This proposal will potentially impact all recipients. The actual percentage of recipients impacted by a proven/probable donor-derived disease or malignancy transmission is relatively small.

An internal analysis of deceased donors found between 1/1/08 and 9/8/15, that 211 out of 63,384 (0.33%) deceased donors transmitted disease with 249 out of 174,338 (0.14%) total recipients developing donor derived disease. From these transmissions, 70 out of 174,338 (0.04%) recipients died from donor-derived disease. Alternatively for living donors during the same time period, 8 out of 47,150 (0.02%) living donors transmitted disease with 5 out of 47,149 (0.01%) of total recipients developing donor derived disease.

The percentage of recipients experiencing an adverse event due to donor-derived transmission involving communication issues hopefully will decrease.

## How does this proposal support the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* This proposal will provide: (1) clarification of expectations regarding OPO reporting of new donor information learned post-transplant (positive results versus negative results), and (2) triaging direction on how this information is shared to reduce the burden of both sharing and receiving this information and reduce the perceived desensitization within the community due to the "noise" currently flooding the current reporting system.
5. *Promote the efficient management of the OPTN:* Modifications to Policy 15.4 are expected to reduce the volume of unnecessary or duplicate reports of potential donor-derived disease transmission events to the OPTN. This reduction in "noise" will allow UNOS staff and patient safety contacts to be more effective and efficient in their roles.

## How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The Ad Hoc Disease Transmission Advisory Committee will review patient safety reports submitted to the OPTN Improving Patient Safety portal to ensure that this policy change serves its intended purpose without unintended consequences.

Since external factors and other changes in policy can have an influence on the period following policy implementation, interpreting the apparent impact of this policy change based on "before vs. after" analysis must be done with caution.

### **Questions that will need to be answered as policy evaluation:**

The following questions will guide the evaluation of the proposal after implementation:

- Has the total number of cases reported to and reviewed by DTAC decreased?
- Has the total number of cases reported to but not reviewed by DTAC decreased?
- Has the geographic variability in the number of deceased donor cases reported to DTAC decreased?
- Has the geographic variability in the number of deceased donors that result in a DTAC case decreased?
- Has the geographic variability in the number of living donor cases reviewed by DTAC decreased?

### **Data used to evaluate the proposal (Policy Performance Measures):**

The following metrics will be used to evaluate the proposal:

- The number of cases reported by year.
- The number of deceased donor cases reported by donor recovery:
  - region
  - encrypted DSA
- The percentage of deceased donors resulting in a case stratified by:
  - region
  - encrypted DSA
- The number of living donor cases reported over time by region.



**Timeline for evaluation:**

Data will be evaluated at 1 year, 1½ years, and 2 years post-implementation. Timeline is subject to change based on the results.

## How will the OPTN implement this proposal?

This proposal will require specific communication and education efforts to OPOs and transplant hospitals to assure that the changes to reporting requirements are implemented effectively within the community.

This proposal will likely reduce the workload of UNOS staff that support disease transmission investigations.

This proposal will require programming in UNet<sup>SM</sup>. Programming will include adding data fields to DonorNet<sup>®</sup> and the deceased donor registration form (DDR) to capture toxoplasmosis testing results. The remainder of the proposal can be implemented while awaiting programming regarding toxoplasmosis.

## How will members implement this proposal?

OPOs and transplant hospitals will need to familiarize staff responsible for PDDTE reporting with the new policy.

OPOs will need to develop a protocol for reporting that includes:

- Testing all deceased donors for toxoplasmosis
- Obtaining all results for any deceased donor testing conducted;
- Uploading all deceased donor testing results to DonorNet<sup>®</sup>;
- Sharing deceased donor test results with tissue banks;
- Reporting certain positive test results to the transplant hospital patient safety contact and/or the OPTN as soon as possible but no later than 24 hours of receipt according to the new policy.

## Will this proposal require members to submit additional data?

OPOs will be required to report toxoplasma IgG testing results to the OPTN Contractor in DonorNet and on the DDR.

