**Complaint Involves: OPO 38658E**
**Complaint:** Received from a former employee of OPO 38658E

**Issue:** The UNOS Department of Evaluation and Quality (DEQ) received a complaint from a former employee of OPO 38658E concerning the operating procedures at OPO 38658E. As a result of this complaint and as follow-up to OPO 38658E's routine site survey on January 13-14, 2010, DEQ conducted a special on-site survey on March 23-24, 2011. UNOS staff investigated all of the allegations in the complaint, which involved donors from 2007 through 2010. The site survey report addressed potential policy violations concerning the donors who occurred on or after February 5, 2010. This summary addresses potential policy violations concerning the donors who occurred prior to February 5, 2010.

**Relevant OPTN Policy:** OPTN Policy 2.2.4 (former OPTN Policy 2.2.3) Donor Evaluation: "Donor evaluation must be performed or coordinated by the Host OPO…"

OPTN Policy 5.4.1 Internal Labeling Requirements: "The Host OPO is responsible for ensuring that a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ…"

**Site survey findings:**

| Donor ID | Surveyors Findings | Policy |
|---|---|---|
| [redacted] | No urine culture<br>No direct Bilirubin | 2.2.4.1 |
| [redacted] | No direct Bilirubin | 2.2.4.3 |
| [redacted] | No EKG | 2.2.4.4 |
| [redacted] | No EKG | 2.2.4.4 |
| [redacted] | No urine culture | 2.2.4.1 |
| [redacted] | No urinalysis done within 24 hours of cross clamp | 2.2.4.1 |
| [redacted] | No blood cultures | 2.2.4.1 |
| [redacted] | Labels for R/L kidney, PA, LI, HR had donor ID# [redacted] | 5.4.1 |

**Relevant Correspondence:** UNOS sent a notification letter to OPO 38658E on May 6, 2011.

received via email 2/4/11

The end of 2007 – beginning of 2008 – I was taking 1st call and received a page from a coordinator in [redacted] (I believe [redacted]) who called to inform me that one of their donors had come back Hepatitis C core positive. The patient was a nineteen year old drug abuser from whom [redacted] had accepted the. The segmented liver was transplanted into a toddler / very young child with a congenital defect (I believe around the age of 18 months). I notified [redacted] and [redacted] of the information. Additionally, I called to relay the information to Dr. [redacted] (accepting / transplanting surgeon) who responded by telling me that the donor was not positive for Hepatitis and that everything had already been handled. He was in a rush to get off the phone and brushed the situation aside. Later in the week, I asked [redacted] about the situation and I was told that those issues were the responsibility of the transplant center [redacted]. He proceeded by reminding me that we were merely the OPO. I told him that [redacted] contested the information that I had relayed. Once again, I was told that these matters were the responsibility of the transplant center. I was also warned not to repeat the information or share the information of anyone. I was told that, "It never happened". I felt the threat in the undertone and left the discussion feeling very frustrated. I am unaware if the parents of the child were notified of the NAT test results.

On February 28th, 2010 – I was on 1st call and was paged to relieve [redacted] for an organ recovery in the AM on UNOS case ID # [redacted] (A 52 year old Caucasian male – [redacted] – found unresponsive at home by his wife secondary to an acute MI). [redacted] had been working overnight at [redacted] in [redacted] on the case. The patient met clinical triggers and the referral was reported to [redacted] on February 27th, 2010. As customary, I arrived at the [redacted] to pack and load the organ recovery supplies, then pick up the surgeons ([redacted] and [redacted] – fellow/trainee). On the way to [redacted], Dr. [redacted] informed me that we needed to expedite the case. He persisted to assert that his child had a soccer practice/game that he had to be home in time to attend. Upon arrival in the O.R., we discovered that the O.R. staff was not present, the O.R. was not prepared for the case, [redacted] was not present, and the patient was not in the room. Dr. [redacted] became very frustrated by this. I called up to the critical care unit to inquire about the status of the case. I was informed that the patient was on the way to the O.R. The patient was accompanied by hospital staff and [redacted] ([redacted]), [redacted] coordinator in training. The chart was not present with the patient. [redacted] (primary coordinator on the case) was not present either. [redacted] told me that he had been instructed to bring the patient to the operating room and told me that she was finishing up a few things and would be right behind him. When the staff transferred the patient to the hospital gurney (the patient was on the donor registry, in his late 50's, early 60's with a wife and young adult son), the patient moved his head back and forth – as if we had disturbed his sleep. Both surgeons expressed concern over the incident, and Dr. [redacted] expressed concern with the comment, "Is this guy dead?!" I explained that I didn't know anything about the patient. He asked about the chart and [redacted] explained that it was with [redacted]. I announced that I was going to track down [redacted] and the chart to determine how the patient had been pronounced to see if he met the criteria for brain death. When I met [redacted] and reviewed the brain death notes on the chart, I discovered that the there were two notes done, but one was based on an apnea test (standard criteria for the pronouncement of brain death), but it was not completed due to the fact that the donor became hemodynamically unstable

