UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

*Working Together. Saving Lives.*

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*Walter Graham, Executive Director*

**MEMORANDUM**

**TO:** Patient Safety Contacts; OPO Executive Directors; Transplant Administrators

**FROM:** Brian M. Shepard
Assistant Executive Director, UNOS

**RE:** Changes in Case Review and Communications Regarding Potential Donor-Derived Disease Transmission Events (PDDTE) Reported to the OPTN

**DATE:** October 11, 2011

This memo is meant to inform members of important changes to the management and review of donor-derived disease transmission events (PDDTE) reported to the OPTN.

When a potential donor-derived disease transmission event (PDDTE) is reported to the OPTN (as required by OPTN Policy 4.5), UNOS staff acknowledges the report and follows up with the Host OPO and recipient transplant centers to confirm notifications. When a report involves a state or nationally notifiable infectious condition[1], a public health investigation may also be pursued in tandem with the Ad Hoc Disease Transmission Advisory Committee (DTAC) review of the reported event. In the past, members often were asked similar questions or asked to provide the same data to both UNOS and CDC.

The CDC and the Health Resources Services Administration's Department of Transplantation (HRSA DoT) recently developed a working agreement in order reduce the burden on OPTN members for reporting similar information to two different organizations, and to prevent duplication of effort between the CDC and DTAC. While reporting requirements outlined in Policy 4.5 will not change, the state or local public health and/or the CDC will lead and coordinate any reported PDDTE that is flagged as public health investigation.

**As of October 1, 2011**, a public health investigation may be pursued when a PDDTE involves:

- A notifiable disease (as listed by each state. Please be aware of reportable diseases in your specific locale.);
- A disease cluster (i.e. two or more recipients infected); or
- A disease or condition with public health implications (e.g. emerging pathogens, diseases with potential for person-to-person transmission).

Once an event is reported to the OPTN, the Host OPO will remain responsible for notifying all

[1] The CDC identifies nationally notifiable infectious conditions on its website: http://www.cdc.gov/osels/ph_surveillance/nndss/phs/infdis.htm#top. Each state's list of notifiable infectious conditions may vary. Members should review reporting requirements for their state to prepare for this change in PDDTE notification and management.

recipient centers and completing a Potential Disease Transmission Report (PDTR) form as required by policy. If the case review is coordinated by the public health service, a state, local, or CDC representative, will follow up with the OPO and all recipient transplant programs to capture information regarding testing, treatment, and any other details germane to the review of a specific diagnosis. All relevant information collected during the public health investigation will then be summarized and shared with the DTAC in order to complete its review and classify the risk of donor-derived disease transmission for transplant community education and policy development.

In cases where a public health investigation is not pursued, members will still be contacted by UNOS staff for confirmation of PDDTE notification, and follow-up information on the donor and recipient(s) in the same manner currently employed for review of reports by the DTAC and UNOS staff.

All OPTN members are encouraged to familiarize themselves with disease reporting requirements for their state, and understand the pathway for communicating PDDTE to the state or local public health department that has jurisdiction for the reported donor and recipient(s). UNOS staff will alert CDC staff to cases involving potential public health investigation. All transplant programs and OPOs should cooperate immediately when contacted by local, state, and CDC public health officials by providing the requested information, including appropriate contacts, needed for investigating potential donor derived disease transmission events.

**HRSA/CDC Working Agreement on Procedure for Potential Organ Donor-derived Disease Transmission Investigations Involving Public Health Authorities**

