Membership and Professional Standards Committee (MPSC)
Indiana Donor Network (INOP)
Informal Discussion Summary
January 21, 2021

MPSC Members Present: [redacted]

SRTR Staff Present: [redacted]

UNOS Staff Present: [redacted]

Member Name Representatives Present: [redacted]

Informal Discussion Summary

The MPSC chair convened the informal discussion pursuant to Appendix L, Section L.8 of the Bylaws to review a report that donor hospital staff inadvertently discarded kidneys when cleaning the OR, prior to INOP staff returning to retrieve the kidneys for packaging. The chair stated the informal discussion was being conducted under confidential medical peer review, and the entire informal discussion and review process, including all related documents and information, are protected by applicable peer review statutes.

Participants from INOP made their introductions and began their presentation. The director of organ services provided an overview of the donor hospital involved in the case, noting it had fewer than 20 donor recoveries per year but more than 100 referrals annually. The director also provided an overview of the donor characteristics. INOP planned to allocated all organs and vascularized composite allografts (VCA) from this donor, but the heart was ruled out after diagnostic testing. The intestine, pancreas and VCA match runs were exhausted. A non-regional center accepted the liver and agreed to recover both kidneys for a local center.

The director then presented a timeline of the case, noting one INOP organ recovery coordinator (ORC) and one recovery hospital operating room nurse were both in orientation during this case. INOP set up its TransNet[SM] table and coolers outside of the OR at the request of the donor hospital. The recovery hospital needed to leave soon after procurement, and did not complete packaging of the kidneys. By 05:46 on the morning of this event, all INOP staff had left the OR to assist the recovery hospital with liver packaging, and also to escort them to the locker rooms and then to the ambulance bay for departure. At 05:50, two of the ORCs began to scrub back in to package the kidneys. A few minutes later, they noticed hospital OR staff cleaning. The ORCs re-entered the OR and observed the back table was no longer intact and they kidneys were discarded. The ORCs followed INOP's informal escalation process and contacted the

administrator on call (AOC), who then contacted a director. INOP held a conference call with the hospital who was primary for the kidneys and INOP's chief medical officer at that time. The OPO and the hospital discussed the possibility of an antibiotic bath, but deemed the kidneys non-transplantable.

The morning after the case, INOP contacted the executive director of recovery services at the hospital and asked her to participate in a root cause analysis (RCA) of the incident. The RCA occurred within five days. The director of organ services noted in addition to her, three other directors, five managers, and process improvement staff participated, as well as the three ORCs and the AOC who worked on this case. Directors, managers and OR staff from the recovery hospital also participated.

INOP and the donor hospital determined there were several root causes that led to the organ discard. Donor hospital staff were not aware the recovered organs were going to multiple locations, and that the liver procurement team was recovering the kidneys for a local transplant center. Donor hospital staff believed the kidneys were packaged with the liver. Because of this, they did not believe they needed to conduct a time out prior to cleaning the OR, since the liver recovery team had left. When cleaning the back table, hospital staff believed all that was remaining was trimmed fat to be discarded. In addition, donor hospital staff were rushing to clean the OR in preparation for another surgery.

Next, the director of organ services described the corrective actions the OPO and hospital implemented as a result of the RCA. Donor hospital staff will conduct a time-out with any remaining OPO and recovery team members prior to cleaning the OR. Hospital staff members were trained on the time-out process. One donor case has occurred at this hospital since this event, without incident.

In addition, prior to incision, ORCs will inform the OR staff which organs will be recovered and remind them some organs may be packaged and sent for transport at different times. To ensure a similar incident does not occur at another donor hospital, INOP ORCs will inform all donor hospital OR teams that clean up should not begin until permission is given by the ORCs. INOP updated its documentation to reflect these changes. INOP trained its ORCs on the new practices at its organ department meeting in July 2020, and reviewed them again at its organ department meeting in September.

The director then addressed the concerns the MPSC expressed regarding INOP's response to this case. The MPSC expressed concern about the level of senior leadership involvement. The director explained the ORCs immediately notified the AOC, who then notified the manager and director of organ services. An ORC contacted the manager of organ services and the surgical director of kidney transplantation at the accepting kidney hospital, and staff notified the chief medical officer (CMO). The AOC, manager of organ services, and the CMO held a conference call and determined the kidneys were not transplantable. The director of organ services notified the director of business analytics and regulatory compliance and the chief operating officer (COO) of the incident, and the COO notified the president/chief executive officer.

