

SFC OPTN Hearing

Exhibit H.61

asked any additional questions. I've explained to [REDACTED] that our objective in inquiring on this event will be to request they tell us what VRL has shared with them. And to also learn if [REDACTED] plans to do anything differently. 2/25/2021 12:00:00 AM

[REDACTED] Member email presented to team at weekly IH meeting with plan to request info from given responsible lab is not OPTN member. All in agreement. 3/2/2021 12:00:00 AM

[REDACTED] Member email Inquiry sent. Response due 3/18/21. 3/4/2021 12:00:00 AM

[REDACTED] Member email Response received. [REDACTED] provides outline summary of actions which includes: Record of Conference between VRL and [REDACTED] administrators. High-level summary of vendor SCAR (supplier corrective action report). SCAR at VRL: staff re-training (no specifics provided), improved oversight of lab operations by lab director (no details), lab review form updated to include verification check of archived sample process. [REDACTED] will conduct onsite visit to verify effectiveness of VRL's corrective actions. [REDACTED] switched onsite audit of VRL from once q 4 years to annual (would perform desk audit in off-years). 3/22/2021 12:00:00 AM

[REDACTED] Member email Reviewed response with team at weekly meeting and recommend closure given [REDACTED] demonstrates compliance with OPTN policy and party responsible for archive disposal is not an OPTN member. Group in agreement. Will send closure. 4/6/2021 12:00:00 AM

[REDACTED] Member email Closure letter sent. 4/8/2021 12:00:00 AM
[REDACTED] Received case. Kidney labeling was switched. The first inner label noted L ki, but inner bag contained R ki, and vice versa. Both accepting centers were able to utilize the kidneys they received, and DonorNet was updated. 6/28/2021 12:00:00 AM

[REDACTED] Inquiry sent. 7/2/2021 12:00:00 AM

[REDACTED] Sent ack on self report from [REDACTED] received 07/01 7/2/2021 12:00:00 AM

[REDACTED] Received call from [REDACTED] - they will have the response to me by the end of the day today. 7/20/2021 12:00:00 AM

[REDACTED] Response received: Outside LI team recovered LI and KIs. Two OHUH staff members in OR - Donation Coordinator (DC), and Organ Recovery Specialist (ORS). Following recovery of LI and KIs, LI packaged, labeled, & verified. KIs ID'd & placed into correct rigid containers. DC then escorted LI team out of OR. ORS completed KI packaging and placed both KIs into large cooler. ORS broke scrub and added KI organ labels, but mislabeled each one. DC returned to OR, where KI packaging & labeling continued using TransNet. Since KIs were not removed from large cooler, neither DC nor ORS noticed the error. Error not found until receiving centers contacted [REDACTED] RCA: [REDACTED] SOP requires two Qualified Health Professionals (QHPs) to complete packaging & labeling process. This was not done. CAP: Entire clinical team of DCs and ORSs notified of deviation by e-mail from Organ Donation Manager (ODM). ODM also held team meeting to review process. Further discussion to take place during clinical team meeting on 7/21. [REDACTED] also included packaging and labeling SOP, as well as verification form (blank). 7/20/2021 12:00:00 AM

[REDACTED] Sent notification for 16.3.B, 16.3.F, 16.5 7/30/2021 12:00:00 AM

[REDACTED] Case received through portal. Phone call to VAFH; spoke with [REDACTED] She indicated that the nodes received with the heart were not labeled which would lead to a potential delay in crossmatching as it's easier to perform with nodes. There was no additional cold time added to the heart; the teams proceeded forward with transplant. VAFH has not communicated this error to [REDACTED]

[REDACTED] Will follow up with [REDACTED] 3/6/2014 12:00:00 AM

[REDACTED] Inquiry sent to SCOP. Response due 3/28/14. Email from [REDACTED] at VAFH; unlabeled cup with nodes identified in the HLA lab; recipient crossmatch was delayed, but negative. Recipient was doing well. 3/14/2014 12:00:00 AM

[REDACTED] Response received. Will review and discuss with group at next weekly meeting. 3/28/2014 12:00:00 AM

[REDACTED] Reviewed response. SCOP verified that the labels were correct prior to procurement and observed the transplant team package and label the heart correctly but did not directly observe the TTM prior to being placed in the container with the heart. Will recommend ppv. 16.4.C-- Internal labeling of blood and TTM and 16.6--Verification of organ and vessel packaging. 4/1/2014 12:00:00 AM

[REDACTED] Reviewed with group at weekly meeting. Group in agreement regarding PPVs. Will send notification letter. 4/2/2014 12:00:00 AM

SCOP [REDACTED] Notification letter sent. Will prepare for July MPSC. 4/9/2014 12:00:00 AM

