

UNOS Site Surveyors conducted an on-site review of the OPO in January, 2010. This review had a Clinical score of 98 percent and an Administrative score of 73 percent. The policy violations included OPTN Policies 2.2.3.1 (Evaluation of all donors), 2.2.3.3 (Evaluation of potential liver donors), 5.0 (Documentation of verification of all organ packaging labels), 7.2 (Submission of Deceased Donor Registration Forms within 30 Days), 7.5 (Submission of deceased donor feedback to UNOS within five working days of the procurement date), and 7.6 (Submission of Potential Transplant Recipient Forms to the OPTN within 30 days of the match run date). At its July 2010 MPSC meeting, the committee directed UNOS staff to perform an administrative desk review of the OPO in one year.

DEQ received a complaint regarding the operating procedures of the OPO. After consultation with the MPSC chair, the one year desk review was changed to a full on-site review and moved to March 2011. During this on-site review UNOS staff would investigate the allegations in the complaint. In addition to the randomly selected sample of donors of attachment 1 (critical data), attachment 2 (policy sample) and attachment 3 (DDR validation) UNOS staff reviewed additional donor charts that the complainant had specifically alleged contained potential violations. In addition to the record review the surveyors interviewed the Executive Director, QA Manager, QA Coordinator, and an experienced Procurement Coordinator. Below is a summary of the allegation, and the surveyors findings while on-site.

Donor ID	Allegation	Surveyors Findings
██████	No urine culture No Bilirubin	Results documented in ITransplant, but no hard copy found in chart No direct Bilirubin Total Bilirubin done
██████	No Bilirubin	No direct Bilirubin Total Bilirubin done
██████	No EKG	No EKG
██████	No EKG	No EKG
██████	No urine culture	Culture ordered, no results found
██████	No urinalysis done within 24 hours of cross clamp	No urinalysis done within 24 hours of cross clamp. Last documented U/A done 07/03/10 at 18:20, cross clamp 07/05/10 00:57
██████	No second signature on kidney labels	Kidney label (for right and left kidney) were verified by two signatures
██████	No second signature on kidney labels	Second signatures on labels for enbloc kidneys
██████	No second signature on kidney labels	Left kidney=correct verification Right kidney= not transplanted
██████	OR verification form not signed (internal form used by 38658E)	Surgeon XXXX signed 07/09/09 0310, no signature/date by OPO staff
██████	No blood cultures	No blood cultures
██████	Check organ labels for incorrect donor ID	Labels for R/L kidney, PA, LI, HR had donor ID# WJK201
██████	Surgical damage to the liver	"one of the major vessels was severed"- liver was accepted and transplanted at a transplant center out of this OPO's DSA

The OPO's internal QA monitoring had already identified the majority of the above missing information. These items were documented as missing at the time of final QA, and chart closing.

In all records reviews, UNOS site surveyors verified the following information:

- name of recovering surgeons,
- absence or presence of surgical damage to organs recovered
- completion of the OPO's internal OR verification form

The information reviewed did not present any patterns.

The complaint also addressed concerns over donor [REDACTED] a 52 year old man with history of sleep apnea who was found [REDACTED] unresponsive. The complainant, a coordinator at the OPO, alleged that the donor was not properly pronounced brain dead. Per the allegation, the chart had two notes, one of which was an apnea test that was abandoned due to the donor becoming hemodynamically unstable. The complainant also alleged that the donor moved his head back and forth as he was being transferred from the gurney. The complainant also stated that the CRNA on the case stated they were "dumping Vecuronium" into the patient.

While onsite the reviewers looked at this donor chart. There were two clinical brain death notes by two different physicians (the same that were available for viewing on DonorNet<sup>®</sup>), as is required by state law. There was no apnea test but this may have been contraindicated due to the history of sleep apnea. There was no documentation in the chart concerning movements of the donor during the OPO's care. There was no copy of the anesthesia flow sheet to verify dosages of Vecuronium given. Per the OPO's policy, there is no requirement that the Coordinators obtain a copy of the Anesthesia flow sheet although some of the other donor charts did contain an anesthesia record.