This proposal clarifies that all donor results (including negatives) will need to be reported to the OPTN via upload to DonorNet<sup>®</sup>. By eliminating unnecessary reporting to the receiving transplant program patient safety contact and the OPTN IPS, the overall data burden should be reduced.

## How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language. In addition to the monitoring outlined below, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

UNOS patient safety staff will continue to process potential donor-derived disease transmission events reported through the OPTN Improving Patient Safety Portal for review and classification by the Ad Hoc Disease Transmission Advisory Committee.

Additionally, the following changes to routine site surveys will occur:

**Policy 2.9: Required Deceased Donor Infectious Disease Testing**

At OPOs, site surveyors will begin reviewing a sample of deceased donor records for documentation of results or other evidence that a toxoplasma Immunoglobulin G (IgG) antibody test was performed and that the results reported through UNet<sup>SM</sup> are consistent with source documentation.

**Policy 2.13: Post Procurement Follow Up and Reporting**

At OPOs, site surveyors will review the OPO's internal policies, procedures, and/or protocols to verify that they include a description of the process for:

- Obtaining deceased donor test results and reporting them to the OPTN Contractor
- Reporting positive test results and relevant information to receiving transplant programs and, when required, to the OPTN Improving Patient Safety Portal

**Policy 15.4.A: Host OPO Requirements for Reporting Post-Procurement Donor Results and Discovery of Potential Disease Transmissions**

At OPOs, site surveyors will review a sample of deceased donor records for the following documentation:

- Evidence of follow-up on deceased donor test results post-procurement
- Evidence that positive test results and other required relevant information received post-procurement are reported to each recipient hospital via phone call or email within 24 hours of the OPO's receipt
- The date and time the OPO received the results
- The name of the individual at the recipient hospital who received the OPO's report of any post-procurement positive test results or other relevant information
- The mode or method of the report of results (by either telephone or email)
- Evidence that any results received post-procurement indicating malignancy or the presence of a Pathogen of Special Interest are reported through the OPTN Improving Patient Safety Portal within 24 hours of the OPO's receipt of the results

## Policy or Bylaw Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

1 **RESOLVED**, that changes to Policies 2.9 and 2.11.C, as set forth below, are hereby approved,  
2 **effective pending implementation and notice to OPTN members.**

3 **FURTHER RESOLVED**, that changes to Policies 2.13 (Post Recovery Follow Up and Reporting),  
4 **15.4 (Reporting of Potential and Proven Disease Transmissions), 15.5 (Requirements for Post-**  
5 **Transplant Discovery of Donor Disease or Malignancy), and 15.6 (Open Variance for the Recovery**  
6 **and Transplantation of Organs from HIV Positive Donors), as set forth below, are hereby**  
7 **approved, effective September 1, 2016.**

### 8 **2.9 Required Deceased Donor Infectious Disease Testing**

9 The host OPO is responsible for ensuring that *all* of the following infectious disease testing is completed in  
10 CLIA-certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers  
11 for Medicare and Medicaid Services (CMS):  
12

- 13 1. Blood and urine cultures
- 14 2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or  
15 cleared tests, as listed below:
  - 16 a. HIV antibody (anti-HIV) donor screening test *or* HIV antigen/antibody (Ag/Ab) combination test
  - 17 b. Hepatitis B surface antigen (HBsAg) donor screening test
  - 18 c. Hepatitis B core antibody (anti-HBc) donor screening test
  - 19 d. Hepatitis C antibody donor screening test (anti-HCV)
  - 20 e. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic nucleic acid test (NAT)
  - 21 f. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening *or* diagnostic test
  - 22 g. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening *or* diagnostic test
  - 23 h. Syphilis donor screening *or* diagnostic test
  - 24 i. Toxoplasma Immunoglobulin G (IgG) antibody test
- 25 3. If the donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to  
26 *the U.S. Public Health Services (PHS) Guideline*. HIV RNA by donor screening or diagnostic NAT or  
27 HIV antigen/antibody (Ag/Ab) combination is *also* required unless *either of the following* is true:
  - 28 • The donor has already been tested for HIV using the HIV Ag/Ab combination test according to  
29 section 2.a above.
  - 30 • The donor's only increased risk factor is having received hemodialysis within the past 12 months.

