

**PAGES UNOS\_2\_000003539-3566**  
**EXTRACTED FROM UNOS 2\_000003499-3645**

# 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.

## Is the sponsoring Committee requesting specific feedback or input about the proposal?

The DTAC is requesting community feedback on the following issues:

- 1.) Vascularized composite allograft (VCA) is a relatively new field in transplant. The Committee is seeking specific feedback on relevant tests that may be reported post-transplant and suggested requirements for communication guidelines.
- 2.) Current policy requires that either OPOs perform donor toxoplasmosis testing or send a tube of blood to the heart center for testing. Anecdotal reports suggest that completion of toxoplasmosis

---

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

testing on a red top tube of blood sent to heart centers is challenging. Further, recent data have shown toxoplasmosis transmissions to non-heart recipients with adverse consequences. Policy does not, however, require positive results completed at the heart center to be communicated to centers transplanting other organs from the same donor. The committee is interested in hearing transplant community experiences with toxoplasma testing. Specifically, the committee is considering proposing that OPOs conduct toxoplasmosis testing for all deceased donors. This would be more consistent with other testing and promote safe practice for all recipients, particularly for non-heart recipients that we now know can be negatively impacted and die from donor-derived toxoplasmosis infection.

# Improving Post-Transplant Communication of New Donor Information

*Affected Policies:* Policies 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 - 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 evident 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. Data have shown significant increases in reporting since that time, yet some of the increased reporting has not led to gains in prevention as evidenced by a significant number of reports not reviewed. The manpower required to report and follow-up as is occurring currently may not be the

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

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 non-relevant reports. 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 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 CDC and DTAC collaborated to develop a list of special pathogens that will be maintained and provided outside of policy (**see Exhibit A**). This list is similar to the CDC nationally notifiable list 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. This will allow 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.

The proposal also addresses an emerging issue with toxoplasmosis infections that have been found to negatively impact non-thoracic recipients. This will help address an identified communication gap and reduce potential morbidity and mortality in recipients.

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. 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 healthy 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>3</sup> The FMEA process would highlight potential failure points throughout the process and provide evidence for policy development meant to enhance patient safety.

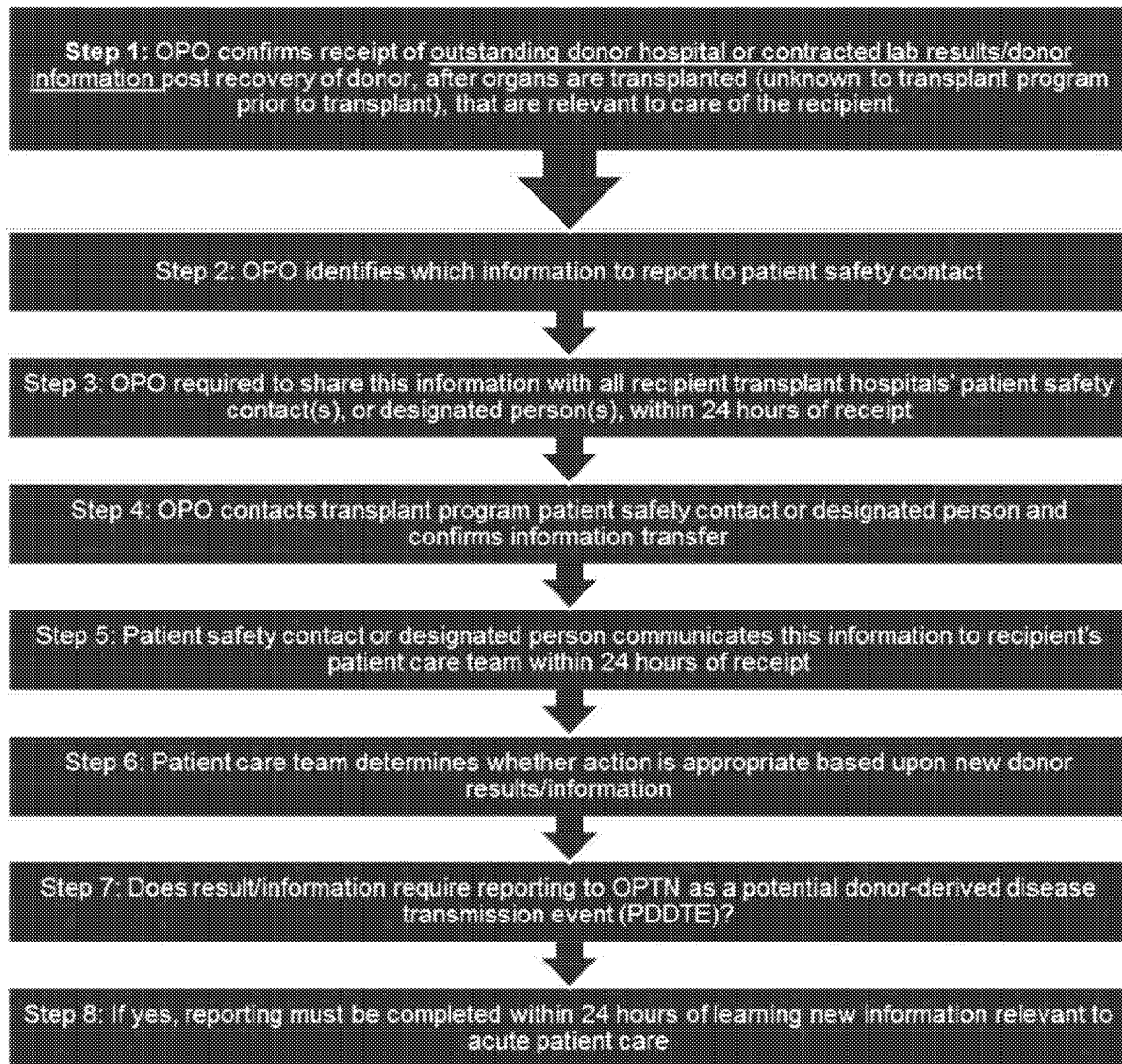
The FMEA was conducted with representatives from the DTAC, OPO, TCC, and TAC to identify latent patient safety risks associated with how new donor information received post-transplant is reported to recipient transplant centers. The FMEA was facilitated by a human factors and quality improvement expert.