during the exam. The donor never met the criteria to conclusively determine brain death by apnea exam. I entered the O.R. with the chart to share the findings with Dr. [redacted] (procurement surgeon). I was horrified to discover that they had already begun the case and in the process of the recovery. Dr. [redacted] had not reviewed the donor's blood type, brain death notes, or consent form prior to incision which is mandated by UNOS policy to verify the correct patient, consent for the specific organs being recovered, and the blood type. I told Dr. [redacted] to stop and explained that the apnea test was not conclusive. They ignored me and continued with the case. Shortly thereafter, the CRNA managing the patient told me… "I'm having to DUMP Vec (meaning Vecuronium, a paralytic) into this guy to keep him still". Following the case, I showed Dr. [redacted] the ABO, brain death notes, and consent. He signed the mandatory form indicating that he had reviewed the data, and I signed the form indicating that I had showed him the data. I refused to time the form or falsify documentation (the data is supposed to be reviewed and the form is supposed to be signed, dated, and timed prior to incision). On the way back to [redacted], I expressed my anger with Dr. [redacted] and told him what I felt about the situation, explaining that he had completely violated UNOS policy. He apologized profusely. When we arrived back at the [redacted] and in the lab, I contacted [redacted] ([redacted] Administrator) about the incident. He stated that [redacted] had already called him and told him about the events. I talked to him about filing a complaint against [redacted]. Mr. [redacted] responded by threatening me. He stated, "If you file a complaint against Dr. [redacted]… you'll also have to report yourself, because it's your responsibility to show the surgeon the paperwork prior to the recovery." I was infuriated and sick over the incident. Dr. [redacted] knows his responsibilities in surgical recoveries, and I was baffled as to how I could be held accountable for presenting paperwork to a surgeon that was not in my possession. You DO NOT assume responsibility of a case until you have possession / access to the chart. This is standard practice in ALL areas of medicine. I felt threatened, but the message was clear… KEEP YOUR SILENCE. Shortly thereafter I shared the information with [redacted] who explained that he had requested the anesthesia record on the case. On March 12th, 2010 at 12:00 PM CST [redacted] had a private meeting with Dr. [redacted]. I am unsure what the meeting was pertaining to or what issues were discussed, but felt certain the issues presented in the meeting related to policy violations of the case. The personal harassment following this incident became very evident. This incident can be verified by contacting/interviewing the Anesthetist who worked the case. I believe she was deeply affected by the situation.

During the month of December on, or around, the 18th or 19th, the [redacted] violated their own Standard Operating Procedure ([redacted]) by forwarding 144 tissue charts to [redacted] without being passed through the quality assurance division for safety review. This was done in an attempt to rapidly recover funding. They have begun to retrospectively Q.A. these charts to cover up the violation. The best way to identify these charts is to get a list from [redacted] of the charts they received from the [redacted] between December 18th and December 21st. Immediately, after opening a tissue chart you should see two sheets… a Q.A. checklist and a sheet that indicates that the chart has been reviewed. This can also be verified by asking to see the audit log in [redacted] which will show that the paperwork was not done concurrently with the process – SOP / FDA violation.

