Indiana Donor Network (INOP)
Ongoing Monitoring 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.

Case Description: Donor hospital staff inadvertently discarded both kidneys 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.

At its meeting in October 2020, the MPSC issued a Notice of Noncompliance and requested an informal discussion in order to offer feedback and process improvement suggestions to the OPO. The MPSC appreciated INOP's self-report and its cooperation with the recovery hospital during the root cause analysis (RCA); however, reviewers were concerned by the lack of INOP senior leadership involvement in the process. Reviewers were also concerned the corrective action plan may not be effective if there was a change in hospital staff prior to the end of a case, or if organ recovery occurred at a hospital other than the one involved in this event. In addition, reviewers noted the RCA lacked acknowledgement of the OPO's responsibility to ensure the organ is packaged and accounted for throughout the case.

The informal discussion took place on January 21, 2021, and included OPO staff who were involved in the case as well as OPO leadership. The OPO presented a detailed timeline of the case; an in-depth review of their RCA and corrective action plan (CAP); and details regarding training and education for OPO staff that resulted from the incident. The OPO also addressed each of the MPSC's concerns listed above. A summary of the informal discussion can be found here.

The MPSC reviewed INOP's updated corrective actions at its meeting on February 24, 2021. Based on its review, the MPSC voted to continue to monitor INOP.

The MPSC recommended INOP consider the following additional actions:

- Develop a chain of custody for all organs
- Conduct a policy review that takes the OPO's growing volumes into consideration
- Develop internal packaging standard operating procedures to promote consistent packaging and mitigate risk of organ discards

The MPSC requested INOP submit any revised CAP, updated protocols, or policies that result from these recommendations for Committee review. INOP submitted the requested documentation on May 21, 2021.

Items for Consideration

The MPSC will need to determine whether the OPO's response addresses the MPSC's concerns, or if more information is required. If the MPSC believes patient safety issues continue to exist, it may recommend further action.

MPSC History:

- Nov 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

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
2018	178	733
2019	198	760
2020	252	982
2021	129*	473*

*As of July 9, 2021

Supporting Documentation: OPO 217427P Ongoing Monitoring