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.

---

<sup>3</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>4</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.

---

<sup>4</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. 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>5</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 ( $\chi^2_{11} = 13.13$ ,  $p = 0.0003$ ). 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>6</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 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

---

<sup>5</sup> R Miller et al, 259.

<sup>6</sup> R Miller et al., 261-263.

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>7</sup>

This article was one of the first to detail 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. 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**

	2015	2014	2013	2012	2011
<b>Reports made to OPTN</b>	406	458	391	235	217
<b>Reports chosen for DTAC review</b>	289	278	284	198	181
<b>Reports not reviewed</b>	117	180	107	37	36
<b>% Reviewed</b>	71.2%	60.7%	72.6%	84.3%	83.4%
<b>Donors transmitting proven/probable</b>	N/A <sup>8</sup>	35	32	33	31
<b>Intervention without documented transmission (IWDT)</b>	N/A	63	73	23	34
<b>Unlikely/Excluded</b>	N/A	166	152	128	98
<b>Possible</b>	N/A	14	27	14	18
<b>Donors transmitting proven/probable</b>		12.6%	11.3%	16.7%	17.1%
<b>IWDT</b>		22.7%	25.7%	11.6%	18.8%
<b>Unlikely/Excluded</b>		59.7%	53.5%	64.6%	54.1%
<b>Possible</b>		5.0%	9.5%	7.1%	9.9%

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 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