Other Violations…

ORGAN COMPLAINTS-excluding tissue- am working on 2010- please never reveal who you got this from. Please re-transcribe and do not give in anything with my name. [redacted]
[redacted]-No blood cultures- violates UNOS 2.2.3.1 AND AOC [redacted] 10/29/09

[redacted]/WJX400 10/27/09 Kidney received with Lymph nodes for tissue typing spleen was sent with pancreas
[redacted]

[redacted] 11/23/09 Organ labels have incorrect UNOS ID on them.
[redacted]

[redacted] 12/14/09
[redacted] Liver vessels labeled incorrectly SOP [redacted]

[redacted]- [redacted] did not label liver vessels correctly [redacted]

[redacted] [redacted]- kidney, liver and panc labels had wrong UNOS # at time of procurement and transplant of organs [redacted]

[redacted] ABO Ver not signed by [redacted] PTC as required prior to incision. [redacted]

[redacted]- No EBV testing violates UNOS 2.2.8.1 [redacted]

[redacted]/ WCP234 Shipped liver in a previously used box- box was not wax coated- violates UNOS 5.5

[redacted] R klidney label not initiated by a 2nd person. [redacted].
[redacted]

[redacted] and [redacted] labels not done for kidneys

[redacted] [redacted] left kidney label not initialed by a 2nd person

[redacted]- [redacted] harrased a family for loved one's organs before family had a chance to understand prognosis. When husband wanted some time to talk with his wife- she said she would come back when he wasn't there- family declined donation

[redacted]- Dr. [redacted]- made a comment that one of the major arteries of the liver were severed during the recovery. Liver could not be transplanted

[redacted]- UNOS Violation HBsAb incorrectly documented in [redacted] as [redacted] does not run this test- the wrong info was therefore uploaded in donornet due to this

Education Activities Documentation Failure
[redacted]

Dr. [redacted] commented that the artery to the pancreas was cut and therefore unsuitable [redacted]

[redacted] no urine cultures UNO 2.2.3.1 [redacted]

[redacted]- family mailed incorrect letter about R kidney recipient to be a 41 yr old male- was actually a 34 y old female.

[redacted]- urine culture not collected- [redacted] UNOS 2.2.

[redacted]- no ekg UNOS 2234
[redacted] no ekg unos 2234

[redacted]/XEQ217 Unos labels incorrect ABO was O+ should have been A -ve

[redacted]- [redacted] unos 2.2.3.3- no bilirubin obtained on liver

[redacted] told family they could see their daughter after the organ recovery..... she also pulled up a chair next to the family and started cryting.
[redacted] 8/11/10- no urinalyis performed with 24 hrs x clamp unos 2.2.3.1

[redacted]- assumption made that the family had consented for research. tissue pulled for rsch

Additionally, pay attention to recovery site inspections. There are many charts that reveal that the paperwork is not being done concurrently with the process – SOP violation and FDA regulation violation.

The hospital development data from June 2010 – January 2011 was lost from the database because of the failure to appropriately back-up the system to SOP regulation.

There is a high suspicion of misappropriation of funds taking place at [redacted]. Many employees have expressed their concern. The clinical CPTC's receive a base salary that compensates them for their office time, and a quarterly bonus based on the number of cases worked. This bonus is distributed on the paycheck of the month following the end of the quarter. There is no explanation of benefit on this or formula used to calculate the amount... it just shows up on each coordinator and administrator's check in amounts anywhere from $8,000 - $20,000. We were told that kidneys recovered from cadaveric donors were included in this figure. The majority of transplants performed annually, from deceased donors are kidney transplants which acquisition fees are paid for, in large part, by Medicare money due to recipient disability. The [redacted] Administrator, [redacted] gets the largest portion of this bonus (but does not take ANY call). The amount that he pays himself is extremely elaborate. When a coordinator asks for an explanation for the calculation of this bonus, the explanation of how the payment was determined is refused. Each coordinator gets a post-it note at the end of a quarter with the amount of their bonus hand written. It is included on the following check as a lump sum bonus without explanation of how it is calculated. Over the past year, the Administrator of the [redacted] has managed to pay up to $2,000,000 in mortgage payments (on three houses), as well as additional lease payments on several luxury vehicles. There is a huge amount of money being distributed within the organization under the guise of a "quarterly bonus structure" that is not appropriately accounted for with a itemized calculated explanation of benefits.