### 34 **2.11.C Required Information for Deceased Heart Donors**

35 The host OPO must provide *all* the following additional information for all deceased donor heart  
36 offers:  
37

- 38 1. Height
- 39 2. Weight
- 40 3. Vital signs, including blood pressure, heart rate, and temperature
- 41 4. History of treatment in hospital including vasopressors and hydration
- 42 5. Cardiopulmonary, social, and drug activity histories
- 43 6. Details of any documented cardiac arrest or hypotensive episodes
- 44 7. 12-lead interpreted electrocardiogram
- 45 8. Arterial blood gas results and ventilator settings
- 46 9. Cardiology consult or echocardiogram, if the hospital has the facilities
- 47 10. Human leukocyte antigen (HLA) typing if requested by the transplant hospital, including A, B,

48 Bw4, Bw6, C, DR, DR51, DR52, DR53, DQA1, DQB1, and DPB1 antigens prior to the final  
49 organ acceptance  
50 11. ~~Toxoplasma antibody (Ab) test result or an appropriate donor sample sent with the heart for~~  
51 ~~testing at the transplant hospital~~  
52

53 For heart deceased donors, if a transplant program requires donor HLA typing prior to submitting  
54 a final organ acceptance, it must communicate this request to the OPO and document the  
55 request. The OPO must provide the HLA information listed above and document that the  
56 information was provided to the transplant program.  
57

58 The heart recovery team must have the opportunity to speak directly with the responsible ICU  
59 personnel or the onsite donor coordinator in order to obtain current information about the  
60 deceased donor's physiology.  
61

## 62 **2.13 Post Procurement Recovery Follow Up and Reporting**

63 ~~The host OPO must establish and implement procedures to do *both* of the following:~~  
64

- 65 1. ~~Obtain post recovery deceased donor test results.~~
- 66 2. ~~Report all positive screening or diagnostic tests to the transplant hospital's patient safety contact,~~  
67 ~~within 24 hours of receipt by the OPO.~~

### 68 **2.13.A Reporting Requirements**

69 The host OPO is responsible for ~~timely~~ follow up and reporting of ~~any new or changed~~ deceased donor  
70 test results received after procurement. The host OPO must develop and comply with written protocols to  
71 do all of the following:

- 72
- 73 1. ~~Obtain and report all deceased donor test results to the relevant transplant programs. The host OPO~~  
74 ~~must report to the transplant programs all of the following: OPTN Contractor~~
  - 75 1. ~~Updates, such as the identification of any potential disease-causing organism and the sensitivity of~~  
76 ~~the deceased donor to that organism, as the host OPO receives the information.~~
  - 77 2. ~~Medical-social history, testing, and laboratory assessments that identify malignant or infectious~~  
78 ~~conditions that may adversely affect a potential transplant recipient.~~
  - 79 3. ~~Any known or suspected infectious or neoplastic conditions that may be transmitted to transplant~~  
80 ~~recipients.~~

81

82 The host OPO must report to the OPTN Contractor's Patient Safety Portal any new disease or  
83 malignancy in the deceased donor that may be transmitted to transplant recipients.

- 84 2. Report all positive test results and relevant information according to *Policy 15.4: Host OPO*  
85 *Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease*  
86 *Transmissions*
- 87 3. Report relevant test results and other information to tissue banks receiving donor tissue  
88

## 89 **15.4 Host OPO Requirements for Reporting Post-** 90 **Procurement Test Results and Discovery of Potential** 91 **and Proven Disease Transmissions**

92 Host OPOs must report any test results or information received post-procurement that indicate there  
93 may be a possibility for donor-derived disease as follows.  
94

### 95 **15.4.A Transplant Program Requirements**

96 When an organ recipient is suspected to have, is confirmed positive for, or has died from a  
97 potential transmissible disease or medical condition, including infections and malignancies, and

98 there is substantial concern that it could be from the transplanted organ, then the transplant  
99 program must do *both* of the following:

