



**UNOS Incident Handling: Triage Form**

**Receipt**

Staff completing: [REDACTED] PSP#: [REDACTED] CMRS#: [REDACTED]

IH Receipt date/time: 6/12/2020 6:51 PM Triage date/time: 6/12/2020 7:19 PM

Date/time management notified: 6/12/2020 7:19 PM

**Case Details**

Subject/blinding code: INOP Date of event: 6/12/2020

Reporter/blinding code: Self-reported Donor ID: [REDACTED]

Issue: INOP reporting that while they were busy wrapping up the donor OR, donor hospital staff threw both kidneys in the trash while cleaning up the backtable.

The kidneys were in bags, but the bags were not sealed or tied, so on the advice of INIM, they assumed they were not sterile. The kidneys were declined for research as well and were discarded. [REDACTED] called INOP and talked to them, and explained that they would be getting an inquiry early in the week, and that their current RCA ("hospital personnel were not familiar with the donation process and assumed the kidneys were left on the back table to be discarded") would probably need revisiting.

Does the issue meet any Wakefield Criteria? ☐ No ☐ Yes:

(see back of page)

**Case Type Determination**

☐ **Common** (*absence/low concern for*: direct/high potential for specific harm to identified patient; member action/inaction that led to direct/potential harm; concern harm may occur again in near future; threat to integrity/trust of OPTN; suspicion/allegation of criminal activity; media involvement)

☐ **Exceptional – Huddle required** (describe):

(see back of page)

**Actions and Notifications (huddle required for exceptional cases, optional for common cases)**

Huddle date/time: Attendees\*:

Huddle notes:

| Special Notifications  | Timeframe to notify** | Notes |
|--|-----------------------|-------|
| <input type="checkbox"/> <b>UNOS leadership</b> : CEO, CCO, CMO, GC, MQ Dir., MQ Asst. Dir., Mgr. Pt.Safety, Other (specify) |                       |       |
| <input type="checkbox"/> <b>HRSA staff</b> (if notifying HRSA, <i>must</i> also notify UNOS leadership and MPSC leadership)  |                       |       |
| <input type="checkbox"/> <b>MPSC leadership</b> (if notifying MPSC leadership, <i>must</i> also notify HRSA and UNOS)        |                       |       |
| <input type="checkbox"/> <b>Other</b> (specify)  |                       |       |

\* Huddle must include Manager of Patient Safety and/or MQ Director and/or MQ Assistant Director

\*\* Notification for Wakefield criteria must be within 24-hours to HRSA, MPSC, and UNOS leaders. Any other notification timeframes should be discussed with manager, but must not exceed next business day after the preliminary investigation is complete.

**Wakefield Criteria: Events must be reported to HRSA, MPSC, and UNOS Leadership within 24 hours**

1. Transplant of the wrong organ into an organ recipient.
2. Near-miss transplant of the wrong organ into an organ recipient.\*
3. Transplant into the wrong organ recipient.
4. Near-miss transplant into the wrong organ recipient.
5. Suspected or confirmed HIV transmission from a deceased or living donor to a recipient.\*\*
6. Any complaint, issue, or concern that may pose a serious or time-sensitive threat to public health or patient safety (including failure to provide a safe environment to patients), regardless of whether there is a suspected or actual violation of OPTN policy or the OPTN final rule.
7. Living donor death, regardless of the time period after surgery and regardless of the cause of death.
8. Failure of a native organ in a living organ donor.
9. Evidence of an attempt to deceive the OPTN or the Department (e.g., falsifying medical records).
10. Use of a device for a condition, diagnosis, or procedure that is contraindicated by the Food and Drug Administration (FDA).
11. Any "Never Event," as included in the Centers for Medicare and Medicaid Services' (CMS) policies for selected hospital-acquired conditions (HAC's), in an OPTN member hospital that impacts transplant patients or living organ donors (including those under evaluation for living organ donation).

\* A near-miss occurs when the error is not caught before the recipient is brought to the surgery holding area.

\*\* "Suspected" means that there is ample evidence to suggest that an HIV transmission was likely.

**Wakefield Criteria: Events to be reported to HRSA, MPSC, and UNOS Leadership within one business day**

12. Suspected or significant potential of non-HIV disease transmission from a donor to a recipient.\*
13. Any sanction taken by a state medical board or other professional body against a transplant professional working for an OPTN member.

\* "Suspected" means that there is ample evidence to suggest that a transmission was likely.

**Is this case *possibly* Exceptional?**

|  | Yes                      | No                       |
|--|--------------------------|--------------------------|
| <b>Any of the Wakefield criteria</b> [note – Wakefield criteria can be met for Common cases]     | <input type="checkbox"/> | <input type="checkbox"/> |
| <b>Any of the following non-Wakefield Criteria</b> [note – criteria can be met for Common cases] |                          |                          |
| Direct/specific harm to an identified patient or high potential for such harm                    | <input type="checkbox"/> | <input type="checkbox"/> |
| Member action or inaction that led to the specified harm   | <input type="checkbox"/> | <input type="checkbox"/> |
| Concern that harm may occur again in the near future   | <input type="checkbox"/> | <input type="checkbox"/> |
| Threat to the integrity or trust of the OPTN   | <input type="checkbox"/> | <input type="checkbox"/> |
| Suspicion or allegation of criminal activity   | <input type="checkbox"/> | <input type="checkbox"/> |
| Media involvement  | <input type="checkbox"/> | <input type="checkbox"/> |
| Identification of a possibly dangerous product/device that may need to be recalled               | <input type="checkbox"/> | <input type="checkbox"/> |
| Identification of contamination or outbreaks   | <input type="checkbox"/> | <input type="checkbox"/> |
| Situation requiring IH/UNOS/OPTN MPSC involvement to resolve in a timely manner                  | <input type="checkbox"/> | <input type="checkbox"/> |

**MPSC Chairs Conflict of Interest**

██████████ AZUA, CASD, FLMP, SCOP, TXSB, WIDN

██████████ MACH, MALC, MAPB, PACP, PAUP

██████████ NCDU, IAIV, FLUF