I. Initial Report

- OPOs report potential donor-derived disease transmissions into the UNOS Improving Patient Safety portal, as per OPTN policy.
- If there is suspected or diagnosed disease in a DONOR that is a potential transplant transmission involving: 1) a notifiable disease (as listed by states), 2) disease cluster (i.e., two or more recipients infected), or 3) disease or condition with public health implications (e.g., emerging pathogens, diseases with potential for person-to-person transmission), *the OPO* will notify the state or local health department that has jurisdiction where the donor organs were recovered and, in accordance with OPTN policy, also will notify transplant centers to which organs were distributed.
- If there is suspected or diagnosed disease in a RECIPIENT that is a potential donor-derived transmission involving: 1) a notifiable disease (as listed by states), 2) disease cluster (i.e., two or more recipients infected), or 3) disease or condition with public health implications (e.g., emerging pathogens, diseases with potential for person-to-person transmission), *the transplant center(s)* will notify the state or local health department(s) that has jurisdiction where the affected recipient(s) was transplanted and, in accordance with OPTN policy, also will notify the OPO from which organs were distributed.
- UNOS will notify DTAC members that a new potential donor-derived disease transmission has been reported and will post redacted donor and recipient information on the SharePoint site. DTAC members (including CDC as an ex-officio member) will review the new case to determine if it is of public health significance.

II. Transplant-related Public Health Case

- In order to determine if a case is of public health significance, the following information will be provided to CDC, as requested:
    - If the case is reported by an OPO, UNOS will provide CDC with the contact information of the OPO.
    - If the case is reported by a transplant center, UNOS will provide CDC with contact information of the reporting transplant center and OPO.
    - The OPO will provide CDC with the contact information of all transplant centers that received organs from the donor.
- If the reported event is determined by CDC and/or state/local authorities to be a transplantation-related case of public health significance, CDC will inform the UNOS Patient Safety Coordinator of the decision within five working days of a new potential transmission being posted on the SharePoint site. The UNOS Coordinator will then flag the case as a public health investigation and will alert DTAC members.
- CDC will verify with OPOs and transplant centers that public health authorities were notified.

- DTAC will not need to pursue case ascertainment with the involved OPO and transplant center(s) during the public health investigation; however, DTAC members will have access to any information posted on the SharePoint site.
- DTAC members can choose to discuss such cases, using a UNOS and DTAC email distribution list that excludes CDC. The DTAC chair is welcome to contact CDC if there are concerns or questions about the public health investigation.
- CDC and/or the state/local health department will seek consultation from DTAC representatives through the committee chair as needed, and CDC will include, with the approval of state/local authorities, a DTAC and UNOS representative on investigation conference calls.
- The CDC Office of Blood, Organ and other Tissue Safety will submit a case summary to HRSA upon completion of the investigation. The case summary will include evidence gathered during the investigation to determine whether transmission occurred and an imputability determination.

III. Not a Transplant-related Public Health Case

- If the reported event is determined by CDC and/or state/local authorities not to be a transplantation-related case of public health significance, CDC will inform the UNOS Patient Safety Coordinator that a transplant-related public health investigation will not be undertaken. CDC will notify UNOS of the decision within five working days of a new potential transmission being posted on the SharePoint site.
- The UNOS Coordinator will notify DTAC members who, according to DTAC's mission, "examine individual potential disease transmission cases reported to the OPTN in an effort to confirm transmissions for these cases" not investigated by public health agencies.
- Case discussions among UNOS and DTAC members will use an email distribution list that excludes CDC.
- The DTAC Chair or designee can seek consultation from CDC at any time on cases of concern under DTAC review.
- Though a state/local health department can decline to review a case of possible transplant-transmission, the health department might investigate other aspects of a case (e.g., to follow up on tuberculosis in a recipient determined to have reactivation of old disease that might have exposed others in the community).

IV. DTAC Meetings

For DTAC meetings, the CDC ex-officio representative will summarize completed investigations and DTAC will summarize cases it has reviewed. DTAC, according to its mission, would review the data to provide education and guidance to the transplant community toward preventing future disease transmission and provide input in developing policy to improve the safety of organ donation through reduction of donor-derived transmission.

V. Additional Comments

- As more information about a case is gathered, some flexibility with respect to which entity will follow the case may need to be determined.
- Public health investigations that are multi-state, will be coordinated by CDC.