- 100 1. Notify the institution that recovered the organ (OPO or living donor recovery hospital), without  
101 waiting for all medical documentation that may eventually become available. The transplant  
102 program must notify the living donor hospital or host OPO by phone and provide  
103 documentation as soon as possible but no later than 24 hours after learning of the event.  
104
- 105 2. Report the event through the OPTN Improving Patient Safety Portal.  
106

107 Any transplant program treating recipients that received organs from a donor who is the subject of  
108 a potential disease transmission report is responsible for *all* of the following:

- 109 1. Responding to host OPO, living donor recovery hospital, and OPTN patient safety staff  
110 requests for information regarding all recipients in a timely fashion and communicating  
111 updated information regarding recipient condition, test results, diagnosis, and plans for  
112 treatment and follow-up.  
113
- 114 2. Submitting copies of any relevant test results including cultures, infectious disease testing  
115 results, imaging studies, or autopsy results to OPTN patient safety staff.  
116
- 117 3. Notifying recipients involved in cases of confirmed disease transmissions and documenting  
118 this notification in the recipient medical record according to *15.3.A: Donors with Additional  
119 Risk Identified Pre-transplant*.
- 120 4. If requested by the Ad Hoc Disease Transmission Advisory Committee, submission of a  
121 *Potential Disease Transmission Recipient Follow-Up Report* within 45 days of the initial date  
122 the potential transmission was reported.

123 OPTN patient safety staff may request additional information related to the recipient beyond 45  
124 days, in an effort to determine the probability of donor-derived disease transmission, depending  
125 on the potentially transmitted disease or malignancy.  
126

#### 127 **15.4.A Host OPO Requirements for Reporting Post-Procurement Donor** 128 **Results and Discovery of Potential Disease Transmissions**

129 The host OPO must report all positive test results and other relevant information received post-  
130 procurement for each donor as soon as possible but no later than 24 hours after receipt as  
131 follows:

- 132 1. All results indicating Pathogens of Special Interest must be reported to the receiving  
133 transplant program's patient safety contact and the OPTN Improving Patient Safety Portal.  
134 The OPTN Contractor provides a list of Pathogens of Special Interest, including any results  
135 that can be excluded from reporting. The OPTN Contractor reviews and updates this list at  
136 least annually.
- 137 2. All other positive test results and relevant information must be reported according to *Table*  
138 *15-1 below*.  
139  
140

141  
142

**Table 15-1: Host OPO Reporting Requirements for Positive Post-Procurement Donor Results and Discovery of Potential Disease Transmissions**

<u>The host OPO must report <i>all</i> of the following positive results:</u>		<u>To:</u>
<u>Samples relevant to all recipients</u>	<u>Serologic, NAT, or antigen results indicating presence of parasites, virus, or fungi</u>	<u>The receiving transplant program's patient safety contact</u>
	<u>Cultures from the following specimens:</u> <ul style="list-style-type: none"> <li>• <u>Ascites</u></li> <li>• <u>Blood</u></li> <li>• <u>Cerebrospinal fluid (CSF)</u></li> <li>• <u>Deep wound</u></li> <li>• <u>Genital</u></li> <li>• <u>Pericardial</u></li> <li>• <u>Pleural fluid</u></li> </ul>	<u>The receiving transplant program's patient safety contact</u>
	<u>Mycobacterial smears and cultures</u>	<u>The receiving transplant program's patient safety contact</u>
	<u>Fungal smears and cultures with the exception of <i>Candida</i> species</u>	<u>The receiving transplant program's patient safety contact</u>
<u>Relevant information</u>	<u>Respiratory samples (bacterial or <i>Candida</i> species) only to transplant programs receiving lungs or head and neck VCAs</u>	<u>The receiving transplant program's patient safety contact</u>
	<u>Urine cultures (bacterial or <i>Candida</i> species) only to transplant programs receiving kidneys or genitourinary VCAs</u>	<u>The receiving transplant program's patient safety contact</u>
	<u>Malignancy or other findings highly suggestive of malignancy recognized after procurement</u>	<ol style="list-style-type: none"> <li>1. <u>The receiving transplant program's patient safety contact</u></li> <li>2. <u>The OPTN Improving Patient Safety Portal</u></li> </ol>
	<u>Histopathology results reported post-procurement</u>	<u>The receiving transplant program's patient safety contact</u>
	<u>All <i>final</i> culture information for any culture results that were reported according to these requirements</u>	<u>The receiving transplant program's patient safety contact</u>
	<u>Other psycho-social history, medical history, autopsy, testing, and laboratory findings identifying infectious conditions that may adversely affect a potential transplant recipient</u>	<u>The receiving transplant program's patient safety contact</u>