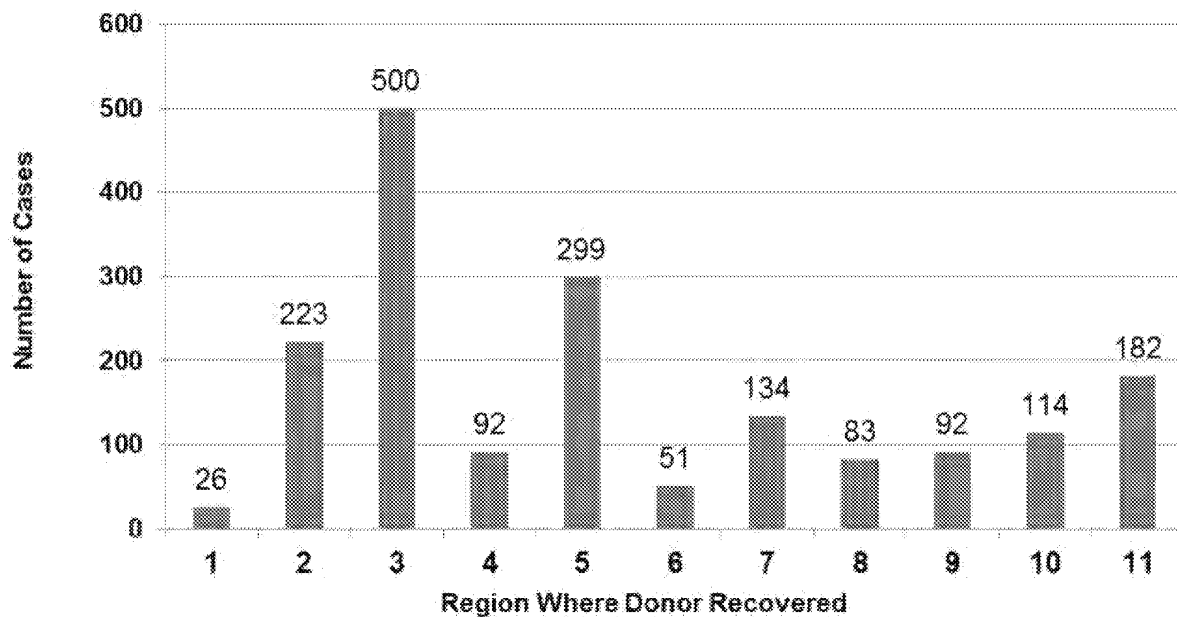
<sup>7</sup> Ibid.

<sup>8</sup> Analysis of all 2015 cases has not yet been completed.

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**).

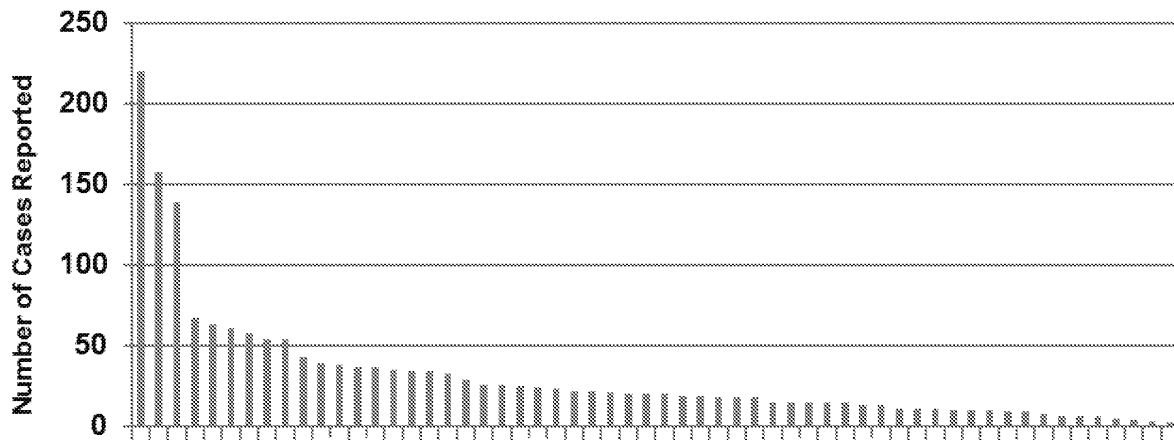
**Figure 2. Total Deceased Donor Cases Reported to OPTN by Region of Donor Recovery, 2006-2014**



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 OPO is evident as well in **Figure 3**. All OPOs 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.