There has been talk of an [redacted] "Watergate Scandal" from [redacted] - who was given a quality assurance manager position without any experience, no college education, or the necessary qualifications for the job. He has absolutely no Q.A. experience or any training/education that qualifies him to manage the Q.A. department. When the former Q.A. manager resigned, a Caucasian Q.A. coordinator ([redacted]) was offered the position in January of 2010 before the former Q.A. manager had officially resigned (This is data can be verified, as it has been recorded via voice recording by [redacted] – tissue Q.A. coordinator). By offering his job to [redacted], administration demonstrated their intention to dismiss [redacted] (Quality Assurance Manager) because of his vigilance and dedication to enforce compliance. He can confirm this information, as well as other specifics regarding FDA and SOP violations not identified in this report. He can be reached via the following contact information... [redacted].

After [redacted] declined the position of Q.A. manager, the other two highly trained and educated Q.A. coordinators were "passed over" for the position. Both coordinators are African American and pursued a racial discrimination complaint with Human Resources, and are currently in the process of filing racial discrimination lawsuits (unbeknownst to the [redacted]). [redacted] was hired for the Q.A. Management position. He has absolutely no Q.A. training or experience, no formal education beyond high school, and is not qualified for the position. The [redacted] rewrote the job description to meet his qualifications so that they could justify placing him in his current position. [redacted] is aware of the corruption within the organization and had verbalized knowledge of what he referred to as a "Watergate Scandal".

[redacted] was fired three years ago from his position as the IT support administrator, then immediately rehired after retaining an attorney. He has stated that he has job security due to his knowledge of certain aspects of corrupt processes within the organization.

There are many issues of concern. I was wrongfully terminated as well. I have clear documentation to support my position. I have been a stellar employee of the [redacted]. I am a living kidney donor, and serve on the [redacted], as well as several subcommittees and work groups… including the [redacted] work-group. My passion for donation and dedication to the "cause" made me naturally curious about processes and procedures that seemed extremely suspicious. I was a "question asker" and my work was based on personal morals and ethical standards. This is just a document, journaling the issues that I have identified while working with the [redacted]. Much of this data will fall into your realm of concern and investigation, while other data may not. I am just forwarding the journal of data that is available to me. Our donor families and recipients have a right to ethical processes that protect their health and well-being, as well as preserve the integrity of organ donation.

**Policy 2.2.4 DONOR EVALUATION**. Donor evaluation must be performed or coordinated by the Host OPO. All donor laboratory testing must be performed in an appropriately accredited laboratory utilizing FDA licensed, approved, or cleared serological screening tests. In the event that a required screening test is not commercially available prior to transplant, then a FDA-licensed, approved or cleared diagnostic test is permissible, and the Host OPO must document in the donor record which assay was utilized to assess the potential donor and must also provide this information to the transplant program(s).

Exceptions: Diagnostic testing is NOT acceptable for Anti-HIV.

FDA-approved diagnostic testing IS acceptable for VDRL/RPR.

2.2.4.1 For all potential deceased donors:

- ABO typing (and confirmation as outlined in Policy 3.2.4) with sub-typing for ABO-A donors;
- FDA licensed Anti-HIV I, II (diagnostic testing not acceptable);
- CBC;
- Electrolytes;
- Hepatitis screen serological testing; including HBsAg, HBcAb, and Anti-HCV;
- VDRL or RPR (FDA-approved diagnostic tests are acceptable);
- Anti-CMV;
- EBV serological testing;
- Blood and urine cultures;
- Urinalysis within 24 hours prior to cross clamp;
- Arterial blood gases;
- Chest x-ray; and
- Serum Glucose.

If a Host OPO completes additional testing in addition to what is required in policy for a potential donor, the results of these tests must be communicated immediately to all recipient institutions.

Additional Organ Specific information is required as follows:

2.2.4.2 For potential renal donors:

- Creatinine; and

• B.U.N.

2.2.4.3 For potential liver donors:

• AST;

• ALT;

• Alkaline phosphatase;

• Direct and total bilirubin

• INR (PT if INR not available); and

• PTT.

2.2.4.4 For potential heart donors:

• 12 Lead ECG; and

• Cardiology consult and/or echocardiogram.