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**15.4.B Requirements for Living Donor Recovery Hospital and Host OPOs**

The living donor recovery hospital or host OPO is responsible for *all* the following:

1. ~~Communication of the suspected donor's and affected recipient's test results and diagnosis that may be relevant to acute patient care as soon as possible, but no more than 24 hours after receipt, to any transplant programs, patient safety contacts, and tissue banks that received organs or tissue from the donor. This includes any test results that were not available at the time of procurement or that were performed after recovery. The living donor recovery hospital or host OPO must document that this information is shared with all receiving transplant programs and tissue banks.~~

- 155 2. ~~Notification of the event to the OPTN Improving Patient Safety Portal as soon as possible, but~~  
156 ~~no later than 24 hours after receipt of test results or diagnosis.~~  
157  
158 3. ~~Potential disease transmission follow up communication as follows, including:~~  
159  
160 a. ~~For deceased donors, completion and submission of the *Potential Disease Transmission*~~  
161 ~~*Report Form* no later than 24 hours after reporting the event through the OPTN Improving~~  
162 ~~Patient Safety Portal. This must include:~~  
163 i. ~~The specific receiving transplant program patient safety contact and tissue bank staff~~  
164 ~~that were notified of the potential transmission~~  
165 ii. ~~Disposition of all organs, tissues, and vessels~~  
166 iii. ~~Any preliminary information available regarding any remaining deceased donor~~  
167 ~~samples for additional testing, notification to state or local health department as~~  
168 ~~appropriate for nationally notifiable infectious diseases, and whether an autopsy was~~  
169 ~~performed on the deceased donor.~~  
170  
171 4. ~~A follow up review of the event, in partnership with OPTN patient safety staff, to determine~~  
172 ~~whether the deceased or living donor was diagnosed with a potentially transmissible disease~~  
173 ~~or condition.~~  
174

175 For all living and deceased donors, the Ad Hoc Disease Transmission Advisory Committee may  
176 request submission of a *Potential Disease Transmission Donor Follow-Up Report* 45 days after  
177 the initial reporting date. Patient safety staff may request additional information related to the  
178 living donor beyond 45 days, including pending test results, depending on the potentially  
179 transmitted disease or condition.  
180

181 If a host OPO learns new information regarding a deceased donor as part of its required donor  
182 follow up that indicates risk of potential transmission of disease or malignancy, the host OPO  
183 must report the information through the OPTN Improving Patient Safety Portal.  
184

185 If a recovery hospital learns new information about a living donor during the first two years post  
186 donation that indicates risk of potential transmission of disease or malignancy, then the recovery  
187 hospital must do *at least* the following:  
188

- 189 1. ~~Disclose to the living donor that a potential disease transmission or malignancy must be~~  
190 ~~reported to the receiving transplant program and the OPTN Improving Patient Safety Portal~~  
191 2. ~~Notify the receiving transplant program~~  
192 3. ~~Report the potential transmission through the OPTN Improving Patient Safety Portal~~  
193

194 The recovery hospital may also need to report the new information to local, state, or federal public  
195 health authorities.  
196

#### 197 **15.4.B Host OPO Requirements for Reporting Post-Procurement** 198 **Discovery of Recipient Disease or Malignancy**

199 If the host OPO is notified that an organ recipient is suspected to have, is confirmed positive  
200 for, or dies from a potential transmissible disease, infection, or malignancy and there is  
201 substantial concern that it could be from the transplanted organ, then the host OPO must do  
202 all the following:  
203

- 204 1. Communicate the suspected donor's and affected organ recipient's test results and  
205 diagnosis that may be relevant to acute patient care, as soon as possible but no more  
206 than 24 hours after receipt, to any transplant program patient safety contacts and tissue  
207 banks that received organs, vessels, or tissue from the donor. This includes any test  
208 results that were not available at the time of procurement or that were performed after

