Staff Summary

Please note that this accompanying summary information is included to only supplement the original documentation, and assist the Committee members in their thorough review of the source documentation provided in the site survey, desk review or case investigation packet.

Please review the summary of potential policy violations and corrective action plans in the attached packet to determine if a policy violation exists, to determine if the corrective action plan addresses the problem, and to identify an appropriate recommended action. Please provide a basis for your decision in the comments section.

Case Description: Donor hospital staff inadvertently discarded both kidneys into the trash when cleaning the OR prior to INOP staff returning to retrieve the kidneys for packaging. INOP self-reported this event through the OPTN Improving Patient Safety Portal.

Possible Action (based on historical MPSC action in similar cases):

- Notice of Noncompliance for Policy 2.2; or
- Close with no action based on self-reporting.

MPSC History:

- November 2019: Notice of Noncompliance for failing to complete required donor serology testing.
- July 2018: Notice of Noncompliance for failing to provide an accurate anatomical description of an allocated kidney.
- May 2018: Released from Probation. The OPO was placed on probation in December 2016 after UNOS site surveyors identified potential missing elements of brain death documentation in donor charts.
- November 2017: Notice of Uncontested Violation for a late report of a positive post-procurement result for Strongyloides.

Survey Information: A routine on site survey of the OPO occurred on July 24, 2019. After analysis of the program's compliance with OPTN policies using the survey evaluation tool approved by the MPSC, UNOS recommended INOP undergo a focused desk review in six months. The focused desk review occurred on May 4, 2020. No areas of noncompliance were identified, and the review was closed with no action.

OPO Volumes:

Year	Donors Recovered	Organs Recovered
2017	165	686
2018	178	733
2019	198	760
2020	167*	630*

*As of September 22, 2020

Historical MPSC Actions: The MPSC would typically close a self-reported case with no action if the member does not have a history of this noncompliance and addressed the issue through its corrective

action plan. While the member self-reported this event, the corrective action plan does not appear to adequately address the issue. The MPSC may consider closing the case or issuing a Notice of Noncompliance.

Reviewer Comments

Reviewer One: Yes, I vote for a notice of non-compliance. I am concerned about the response to the issue. It does not appear that OPO senior leadership was involved in the RCA. I am also concerned that the corrective action may not be enough to ensure that this issue is not reoccurring. It seems like the time out at the beginning of the case will only be effective if there is not a change in hospital staff prior top the end of the case.

Reviewer Two: Yes, I would support notice of non-compliance. I think the RCA is missing the responsibility of the OPO to ensure the organ is packaged and accounted for throughout case. The CAP focused on the communication opportunities with the hospital staff which is important, but in my opinion, missed addressing other issues the OPO owns and should correct in an effort to prevent this from reoccurring.

Reviewer Three: The OPO self-reported this event and submitted a CAP that focuses on what the hospital should do to prevent further occurrences. in addition to the concerns raised by the other reviewers, I believe the CAP is insufficient in that this event could happen at any hospital, not just the currently involved hospital. What is the OPO's plan to address that? The CAP also does not address problems such as Why were the OPO coordinators all outside of the room while unpackaged kidneys were not packaged? It is the OPO's responsibility to protect the kidneys and I don't see acknowledgment of that. I think it would be useful to engage the committee in a conversation about this event so the transplant center perspective can be included....and their feedback also provided to the OPO so their CAP can be strengthened. On the condition the CAP is improved I would vote for a notice of non-compliance.

Issue Involves: OPO 217427P
Self-Report received from: OPO 217427P

Issue: OPO 217427P self-reported this event through the OPTN Improving Patient Safety Portal.

Donor hospital staff inadvertently discarded both kidneys into the trash when cleaning the OR prior to OPO 217427P staff returning to retrieve the kidneys for packaging.

Relevant OPTN Policy:
2.2 OPO Responsibilities: "The host OPO is responsible for all of the following...10. Preserving, labeling, packaging, and transporting the organs."

Relevant Correspondence:
Inquiry to OPO 217427P - sent on June 16, 2020
Response from OPO 217427P - received on June 30, 2020
Notification letter to OPO 217427P - sent on July 8, 2020

Member Response:

OPO 217427P reported:

- OPO staff involved in this donor recovery included three Organ Recovery Coordinators (ORCs). The liver and kidneys were recovered by the procuring liver team.
- During organ recovery, two ORCs (ORCs 1 and 2) were primarily responsible for documentation of organ anatomy in the OR while the third ORC (ORC 3) completed charting, labeling and packaging in the hallway.
- As the liver team exited the OR, a surgeon asked ORC 3 to escort her to the locker room. ORC 3 escorted the surgeon. When ORC 3 returned to the hallway, ORC 1 was completing the liver packaging.
- After the liver team's departure, ORC 3 communicated that the kidneys needed to be packaged. At that time all three ORCs were outside of the OR. ORC 1 noticed the OR being "aggressively" cleaned and asked ORC 2 to make sure hospital staff were keeping the kidney table sterile.
- Upon return to the OR, ORC 2 discovered that the back table had been torn down. A CST from the donor hospital began searching through the trash. Both kidneys were retrieved from the trash. Both kidneys remained triple bagged and were submerged in preservation solution, however the bags had not been closed.
- ORC 3 informed the AOC who contacted OPO leadership. They decided to seek advice from a local transplant surgeon whose center was primary for the kidneys. The surgeon expressed concern that the kidneys may not have maintained sterility while in the trash since the bags were not closed. The OPO's CMO agreed. OPO 217427P concluded that the kidneys could not be used for transplant or research but kept the kidneys for internal education and training.
- OPO 217427P determined the root cause of the event to be that hospital staff were unaware that the liver and kidneys were going to different locations. Hospital staff assumed the kidneys had been packaged and were taken by the liver team. Contributing factors considered were the hospital staff's rush to prepare the OR for another procedure and the absence of a time-out prior to cleaning the OR.

