From: [redacted]
To: [redacted]
Subject: Donor ID AFBP150
Date: Monday, May 6, 2019 3:13:04 PM
Attachments: LQ 210 Brain Death Donor Procedure.doc

Dear [redacted],

Thank you for your letter this morning regarding our root cause analysis (RCA) package from donor [redacted] we sent to UNOS. We truly appreciate the subcommittee's interest in our staff's training on physical examinations of donors and the process by which they alert someone if a suspicious finding appears on physical assessment. The reason we can appreciate this, is because we discussed this for hours, if not days, and did a lot of research on this topic to determine if this was pertinent to the particulars of this case, and whether or not we should include it in our RCA.

Here are the reasons we chose NOT to include it in our RCA:

1. The intensive process we use to perform an RCA results in considerable conversation about many things with many people at the table, but the goal of the RCA is just that—to find the things that are the Root Cause for the problem at hand. We agreed as an executive team and quality committee that staff training and the subsequent physical exam of the patient were not the root cause of the overlooked cancer in the autopsy report. We agreed that the root cause was because:
    a. The Medical Examiner found a suspicious mass and did not notify the OPO.
    b. The Medical Examiner received a pathology report that confirmed malignancy and did not notify the OPO.
    c. The Medical Director of the OPO received the Medical Examiner report four months after the death of the patient and overlooked the mention of embryonal testicular cancer within the report.
    d. The OPO did not have a process in place that had a second person review the autopsy reports.

    Therefore, it was these things that were included in the RCA and addressed with changes and follow up to prevent the problem from ever

occurring again.

2. We had three organ procurement coordinators work on this donor case due to staff relief after a certain number of hours worked. Each time LifeQuest replaces a coordinator, another physical exam is done on the donor. We did include in our RCA that two coordinators documented scrotal swelling. We believe palpation of significantly swollen scrotum to find a 0.4 – 1.8 cm nodule by a coordinator (not a nurse practitioner, PA, DO or MD) would be beyond what is expected of a coordinator even with our extensive physical assessment training that includes visual inspection, auscultation, and manual palpation to a certain degree.

3. The Medical Examiner did not find the mass on palpation; it was on dissection that he discovered it and sent it for pathology. The Medical Examiner's report included in the "External Examination" that "The scrotal sac is markedly edematous..." The "Internal Examination" stated that "The right testis is distorted and enlarged by numerous hemorrhagic nodules ranging from 0.4 - 1.8 cm".

4. LifeQuest called several OPOs to ask if they train and have their staff perform testicular cancer exams, breast cancer exams, oral and anal cancer exams. None of them do. There is a visual inspection and manual exam to some degree—the degree to which they are trained as RNs and RTs. One OPO explained that due to a donor/recipient cancer transmission that was thought to be from a donor breast cancer, they trained their staff (Paramedics, RNs and RTs), to perform breast exams on all female donors. They learned very quickly that many female patients have cystic breasts and they found their coordinators spending hours and hours getting ultrasounds and biopsies, and they began having trouble placing the organs because the transplant centers didn't like the risk now that there was "worry of breast CA". This OPO ceased that practice.

5. There are **no** UNOS policies, CMS standards, or AOPO standards that detail all that should go into a physical exam. Should it include a

comprehensive exam of the testes, a manual vaginal exam to assess ovaries, a speculum exam of the vagina, anal exam to assess the prostate, or even a more in-depth oral exam if the patient has a history of tobacco use? UNOS policy states: "Complete a physical examination of the deceased donor, including the donor's vital signs." We firmly believe we meet or exceed industry standard.

We hope the subcommittee will agree with us that organ procurement coordinator training on physical exams is not a contributing factor in this particular case. We mentioned in the RCA at the bottom of page 5, that "Physical exam training begins during orientation and is ongoing as evidenced in our training records. Our physical exam training is comparable to OPOs throughout the industry." We wanted UNOS to know that this was discussed, but the RCA process brought us to the root, as it should, and this wasn't it. We are confident that items 1. a.- d. above constitute the root cause in this case.

For your reference, attached is our brain dead donor procedure, which does include what the coordinator should do if an abnormal finding is discovered on exam. This can be found on page two under #7.

We are happy to discuss if needed or provide additional information.