To address concerns regarding OR staffing changes, INOP staff will repeat introductions among all individuals present in the OR if staff changes. INOP staff will re-review anesthesia guidelines if needed; will provide new timeout information regarding clean up and the packaging process; and will explain organs may leave the OR at different times. An ORC will be present during staff changes. This process will be implemented at all INOP donor hospitals, not just the hospital involved in this case.

Next, the director described additional improvements INOP implemented. The OPO is in the process of developing a new time-out form that will include the patient's name and date of birth; the organs to be recovered; which teams will recover and leave with which organs; and whether INOP will reallocate organs

if they are declined in the OR. The form calls for introductions of all individuals present in the OR, including their roles; and stipulates no tables can be broken down without ORC approval. Any family requests for the moment of silence are also included on the form. The completed form is read aloud and provided to the OR charge nurse prior to cross-clamp.

The director of organ services concluded the presentation by stating INOP takes responsibility for the recovered organs and the discard of the kidneys. By self-reporting this incident, INOP acknowledged their noncompliance with OPTN policy. She also expressed INOP's desire that this incident be used as a case study to prevent recurrence at other OPOs, and thanked the subcommittee for the opportunity to participate in the informal discussion.

The MPSC chair thanked INOP for their comprehensive presentation and opened the floor for questions. A subcommittee member asked if it is standard practice for all INOP coordinators to be out of the OR at one time. The director of organ services explained that during recovery, INOP staff is in the room at all times. Post-recovery, there may be times when staff are out of the room if the TransNet table is set up outside. The same subcommittee member commented the MPSC was concerned about the fact that all INOP staff left the room at once, and that INOP did not identify this as a root cause of the incident. The manager of organ services added the OPO acknowledges that during the OR, staff may feel as though they are in the OR when they are actually in an adjacent anteroom, and noted this was discussed during the RCA.

Another MPSC member then asked how INOP is implementing the corrective actions across all cases at all hospitals within their service area, and asked for a timeframe for the implementation of the new timeout form. The director explained the corrective actions, including the huddle and the timeout form, will be used at all donor hospitals. She noted the new in-house organ recovery manager, who recently joined INOP, recommended the form as a process improvement. The form is in the process of being approved internally.

Another MPSC member asked if INOP staff or the recovery team usually packages organs. The manager explained transplant teams typically package the organs, but with allocation changes and varying programs now coming to procure organs, at times the transplant programs either refuse to package the organs, or urgently leave immediately after they procure their organ(s). In this case, the recovering team placed the organs in three sterile barriers, but did not close them. INOP often has to finish this part of the packaging. The MPSC member then asked if INOP discussed not leaving the organ unattended until the bag is closed. He observed that in this case, if the kidneys had been bagged and closed, even if not fully packaged, they could have maintained their sterility after they were placed in the trash. The manager replied that INOP did discuss that if the bags had been closed, sterility may have been maintained.

The chair then noted INOP had significant growth in 2020, and congratulated the OPO for this achievement. He asked if INOP expected this growth to continue in 2021. INOP's CEO noted they had a record year as a result of the way they evaluate referrals, their presence in hospitals, improvements in the way their teams interact with families, and changes to donor management. In response to CMS recommendations, in October 2019 INOP implemented an initiative to improve its processes and increase donors. She stated she believes the results of this initiative are sustainable.

Another subcommittee member agreed INOP has had remarkable growth in its number of donors and recovered organs, and asked if this increase could have contributed to this incident. She observed staff fatigue or case volume could have been a factor. She also asked if INOP had reviewed its staffing models

as a result of this accelerated growth. The CEO replied they have added almost 20 staff members in their hospital services and organ teams in the past year. Because of this, they frequently have new staff in orientation. She agreed with the subcommittee's recommendation that INOP needs to ensure organs are completely packaged before they are left unattended by INOP staff, and that staff must always be present in the OR to safeguard the integrity of the organs.

The MPSC chair concluded the informal discussion by thanking the INOP participants for the work they are doing for donor families and transplant recipients. He explained the MPSC will deliberate on this matter and UNOS Staff will send a summary of the proceedings to the Member.