[REDACTED] Packet posted for PCSC review. Transferred to COA. 5/7/2014 12:00:00 AM

SCOP 79907 FLJM Case reported through the portal. Kidney was accepted by FLJM but was ultimately declined due to added CIT as a result of airline issues.. According to FLJM, the kidney was not found until 0700 at American Airlines at which time, it was sent back to the OPO. Will review with group. 9/25/2015 12:00:00 AM

SCOP 79907 FLJM Reviewed with group at weekly meeting. Will reach out to SCOP to ensure that there is no responsibility on behalf of the OPO and this was truly an airline issue. If so, can close as done with previous cases. 9/30/2015 12:00:00 AM

SCOP 79907 FLJM Email RFI sent to Nancy Kay at SCOP. 10/6/2015 12:00:00 AM

SCOP 79907 FLJM Response received. Reviewed with group at weekly meeting. Email confirmed that SCOP's courier used a different airline than normal, American versus Delta. American had accidentally left the kidney on a luggage tug and by the time it was found, there was too much CIT for reallocation. Reviewed again with group and group in agreement to close. 10/21/2015 12:00:00 AM

Called (reporter of PSP, 843-763-7755) to clarify, as PSP was vague and hard to understand. Clarified that SCOP procured two KIs from one donor for two tx recipients at SCMU. Somehow, laterality was mixed up, most likely during the procurement process, but they are not exactly when or how it happened. 12/17/2015 12:00:00 AM

procured two KIs from one donor, with both set for recipients at SCMU. KIs brought back to OPO office and pumped. What was thought to be L KI was delivered to OR for tx; the tx surgeon realized it was actually the R KI and called the OPO. The OPO brought this surgeon the correct actual L KI. Both recipients ended up being tx with the KIs they were allocated. SCOP believes that the mix up occurred during the procurement process, not the process of placing them on the pump. 12/17/2015 12:00:00 AM

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Inquiry letter sent 12/18/15. Response received 1/5/16. 12/18/2015 12:00:00 AM

Notification Letter sent 1/7/16. 1/7/2016 12:00:00 AM

MPSC packet has been posted for the March 2016 meeting. 1/18/2016 12:00:00 AM

Case received from TXPM; right kidney was delivered when the left kidney had been accepted. Kidney also had anatomical differences than were reported in DonorNet. Both kidneys were ultimately transplanted. Per report, it appears as if SCOP indicated a courier issue what picked up the wrong box. Will review with group. 6/9/2016 12:00:00 AM

Inquiry sent. REsponse due 8/22. 8/8/2016 12:00:00 AM

Response received and reviewed with group at weekly meeting. Group in agreement with recommendation to close as these kidneys were labeled correctly and were directed to the correct place with the courier according to the associated job numbers. The NGL courier sent the incorrect kidney to the a center. Both centers agreed to keep the kidney they received and transplanted the intended recipient as expected. No policy violations have been identified. Case closed. 8/23/2016 12:00:00 AM

The kidney jar was labeled with a dry erase marker and not a permanent marker. The label info had washed off--the TXC declined due to labeling. Kidney was reallocated. Report submitted by both OPO and TNVP. Intake done by Marc. Will review with group. 11/4/2016 12:00:00 AM

Reviewed with group. Group agrees to request photos and confirm that the internal label around the bags holding the kidney jar was labeled correctly. OPTN policy does not require the jars to be labeled themselves...therefore no policy violation has been identified here. 11/8/2016 12:00:00 AM

Received confirmation that the internal tag was the one where the dry erase marker print was washed off. Will send formal inquiry to obtain RCA and CAP. 11/29/2016 12:00:00 AM

Inquiry letter sent; response due 12/16. 12/2/2016 12:00:00 AM

Response received and reviewed with group at weekly meeting. Group in agreement to cite for internal labeling as a dry erase marker was used and it rubbed off the jar. Will send notification and prepare for MPSC. 12/20/2016 12:00:00 AM

Additional response received on 12/29/16 from SCOP regarding their standard practice. Included in MPSC prep materials. Packet posted and case transferred to 1/3/2017 12:00:00 AM

Ex-employee of OPO Initially reported by SCOP ex-employee to HRSA. HRSA called who asked IH about it. At that point, it was being presented as a patient complaint. We referred it to in Patient Services who talked to the person, and it became clear it was not a patient complaint. IH then took over. 12/19/2016 12:00:00 AM

Ex-employee of OPO Ex-employee of SCOP making allegations that SCOP is pushing Organ Recovery Coordinator's to maintain an 80% consent rate, and that those who can't are terminated or threatened with termination. SCOP requires tactics that are unethical, bullying, and harassing.