VI. Long-term Planning

- As OPTN members more actively report suspected cases of disease transmission to the state/local health departments, and as state/local health departments become more educated and skilled in conducting transplantation investigations, the above process can be revisited and modified by HRSA and CDC.
- The goal would be to move toward
    - adopting uniform case definitions and terminology aligned by HHS agency agreement
    - developing a robust Biovigilance system of public health surveillance and regulatory reporting

**Transplant Related Public Health Investigations: Final Case Synopsis**

1. Background
    - Reported condition
    - Dates and events surrounding diagnosis / discovery
2. Donor
    - Events surrounding death
    - Cause of death
    - Pertinent cultures / test results
3. Recipients
    - All organs transplanted:
        - Status and symptoms of infection
        - Pertinent cultures / test results
4. Case determination
    - Proven, Possible, Excluded, Unlikely, IWDT
5. Process concerns noted during investigation
    - Any processes that may have lead to disease transmission that if modified / noted may prevent future transmissions

CDC/HRSA Working Agreement: Response to UNOS questions
(June 17, 2011, with modification to Question 3 response on August 5, 2011)

1. OPTN could create policy saying OPOs need to report to public health, but would OPTN be expected to enforce such a policy?

   HRSA does not expect OPTN to "enforce" such a policy in terms of routine ongoing active data collection but simply include that policy as one of the many items that the on-site reviewers look for when OPTN does periodic site reviews of the OPOs.

2. Would OPTN still have notification responsibility (of reported transmissions to all hospitals involved) if CDC took over investigation?

   HRSA is not confident at this point that local and state public health agencies will necessarily notify all involved recipient hospitals (and the source OPO) in timely enough fashion to assure optimal measures can be implemented for the transplant recipients. We think the UNOS Patient Safety System should continue to make sure that appropriate communications and notifications have been done.

3. There might be concern about quality of follow up reporting and if can be used for policymaking—can UNOS and/or DTAC report back at a time certain about whether the reports are of sufficient quality to meet OPTN needs?

   HRSA addressed this specific concern in our final discussions with CDC. They assured us that they would send a complete final case summary. This could take up to two months to complete in some cases depending on complexity and number of recipients involved. We have already reinforced our expectations with CDC of the timeliness and the completeness of the case summaries that CDC will provide to HRSA. If this appears to be a problem after the first few cases, then HRSA will need to provide that sort of feedback to CDC so they can modify their workflow process.

4. HRSA understands that the UNOS Patient Safety staff does not anticipate any logistical problems with sending only the initial notification to CDC of reported events and then subsequently excluding CDC (per CDC request) from all additional email distributions/discussions with DTAC.

5. Many transplants occur in a different state from the donor and often from each other. Does CDC anticipate that all "multiple-state" cases would be investigated by CDC as considered "of public health importance" (per item in Section V of agreement)?

   HRSA understands that CDC intent in Section V is to clarify that CDC, not the local/state agency, would coordinate any public health investigations that involve OPO and/or hospitals in more than one state (per longstanding custom within the public health community). Unless a case involves a nationally notifiable disease or of sufficient concern to CDC to represent a public health case, simply a "multiple-state" involvement does not in and of itself automatically defer to CDC for public health investigation.

6. If the OPTN determines that a "Category 1" event has occurred that involves a specific reported case, and CDC elects to coordinate a public health investigation based on nationally notifiable disease or public health interest, would OPTN/UNOS be restricted from further inquiries and actions that it would typically take as part of the "Category 1" process?

   HRSA considers "Category 1" process to proceed as usual regardless of whether CDC elects to coordinate a public health investigation or whether the UNOS Patient Safety System staff would process the case for DTAC. There could obviously be situations in which both entities would be conducting independent investigations for different purposes (OPTN policy/transplant safety vs CDC for public health interest) and these processes can proceed independently of each other. This will require some clarification for the involved OPTN members.

7. HRSA and CDC understand this new working agreement will likely involve a learning curve and we do expect to hit some bumps in the road as everybody becomes more familiar with the new process and expectations of various stakeholders. We do anticipate that mutually shared feedback will only serve to improve the process.