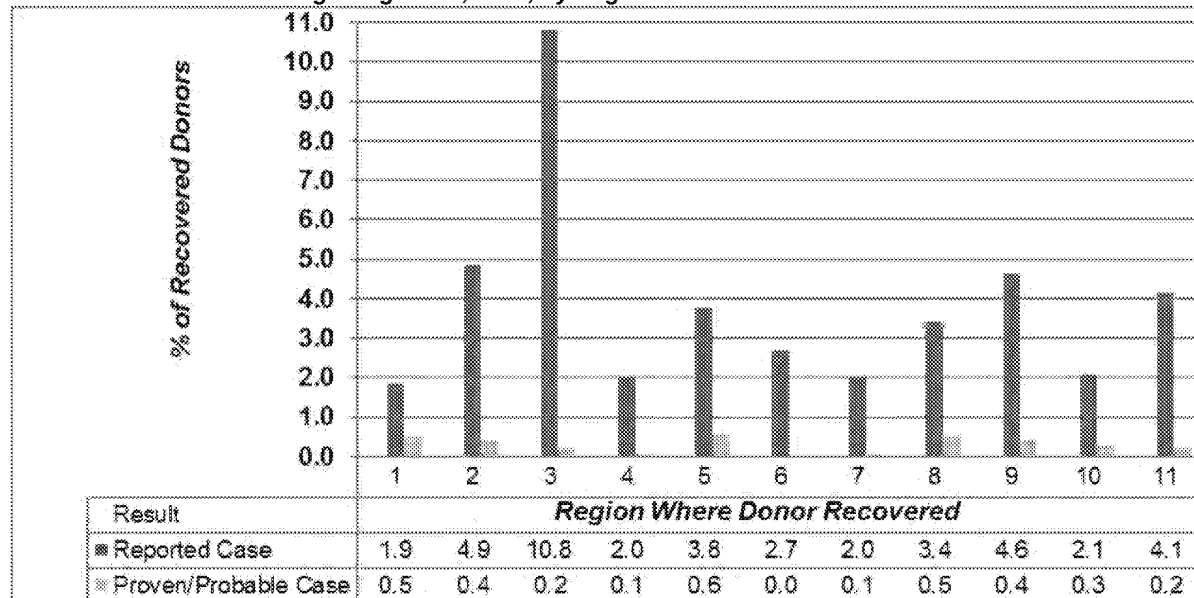
**Figure 3. Deceased Donor DTAC Cases Reported by the Recovering DSA 2006-2014**



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 IWDT cases as these may represent prevented proven or probable cases.

The number of proven/probable cases in any region during the 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 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.

### **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.

Regarding deceased donors between 1/1/08 and 9/8/15, 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. Only one out of 47,149 (0.002%) recipient died from 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 not require programming in UNet<sup>SM</sup>.

## 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:

- Obtaining all results for any deceased donor testing conducted;
- Uploading all deceased donor testing results to DonorNet;
- 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.

Transplant hospitals will need to do the following:

- Report all toxoplasmosis results (including negative results) conducted on deceased donor samples to the host OPO

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

This proposal clarifies that all donor results (including negatives) will need to be reported to the OPTN via upload to DonorNet. 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.

**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 and (example) and language that is proposed for removal is struck through (example).

## Policy 2: Deceased Donor Organ Procurement

### 2.13 Post Recovery Procurement Follow Up and Reporting

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

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

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

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

1. Updates, such as the identification of any potential disease-causing organism and the sensitivity of the deceased donor to that organism, as the host OPO receives the information.
  2. Medical-social history, testing, and laboratory assessments that identify malignant or infectious conditions that may adversely affect a potential transplant recipient.
  3. Any known or suspected infectious or neoplastic conditions that may be transmitted to transplant recipients.
1. Obtain all deceased donor test results and report them to the OPTN Contractor
  2. Report all positive test results and relevant information according to Policy 15.4: Host OPO Requirements for Post-Procurement Test Results and Discovery of Potential Disease Transmissions
  3. Report relevant test results and other information to tissue banks receiving donor tissues

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.

## Notes

- Policy 2.13: Post Procurement Follow Up and Reporting requires host OPOs to obtain all deceased donor test results and report them to the OPTN Contractor. Uploading all test results to DonorNet® meets this policy requirement. See Policy 15.4: Host OPO Requirements for Reporting Post-Procurement Test Results and Discovery of Potential Disease Transmissions for specific types of results that also must be reported to the OPTN Contractor through the Improving Patient Safety Portal.<sup>9</sup>

---

<sup>9</sup> This statement will be added to the notes . Notes do not need OPTN/UNOS Board of Directors approval and are explanatory text rather than enforceable policy

## Policy 15: Identification of Transmissible Diseases

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

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

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

~~When an organ recipient is suspected to have, is confirmed positive for, or has died from a potential transmissible disease or medical condition, including infections and malignancies, and there is substantial concern that it could be from the transplanted organ, then the transplant program must do *both* of the following:~~

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

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

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

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

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

1. All results indicating pathogens of special interest must be reported to the receiving transplant program's patient safety contact *and* the OPTN Improving Patient Safety Portal. The OPTN Contractor provides a list of pathogens of special interest, including any results that can be excluded from reporting. The OPTN Contractor reviews and updates this list at least annually.
2. All other positive test results and relevant information must be reported according to *Table*

15-1 below.