**Policy 5.4 INTERNAL LABELING REQUIREMENTS**

5.4.1 Solid organ

The Host OPO is responsible for ensuring that a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ. The OPTN contractor distributes a standardized internal label that must be utilized for this purpose. In addition to the contents of the package, the label information must include the UNOS Donor I.D. and donor ABO type.

UNOS DONATE LIFE
UNITED NETWORK FOR ORGAN SHARING

*Working Together. Saving Lives.*

[redacted]

*Walter Graham, Executive Director*

CONFIDENTIAL MEDICAL PEER REVIEW

May 6, 2011

**VIA FACSIMILE AND CERTIFIED MAIL/RETURN RECEIPT REQUESTED**

[redacted]

Dear [redacted]:

The United Network for Organ Sharing (UNOS) is the facilitator of the Organ Procurement and Transplantation Network (OPTN). The UNOS Department of Evaluation and Quality staff continuously reviews organ allocations for all OPTN members.

The UNOS Department of Evaluation and Quality received a complaint regarding the operating procedures of [redacted]. As a result of this complaint and as follow-up to [redacted]s routine site survey on January 13-14, 2010, DEQ conducted a special on-site survey on March 23-24, 2011. UNOS staff investigated the allegations in the complaint, which involved donors from 2007 through 2010. The site survey portion of the review focused on donors who occurred on or after February 5, 2010. Donors who occurred prior to February 5, 2010 were not included in the site survey report, but are addressed below.

After a detailed review of the information provided by the site survey, the following potential violations of OPTN Policy have been identified:

- Policy **2.2.4** (former OPTN Policy 2.2.3) Donor Evaluation: "Donor evaluation must be performed or coordinated by the Host OPO…"

- Policy **5.4.1** Internal Labeling Requirements: "The Host OPO is responsible for ensuring that a secure label identifying the specific contents (e.g., liver, right kidney, heart) is attached to the outer bag or rigid container housing the donor organ…"

Please see the chart below for more detailed information:

[redacted]

[redacted]

May 6, 2011
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CONFIDENTIAL MEDICAL PEER REVIEW

| Donor ID | Surveyors Findings | Policy |
|---|---|---|
| [redacted] | No urine culture<br>No direct Bilirubin | Policy 2.2.4.1 |
| [redacted] | No direct Bilirubin | Policy 2.2.4.3 |
| [redacted] | No EKG | Policy 2.2.4.4 |
| [redacted] | No EKG | Policy 2.2.4.4 |
| [redacted] | No urine culture | Policy 2.2.4.1 |
| [redacted] | No urinalysis done within 24 hours of cross clamp | Policy 2.2.4.1 |
| [redacted] | No blood cultures | Policy 2.2.4.1 |
| [redacted] | Labels for R/L kidney, PA, LI, HR had donor ID# [redacted] | Policy 5.4.1 |

UNOS will submit this matter to the Membership and Professional Standards Committee (MPSC)/Policy Compliance Subcommittee (PCSC). If you would like to provide any additional information or documentation to the MPSC/PCSC as further detail or explanation, please forward this information no later than **May 13, 2011**. Please note submission of additional information is optional. If you do not respond by May 13, 2011, this matter will be forwarded to the MPSC/PCSC for review as summarized above.

The MPSC/ PCSC will review all the information and determine whether a policy violation occurred. Please be assured that UNOS will blind member specific information, including member name/location, employee names and patient/donor identifying information.

The bylaws and policies, which guide the sequence of allocation and listing practices, were developed after circulation and discussion among organ transplant professionals and patient representatives. OPTN/UNOS Bylaws and Policies have been adopted by the OPTN/UNOS Board of Directors in accordance with UNOS' contract with the Health Resources and Services Administration within the U.S. Department of Health and Human Services. UNOS is responsible under this federal contract for keeping these bylaws and policies current and for monitoring compliance by OPTN members.

The transplant community relies on its member's assistance to improve patient safety and the quality of care for transplant recipients. If you have any questions or need any additional information about the policy compliance process, please feel free to contact me at [redacted]

[redacted]



[redacted]

Sincerely,

[redacted]