209 procurement. The host OPO must document that this information is shared with all  
210 receiving transplant programs and tissue banks.  
211 2. Report the event to the OPTN Improving Patient Safety Portal as soon as possible but no  
212 more than 24 hours after notification or receipt of recipient test results or diagnosis.  
213

214 **15.4.C Host OPO Requirements for Post-Reporting Follow Up**

215 If the host OPO reports test results or other relevant information to the OPTN Contractor  
216 through the OPTN Improving Patient Safety Portal, then the host OPO must also do all the  
217 following:

- 218
- 219 1. Complete and submit the *Potential Disease Transmission Report Form* no later than 24  
220 hours after reporting the event through the OPTN Improving Patient Safety Portal.
- 221 2. Contribute to a follow up review of the event, in partnership with OPTN patient safety staff.
- 222 3. Provide additional information or specimens related to the deceased donor if  
223 requested.
- 224

225 **15.5 Transplant Program Requirements for Communicating**  
226 **Post-Transplant Discovery of Donor Disease or**  
227 **Malignancy**

228 ~~If any new, clinically relevant findings about a deceased or living donor are discovered after~~  
229 ~~transplant, the transplant program must complete all of the following:~~

- 230
- 231 ~~1. Notify the recipient, or the recipient's agent, of the risk of transmissible disease that was not~~  
232 ~~previously identified and is noted as clinically relevant by the recipient's care team.~~
- 233 ~~2. Document new information about the donor and potential risk for disease or malignancy in the~~  
234 ~~recipient's medical record.~~
- 235 ~~3. Follow a recipient at increased risk for disease or malignancy for the development of the disease or~~  
236 ~~malignancy after transplant.~~
- 237 ~~4. Offer the recipient additional testing, monitoring, and treatment as appropriate, in addition to routine~~  
238 ~~follow up care.~~
- 239

240 Transplant programs must communicate any test results or information received post-transplant that  
241 indicate donor-derived disease is possible as follows.

242

243 **15.5.A Transplant Program Requirements for Post-Transplant Discovery**  
244 **of Donor Disease or Malignancy**

- 245 1. If the findings are from transplant program testing of the donor, then the transplant program  
246 must notify the host OPO or living donor recovery hospital of the findings.
- 247 2. Notify the recipients under care at the transplant program, or the recipient's  
248 agents, of the risk or confirmation of transmissible disease or malignancy.
- 249 3. Document the new information about the donor and potential risk or  
250 confirmation of transmissible disease or malignancy in the recipients' medical  
251 records.
- 252 4. Follow the notified recipients for the development of the disease or malignancy after  
253 transplant.
- 254 5. Offer the recipients additional testing, monitoring, and treatment as appropriate,  
255 in addition to routine follow up care.
- 256
- 257



258 **15.5.B Transplant Program Requirements for Reporting Post-Transplant**  
259 **Discovery of Recipient Disease or Malignancy**

260 When an organ recipient is suspected to have, is confirmed positive for, or has died from a  
261 potential transmissible disease, infection, or malignancy and there is substantial concern  
262 that it could be from the transplanted organ, then the transplant program must do *all* of the  
263 following:

- 265 1. Notify host OPO or living donor recovery hospital that procured the organ without waiting  
266 for all medical documentation that may eventually become available. The transplant  
267 program must notify the host OPO or living donor recovery hospital by phone and provide  
268 documentation as soon as possible but no more than 24 hours after learning of the event.
- 269 2. Report the event through the OPTN Improving Patient Safety Portal as soon as possible but  
270 no more than 24 hours after learning of the event.
- 271 3. Provide additional related information or specimens if requested.

