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UTMC review finds nurse failed to follow procedures in botched kidney transplant

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A Texas transplant surgeon hired by the University of Toledo Medical Center to review its living-donor kidney transplant program after a viable kidney was thrown into the trash concluded the debacle was the “baffling” act of a nurse who didn’t follow procedures.

“Our review identified no systemic process or team culture which could have indicated the program was at risk of experiencing the noted discard,” wrote Dr. Marlon Levy, surgical director, transplantation, at Baylor All Saints Medical Center in Fort Worth.

“It does indeed seem to be an act of an experienced nurse who did not follow procedures or standard operating-room behavior in her actions, and who was not able to explain her actions. ... Her actions were indeed baffling.”

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Dr. Levy’s six-page report, which was obtained by The Blade on Wednesday, revealed new details about the Aug. 10 surgery in which a kidney was removed from a Toledo man at the hospital and was supposed to be transplanted into his sister.

The organ was inadvertently discarded with medical waste by a part-time nurse, Judith Moore, who resigned Sept. 10. On Monday, UTMC said it had fired Melanie Lemay, a 30-year employee and full-time registered nurse who was the "RN circulator" in the operating room at the time of the incident.

UTMC President Lloyd Jacobs said Wednesday he agreed with Dr. Levy's conclusions about the incident, but he stressed the mistake represented "outlier" behavior, and that UTMC, the former Medical College of Ohio, has a long-standing culture of safety.

"The important thing is we have procedures and checklists and policies and educational efforts in place to try to limit human errors and ameliorate the impact of human error," Dr. Jacobs said.

The two nurses who are no longer employed by the hospital failed to follow just such procedures, he said.

"We did not terminate them or allow them to retire in lieu of termination because they made a mistake," Dr. Jacobs said. "We terminated them because they violated policy."

Dr. Michael Rees, the transplant surgeon who had removed the donor patient's kidney, lost his director's title, but otherwise has not faced disciplinary action and remains a surgeon at the medical center.

"As far as we are able to ascertain, the surgeon did everything absolutely correctly," Dr. Jacobs said, adding that the idea the surgeon is responsible for everything that happens in the operating room is no longer an accurate one. "Surgeons frequently have tunnel vision because of goggles and visual aids. The circulator nurse is supposed to have surveillance of the entire room."

According to disciplinary records released by UTMC on Wednesday, Ms. Lemay had relieved Ms. Moore in the operating room while Ms. Moore went on a lunch break. During that time, the patient's kidney was removed, cleaned, and placed in a slush machine — an apparatus that keeps the organ cool until it is transplanted. When Ms. Moore returned from her break, Ms. Lemay did not update her, the reports state, and Ms. Moore proceeded to remove the contents of the slush machine and flush them down a hopper where liquid waste is flushed into the hospital's waste-collecting system.

"The missing kidney was discovered when the recovery surgeon looked up from the operative field, noticed the empty ice machine, and asked as to the kidney's whereabouts," Dr. Levy wrote in his report.

"The discard was discovered within a short period of time, but two and a half hours had elapsed until the kidney could be recovered from the waste system."

The kidney ultimately was discarded after "extensive consultation amongst clinical leadership of the program and the family, including the donor and recipient. ... The recipient, having been anesthetized but not incised, had been awakened and informed of the events," his report stated.

Joseph Klep, interim director of labor/employee relations at UT, said in his recommendation to fire Ms. Lemay that she had failed to follow several procedures. She did not log off Ms. Moore after she relieved her nor did she log in Ms. Moore's return.

She neglected her duty, Mr. Klep wrote, because she did not update Ms. Moore when she returned.

"From the vantage point of Ms. Lemay in the [operating room] suite, she could have not helped but notice that Nurse Moore was removing items prior to the closing of the patient," Mr. Klep said.

"As circulating nurse, it was Ms. Lemay's duty to stop or halt Ms. Moore from taking items out of the O.R.."

Dr. Levy, in his report, did not single out Ms. Lemay, but said he was "baffled that no other team member saw [Ms. Moore] dismantle the slush machine and remove the contents from the room."