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

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

\*Mycobacterial and fungal (with the exception of *Candida species*) positive results must be reported to the transplant program's recipient of any organ

#### **15.4.B Requirements for Living Donor Recovery Hospital and Host OPOs** **Host OPO Requirements for Reporting Post-Procurement** **Discovery of Recipient Disease or Malignancy**

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.

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

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

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

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

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

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

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

1. Communicate the suspected donor's and affected organ 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 program patient safety contacts and tissue banks that received organs, vessels, or tissue from the donor. This includes any test

results that were not available at the time of procurement or that were performed after procurement. The host OPO must document that this information is communicated to all receiving transplant programs and tissue banks.

2. Report the event to the OPTN Improving Patient Safety Portal as soon as possible but no more than 24 hours after notification or receipt of recipient test results or diagnosis.

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

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

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

### **15.5 Requirements for Post-Transplant Discovery of Donor Disease or Malignancy Transplant Program Requirements for Communicating Post-Transplant Discovery of Disease or Malignancy**

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

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

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

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

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

1. If the findings are from transplant program testing of the donor, then the transplant program must notify the host OPO or living donor recovery hospital of the findings. If toxoplasmosis testing is conducted by the transplant program, then all results, including negative results, must be reported back to the host OPO.
2. Notify the recipients under care at the transplant program, or the recipients' agents, of the risk or confirmation of transmissible disease or malignancy.
3. Document the new information about the donor and potential risk or confirmation of transmissible disease or malignancy in the recipients' medical records.
4. Follow the notified recipients for the development of the disease or malignancy after transplant.

5. Offer the recipients additional testing, monitoring, and treatment as appropriate, in addition to routine follow up care.

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

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

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

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

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

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

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

## **15.6 Living Donor Recovery Hospital Requirements for Reporting Post-Donation Discovery of Disease or Malignancy**

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

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

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



1. Disclose to the living donor that the potential disease transmission or malignancy will be reported to the receiving transplant program and the OPTN Improving Patient Safety Portal
2. Notify the receiving transplant program
3. Report the potential transmission through the OPTN Improving Patient Safety Portal as soon as possible but no more than seven days after receipt of the new information

#### **15.6.B Living Donor Program Requirements for Post-Reporting Follow-Up**

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

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

### **15.67 Open Variance for the Recovery and Transplantation of Organs from HIV Positive Donors**

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

#

**Exhibit A: Pathogens of Special Interest**  
**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
NOTE: Previously resolved infectious diseases from this list without potential reactivation do not need reporting

**UNOS Member Quality Staff Summary  
Improving Post-Transplant Communication of New Donor Information  
DTAC Public Comment Proposal**

The MPSC will review the Ad Hoc Disease Transmission Advisory Committee's (DTAC) public comment proposal "Improving Post-Transplant Communication of New Donor Information" during the MPSC's March 15-17 MPSC meeting. This proposal does not require any changes to the overall OPO site survey process. Site surveyors will continue to review deceased donor records to verify compliance with disease transmission reporting. Surveyors will also review OPO protocols to make sure each OPO has a process for follow up and reporting of test results. Compliance monitoring details can be found under the header "How will members be evaluated for compliance with this proposal?" in the public comment document.

At its October 2015 meeting, the MPSC reviewed a case involving a toxoplasmosis disease transmission. Afterwards, the MPSC sent DTAC a memo suggesting that DTAC consider revising toxoplasmosis testing and reporting requirements. (See attached memo) This policy proposal addresses toxoplasmosis and other testing and reporting requirements. Staff would like the MPSC to review the proposal and provide feedback on whether it addresses the MPSC's previous concerns regarding toxoplasmosis testing and reporting. Additionally, the MPSC should consider whether the proposed language sets out clear requirements that the MPSC would be able to enforce if the MPSC were presented with another disease transmission case.