Sincerely,

[redacted]

Executive Director/CEO
LifeQuest
[redacted]

LIFEQUEST ORGAN RECOVERY SERVICES

POLICY NUMBER: 210
CATEGORY: CLINICAL
REVIEW: FEBRUARY 2020

SUBJECT: Brain Death Donor Procedure

POLICY STATEMENT: The following standard procedures for the clinical coordinator for all organ donor cases will follow these general guidelines. These guidelines cover the evaluation, consent, medical management, organ allocation, coordination of organ recovery and recovery surgery. The clinical coordinator or family advocate will maintain open lines of communication with the AOC as outlined in the LifeQuest Administrator On-call Policy.

CONTENTS:

1. After completion of donor evaluation and consultation with the administrator on-call and the potential donor has been deemed suitable, the clinical coordinator or family advocate will team huddle with the medical, nursing and other appropriate staff to develop a plan of action (schedule for brain death testing, on-going referral follow-up, family intentions for plan of care, etc.).

2. If brain death has been declared, the family advocate or clinical coordinator and AOC will verify collaboratively that death has been documented and will obtain a copy of the declaration of death note(s). (see LifeQuest Policy Verification of Death)

3. The clinical coordinator will contact the medical examiner to obtain clearance for organ and tissue donation on applicable medical examiner (ME) cases. The procedure for medical examiner clearance will follow the LifeQuest policy regarding the ME.

4. If the patient is deemed not suitable for organ donation, a note to that effect will be written in the progress notes. This information will also be shared with the nursing and/or physician staff caring for the patient. The clinical coordinator or family advocate will then advise the hospital personnel to call the tissue bank per their hospital policy.

5. For patients without a recorded donation directive, the family advocate or clinical coordinator will approach the appropriate person for consent. If the health care surrogate (HCS) or proxy does consent to donation, the family advocate or clinical coordinator will have the appropriate authorization forms signed for organ and/or tissue donation according to LifeQuest policy on obtaining consent. For patients who have executed a donation directive, signed documents for HCS or proxy consent are not necessary. The donation directive will follow LifeQuest's policy on obtaining consent and medical/social history.

    a. A medical/social history (MSH) will be obtained in all donor cases in accordance with LifeQuest policy on obtaining consent and medical social history. The information from the MSH combined with data from the medical record and physical examination will be discussed with the AOC to evaluate if the donor meets PHS increased risk criteria.
    b. All donors are screened in accordance with HIV and other serological testing per UNOS policy and USPHS Guidelines as referenced in LifeQuest policy on PHS increased risk.

6. Contact the appropriate tissue and / or eye bank coordinator on-call if consent is obtained to review medical-social history (donor risk assessment) and make arrangements for tissue recovery after completion of the organ procurement.

LIFEQUEST ORGAN RECOVERY SERVICES

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7. The clinical coordinator will oversee maintenance of the donor and request all necessary organ evaluation consults. A through physical assessment will be performed for all donors after sending serological testing. Additional physical examinations will be performed anytime a new coordinator assumes care of the donor.
    a. All physical assessments must be documented on the body diagram form.
    b. The physical assessment entered in naviGator will be the initial assessment.
    c. All unusual tactile findings will be documented and reviewed with the AOC and/or medical director to determine if there should be further testing done.
    d. Under the direction of the AOC, any visible abnormal finding will be photographed and uploaded to DonorNet for review by the transplant teams.

8. If a case is handed off from a family advocate to clinical coordinator or clinical coordinator to another, the following hand-off procedure will occur:
    a. The family advocate will complete the hand-off report filling in all information associated with the consent discussion and any critical information obtained from the medical record review.
    b. The case hand-off report will be labeled with an approved donor label when report is being passed from one case clinical coordinator to another.
    c. All information within the case hand-off report will be filled in or marked as N/A.
    d. The oncoming clinical coordinator will read aloud the UNOS ID from the DonorNet screen for verification by the off-going coordinator.
    e. The information will be shared verbally between coordinators and all questions answered.
    f. Once report is complete, the oncoming clinical coordinator will contact the AOC and verbalize the UNOS ID and blood type as a second verification.
    g. The case hand-off report will be submitted to QA but not maintained as a permanent part of the donor record.

9. The clinical coordinator will coordinate recovery of all organs and tissue. The coordinator will also place organs for research per LifeQuest's policy on placement of organs for research.

10. The clinical coordinator will contact the donor hospital operating room staff to request a surgical suite and full support staff including anesthesia, scrub tech and circulating nurse. The clinical coordinator will share what organs are being recovered and the approximate time the surgical suite is needed.

11. Once organs have been placed and surgical teams identified, the clinical coordinator will verify non-local surgeon's credentialing by accessing AOPO's credentialing site, ACIN. If a recovery surgeon is not listed as credentialed on ACIN, the clinical coordinator will contact the AOC for direction. Contract clinical coordinators do not have ACIN access, therefore AOC will verify credentials on ACIN prior to OR for any contracted clinical coordinator.