OPO 217427P corrective actions:

- OPO 217427P added a step to their donor recovery process requiring ORCs to inform hospital OR staff prior to incision of the organs being recovered, that organs may be packaged and depart for transport at different times and that clean-up should not begin until permission is given by the ORCs. Written policies will be revised to reflect this change.

Confidential Information

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Improving Patient Safety

Safety Situation Details

Situation ID [redacted] **Reported 06/12/2020**

The goal of the Improving Patient Safety system is to collect information about safety related incidents occurring system-wide, in order to increase organ utilization and decrease the morbidity and mortality of transplant patients.

What is a Safety Situation?
A situation or activity that affected or could have affected patient safety.

What to report:

- Any patient safety situation
- Any other situation that causes a safety concern from a transplantation, donation, and/or quality perspective.

Please report such situations in a timely manner.

Situation Information

Reporting Institution: * [redacted]**-Independent OPO(Member)**

Type of Safety Event (Choose all categories and subcategories that are applicable): *

- ☐ Communication
- ☐ Data Entry
- ☐ Transportation
- ☐ Packaging/Shipping
- ☐ Labeling
- ☐ Recovery Procedure/Process
- ☐ Transplant Procedure/Process
- ☐ Testing
- ☐ Organ Allocation/Placement
- ☑ Other (please describe in description field below)

The Issue reported involves the following (choose all categories that are applicable): *

- ☐ **Recipient/Candidate**
- ☐ **Donor Organ/Extra Vessels**
- ☑ **Other (please describe in the description field below)**

Date Event Occurred: * 06/12/2020

Detailed Description of the Event: * UNOS ID [redacted] Upon recovery of the liver and bilateral kidneys, ORC 1 was completing liver anatomy with ORC 2 while ORC 3 was organizing TransNet in the hallway and getting ice for shipping box. The liver came out in the hallway with ORC 1 and 2 and ORC 3 had the shipping box set up for it so ORC 1 placed in on the ice and he returned to the OR to finish kidney anatomy with ORC 2. ORCs were still waiting for vessels to officially package the liver. ORC 3 stepped into the OR for a few minutes to obtain nodes/spleen and observed the CST (donor hospital employee) assisting the surgeon with liver flush/packaging. The kidneys were still being recovered at this point by the other two people scrubbed in. ORC 3 returned to the hall to continue charting. Th [redacted] team emerged from the OR and the one woman began asking if ORC 3 could escort her to the locker room so she could change out of her bloody scrubs. ORC 3 walked back to the OR and ORC 1 was packaging the liver for transport. He vocalized that the liver and vessels were going directly on ice while the biopsy was going on top of the bag. ORC 3 watched and responded that it looked good. ORC 3 also made sure documentation made its way into the box before it was closed. Meanwhile, ORC 3 was trying to get the liver surgeon to sign the operative report before leaving and finding an

OR staff member to escort them out. Upon them leaving the hall, ORC 3 realized she hadn't had any kidneys brought out to from them so she vocalized to the teammates that we will need to package kidneys and that she had the rigid containers ready with ice in them. ORC 1 began to scrub and show ORC 2 how to do so as she has not seen it before. While he was doing this, ORC 3 was transmitting kidney anatomy to DonorNet. ORC 1 asked ORC2 if she could make sure the OR team was keeping the kidney tables sterile as he noticed they were aggressively cleaning up. The patient was closed by the liver surgeon so ORC 3 figured they were beginning to un-drape her and get her ready for the morgue but leaving the tables alone. Upon checking with the OR staff, ORC 2 reported that the kidneys were not in the room. ORCs 1 and 3 began looking around to see if they were placed in the cooler by the liver team by mistake but made their way to the room where the CST was frantically pulling garbage out of the trash bin. RN began to help look through garbage at this time and it was discovered that the CST had inadvertently discarded both kidneys while tearing down sterile draping in the OR. The kidneys were recovered from the garbage bin and were noted to still be inside the three bags submerged in Servator H. ORC 3 contacted AOC who informed organ manager , organ director, and CMO. It was decided that we should call Dr [redacted], a kidney transplant surgeon from [redacted]. Upon informing Dr [redacted] of situation, he advised that we cannot confirm whether or not the kidneys maintained sterility while in the trash since the bags were not closed or tied [redacted] offered the kidneys for research, but they were unable to be used for transplant.

Has a root cause analysis (RCA) been completed? ✳ (●) **Yes** ( ) **No** ( ) **In Progress**

Please specify additional details regarding the RCA: An immediate debrief and RCA was performed on 6/12/20. It was identified that the incident occurred because hospital personnel were not familiar with the donation process and assumed the kidneys were left on the back table to be discarded.

Please upload any relevant attachments:

Contact Information

Who at your institution should UNOS contact about this case?

First Name: ✳ [redacted] **Last Name:** ✳ [redacted]

Phone contact (Enter at least one): ✳

Office: ✳ **ext.** **Pager/beeper:** **ext.**

Mobile: [redacted] **ext.** **Other:** **ext.**

Email: ✳ [redacted]

Other contact info:

UNOS Only

Reported by: [redacted]

Initial UNOS Action

Date: ✳ 06/12/2020 **Staff member:** [redacted]

Status: ✳ In process **Urgency:** ✳ Low

Category: ✳ Critical

Potential policy violation: ( ) **YES** ( ) **NO**

Committee notification? ( ) **YES** ( ) **NO**

Type of Safety Event (Choose all categories and subcategories that are applicable):

- ☐ **Communication**
- ☐ **Data Entry**
- ☐ **Transportation**
- ☐ **Packaging/Shipping**
- ☐ **Labeling**