Please review both the public comment document and the questions below, and be prepared to provide your feedback on the proposal during the meeting.

**Specific feedback requested by DTAC:**

1) Vascularized composite allograft (VCA) is a relatively new field in transplant. The Committee is seeking specific feedback on relevant tests that may be reported post-transplant and suggested requirements for communication guidelines.

2) Current policy requires that either OPOs perform donor toxoplasmosis testing or send a tube of blood to the heart center for testing. Anecdotal reports suggest that completion of toxoplasmosis testing on a red top tube of blood sent to heart centers is challenging. Further, recent data have shown toxoplasmosis transmissions to non-heart recipients with adverse consequences. Policy does not, however, require positive results completed at the heart center to be communicated to centers transplanting other organs from the same donor. **The committee is interested in hearing transplant community experiences with toxoplasma testing. Specifically, the committee is considering proposing that OPOs conduct toxoplasmosis testing for all deceased donors.** This would be more consistent with other testing and promote safe practice for all recipients, particularly for non-heart recipients that we now know can be negatively impacted and die from donor-derived toxoplasmosis infection.

**Additional questions and concerns:**

**Policy 2.13:**

1) The proposal requires OPOs to develop and comply with a written protocol to obtain all deceased donor test results. However, the proposal does not specify what OPOs must include in the protocol and does not specify timelines by which OPOs must obtain the deceased donor test results. Specifically, the proposal removes the word "timely" from policy; "The host OPO is

responsible for timely follow up and reporting of any new or changed deceased donor test results to the relevant transplant programs.” (Lines 9-10)

Should the proposal specify specific elements and timeframes that OPOs must include in their protocols for obtaining test results? If so, what elements do you recommend including in policy?

Consider this scenario: An OPO creates and follows its protocol for obtaining deceased donor test results. The OPO follows its protocol, obtains a test result according to its policy, and reports it to transplant programs. However, the test result was available for a period of time before the OPO obtained the results, and a recipient contracts a disease before the OPO notifies the transplant program of the results. What impact would the proposed language have on the MPSC’s review of this case and ability to take action against the OPO, if desired? Would the MPSC feel comfortable citing this policy?

**Policy 15.4.A:**

2) The list of special interest pathogens, which was developed in collaboration with the CDC, will not be included in policy. However, the proposal requires an OPO that receives post-procurement results indicating one of these pathogens to report the results to receiving transplant programs and the OPTN Improving Patient Safety Portal within 24 hours of receipt. The specific location for this document has yet to be determined, but options include one of the OPTN/UNOS websites or one of the OPTN computer systems (such as the patient safety portal). Do you have any concerns about members’ ability to report results as required if the list of pathogens is not located in policy?

DTAC will review the list at least once a year and update it as needed, but they may also update the list more frequently if warranted. Operationally, this means that changes to the list will need to be formally tracked so that when the MPSC reviews disease transmission events, the committee will know which diseases were on the list when the transmission occurred. Do you have any concerns about the MPSC’s ability to review disease transmission events under these circumstances? Would the MPSC feel comfortable citing this policy?

3) Is Table 15-1 written clearly enough that members can understand and comply with the requirements?

- The header refers to positive results, but the body of the table also refers to negative histopathology results.
- Several exceptions are written into the table. (See section on fungal cultures and rows with asterisks)

**Policy 15.5.A:**

4) If the DTAC decides the proposal should not include a requirement that OPOs perform toxoplasmosis testing, does the proposed language in policy 15.5.A appropriately address the requirement for transplant hospitals to report the results of toxoplasmosis testing that they perform back to the host OPO?

- Does the policy need to specify a timeframe for reporting the result?
- The policy begins with **“If any new, clinically relevant findings about a deceased or living donor are discovered after transplant,** the transplant program must complete all of the following...” Do you think that the phrase “discovered after transplant” could be a loophole for the reporting requirement? In other words, if the test is resulted before the transplant occurs, will the MPSC be able to hold the transplant hospital accountable if they do not report the test result to the OPO?

**Policy 15.6.A:**

5) Does policy need to specify a timeframe for notifying the receiving transplant program when a living donor recovery hospital learns new information about a living donor during the first two years post-donation that indicates a risk of potential disease or malignancy transmission? (See #2 under Policy 15.6.A)