12. When the operating room time is confirmed, the on-site clinical coordinator will order a urinalysis. Final urinalysis results will be documented in the laboratory section of naviGator and in DonorNet.

13. Operating Room Procedures

    a. Specialty services such as pathology will be contacted by the clinical coordinator to inform them of the need for their service and the approximate time the service will be needed.
    b. The clinical coordinator will ensure that at the time of transfer from ICU to OR, the operating room staff is ready to receive the donor.

c. The clinical coordinator will ensure any needed ground transportation from the donor hospital to the airport is provided for incoming teams.
d. Upon arrival to the OR, the clinical coordinator will show the circulating nurse and the anesthesia provider the notes of brain death and the organ donation consent form or donation directive documentation, as appropriate.
e. The clinical coordinator will give the anesthesia provider the LifeQuest anesthesia checklist (see naviGator/forms) and a briefing on overall stability of the donor and what actions that should be taken to treat donor instability.
f. The clinical coordinator will give the anesthesia provider the LifeQuest issued operating room medications (Mannitol, Heparin, as indicated) if available and allowed by the donor hospital.
g. OR medication routine for all donors includes Heparin 300 units/kg, five minutes prior to aortic cross clamp or dosing as instructed by recovery surgeon. For kidney donors, Mannitol 100 grams IV 30 minutes prior to aortic cross clamp or as instructed by AOC will also be administered when medication is available.
h. Surgical recovery of extra-renal organs is the responsibility of the recovering team. The clinical coordinator will provide all requested support for these teams. The clinical coordinator will provide all needed donor documentation in paper or electronic format for each extra-renal recovery team. This will include a copy of the HLA report (screenshot) from DonorNET, the brain death declaration, ABO verification with sub-type when used for organ allocation, organ donation consent and serology results.
i. Pre-Recovery Verification process:
    1) Prior to organ recovery the clinical coordinator will verify with the on-site recovering surgeon the UNOS ID, organ(s) and laterality if applicable and donor blood type (and subtype if used for organ allocation) utilizing the OPTN computer system, donor ID band, donor medical record and/or the source documentation.
    2) If the intended recipient is known prior to organ recovery the clinical coordinator will verify all the following information with the on-site recovering surgeon utilizing the OPTN computer system:
        a. Intended recipient unique identifier
        b. Intended recipient blood type
        c. Donor and intended recipient are blood type compatible or intended incompatible.
j. The clinical coordinator will ask a member of each transplant team to recite the donor's UNOS ID and ABO from the DonorNet print out.
k. The DonorNet print out will be affixed to the wall of the OR nearest to the back table for use by the person(s) responsible for sterile packaging of the organ(s).
l. Lung procurements may require an intra-operative bronchoscopy. The clinical coordinator will ensure a bronchoscope is available in the OR at the time of recovery.
m. Kidney recovery is performed by the liver recovery team, kidney-pancreas recovery team, or a surgeon specific only to kidney recovery depending on individual case circumstances.
n. Biopsy of the liver, kidneys or other intra-operative findings (tumors, lesions) will occur on a individual case basis. The clinical coordinator will make arrangements for pathology services at the donor hospital, if available.
o. Anatomical information for liver and kidneys will be documented according to LifeQuest policy on required documentation.
p. Tissue typing material including mesenteric lymph nodes and splenic tissue (whenever available) will be recovered from all donors. This material, in conjunction with donor blood samples, will be sent with all organs according to LifeQuest policy on packaging and shipment of organs in compliance with UNOS policy.

q. Kidney anatomy and intra-operative information will be relayed by the clinical coordinator to the accepting kidney transplant centers. This may occur via UNOS for kidneys accepted outside LifeQuest local kidney transplant centers.
r. Kidneys will be packaged and shipped according to LifeQuest policy on shipment of organs. Additional required paperwork to include or be uploaded to DonorNet:
    aa. Copy of all operative notes
    bb. Anesthesia flow sheet
    cc. Biopsy reports (if applicable)

14. Coordinator will discard any remaining organs that were procured and unable to be transplanted or sent for research according to LifeQuest policy on discarding organs.

15. It is the policy of the OPO to treat the remains of the donor with dignity and respect. The OPO endeavors to close all wounds in a standard surgical fashion, which is integral to maintaining the funeral arrangements according to the family's wishes.

16. Completion of all required paperwork will follow LifeQuest policies on quality assurance and donor documentation and information.