272  
273 **15.5.C Transplant Program Requirements for Post-Reporting Follow-Up**

274 If the transplant program has a recipient that involved in an OPTN Improving Patient Safety  
275 Portal report, then the transplant program must also do *all* of the following:

- 276 1. Submit any relevant test results including cultures, infectious disease testing results,  
277 imaging studies, or autopsy results to OPTN patient safety staff.
- 278 2. Respond to host OPO, living donor recovery hospital, and OPTN patient safety staff requests  
279 for information regarding the recipient and communicate updated information regarding  
280 recipient condition, test results, diagnosis, and plans for treatment and follow up.
- 281 3. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.
- 282 4. Provide additional related information or specimens if requested.

283  
284  
285 **15.6 Living Donor Recovery Hospital Requirements for**  
286 **Reporting Post-Donation Discovery of Disease or**  
287 **Malignancy**

288 Living donor recovery hospitals must report any post donation test results or information that indicate  
289 there may be a possibility for donor-derived disease.

290  
291 **15.6.A Living Donor Recovery Hospital Requirements for Reporting Post-**  
292 **Donation Discovery of Living Donor Disease or Malignancy**

293 If a living donor recovery hospital learns new information about a living donor during the first  
294 two years post donation that indicates risk of potential transmission of disease or malignancy,  
295 then the living donor recovery hospital must do *all* of the following:

- 296 1. Disclose to the living donor that the potential disease transmission or malignancy will be  
297 reported to the receiving transplant program and the OPTN Improving Patient Safety  
298 Portal.
- 299 2. Notify the receiving transplant program.
- 300 3. Report the potential transmission through the OPTN Improving Patient Safety Portal.

301  
302  
303 **15.6.B Living Donor Program Requirements for Post Reporting Follow-**  
304 **Up**

307 If the living donor recovery hospital reports test results or other information to the OPTN  
308 Contractor through the Improving Patient Safety Portal, then the recovery hospital must also  
309 do *all* of the following:

- 310  
311 1. Contribute to a follow up review of the event in partnership with OPTN patient safety staff.  
312 2. Provide additional information or specimens related to the living donor if requested.  
313

314  
315 **15.67\_\_ Open Variance for the Recovery and Transplantation**  
316 **of Organs from HIV Positive Donors**

317  
318 [*Subsequent headings affected by the re-numbering of this policy will also be changed as necessary.*]  
319

#

## Appendix A: Donor Pathogens of Special Interest

- Amebic encephalitis
- Anaplasma or Ehrlichiosis
- Anthrax
- Babesiosis
- Brucellosis
- California Serogroup Virus Diseases
- Chagas
- Chikungunya Virus Disease
- Coccidioidomycosis/Valley Fever \*\* Specifically identified by autopsy, biopsy, or cultures. Exclude serology only
- Crimean-Congo Hemorrhagic Fever virus
- Dengue virus infections
- Eastern Equine Encephalitis Virus Disease
- Ebola virus
- Enterovirus D68
- Hantavirus
- Hepatitis A
- Hepatitis C (acute, past or present)
- HIV Infection
- Influenza-associated pediatric mortality
- Lassa virus
- Lymphocytic choriomeningitis virus (LCMV)
- Leptospirosis
- Listeriosis
- Lujo virus
- Lyme disease
- Malaria
- Marburg virus
- Measles/Rubeola
- Microsporidia
- Middle East Respiratory Virus (MERS)
- Mumps
- New World Arenavirus – Guanarito, Junin, Machupo, or Sabia virus
- Pandemic Influenza strains
- Plague
- Poliomyelitis, paralytic
- Poliovirus infection, nonparalytic
- Powassan Virus Disease
- Q fever (acute, chronic)
- Rabies, animal or human
- Rubella/ German Measles
- Severe Acute Respiratory Syndrome (SARS)-Associated Coronavirus Disease
- Smallpox/Variola
- Spotted Fever Rickettsiosis (including but not limited to Rocky Mountain Spotted Fever)
- St. Louis Encephalitis Virus Disease
- Strongyloides
- Tuberculosis (TB) \*\* Identified through a culture or DNA probe in the organ donor or other evidence suggesting TB
- Tularemia
- Varicella / Chickenpox
- Viral Hemorrhagic Fever
- West Nile Virus Disease
- Western Equine Encephalitis Virus Disease
- Yellow fever
- Zika virus
- NOTE: Previously resolved infectious diseases from this list without potential reactivation do not need reporting