Through her union, AFSCME Local 2415, Ms. Lemay on Monday filed a grievance contesting her termination. The grievance accuses UTMC of "publicly making an example of Ms. Lemay and ... attempting to take the public eye off of the University of Toledo Medical Center's management's responsibility in this case. Ms. Lemay was not the only individual in the O.R. suite, and was not the primary authority figure over the organ that was removed."

UTMC voluntarily suspended its live-donor kidney transplant program after the incident, although Dr. Jacobs said on Wednesday that he's confident it will be reinstated in the next few weeks.

Records released to The Blade indicate the hospital instituted two policies in the weeks after the botched transplant. One states that all contents of the operating room are to remain there "until the patient physically leaves the operating room following a surgical procedure."

The other says staff members may take breaks during a procedure only after they have consulted with the attending surgeon.

New, higher-visibility donor kidney containers also are to be used during procedures along with donor kidney idenitifer signs that are to placed on the slush machine when a kidney is inside.

Also Wednesday, Dr. Jacobs confirmed reports that a number of UTMC employees as well as community members have come forward to offer to be screened as possible kidney donors in the aftermath of the incident.

However, kidney donations cannot be made to a particular patient; they must follow the nationwide registry for patients, experts have said.

"I can't tell you too much detail, but every cloud has a silver lining or two, and this is one silver lining for this cloud," he said.

Officials have declined to comment on the status of the woman who was to receive her brother's kidney, citing privacy laws and the family's desire for privacy.

Dr. Jacobs said he was confident she would receive a kidney through the chain of kidney donations pioneered by Dr. Rees and his Alliance for Paired Donation Inc.

"Ultimately along the chain, this particular patient will receive a kidney," he said.

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The University of Toledo

Kidney Transplant Program (OHCO) Site Visit

30 August 2012

Marlon F. Levy, MD, F.A.C.S. and Irene Woods, BSN, RN, CNOR

INTRODUCTION AND BACKGROUND

On 10 August 2012 near the end of a live-donor nephrectomy at The University of Toledo Medical Center the live–donor kidney, which had been located in a basin in the sterile ice machine of the donor operating room was unintentionally discarded by one of the circulating nurses assigned to the case.

The details of the event are consistently explained by various team members: upon returning from lunch, the circulating nurse for the case began breaking down the "back table" without asking the surgeon/surgical team for clearance. She began by clearing the ice machine which contained the kidney. She inverted the sterile clear plastic drape sheet containing ice, kidney, sterile basin, and surgical sponge. She noted the presence of the basin and removed it from the bag, then took the ice kidney and sponge to the 'hopper', the toilet-like waste-disposal apparatus in the operating suites where liquid waste is flushed into the hospital waste-collecting system. With the contents of the drape in the hopper but not yet flushed, she noted the presence of the sponge and retrieved it, but did not notice that the residual ice contained the kidney, and flushed both ice and kidney. She was not seen by members of the surgical team, anesthesia personnel, or the lunch-relief circulating nurse who had remained in the room and was charting. There had been no hand-off between the two circulating nurses, presumably since they had both stayed in the room. The missing kidney was discovered when the recovery surgeon looked up from the operative field, noticed the empty ice-machine, and asked as to the kidney's whereabouts. The discard was discovered within a short period of time, but $2^{1/2}$ hours had elapsed until the kidney could be recovered from the waste system, with warm ischemia the entire time. After extensive consultation amongst clinical leadership of the program and the family including the intended donor and recipient, the decision was made to discard the kidney. The recipient, having been anesthetized but not incised had been awakened and informed of the events.

The hospital and transplant program leadership took the following actions:

1. Voluntarily inactivates both the live-donor and cadaveric kidney transplant programs August 10.
2. Begins a Root Cause Analysis (RCA) August 10
3. Begins interviews in support of the RCA August 13
4. Reports events and inactivation to OPTN/UNOS promptly.

5. Arranges for external review August 14
6. Reactivates the cadaveric kidney transplant program August 17, after consultation with OPTN/UNOS. The other transplant surgeons have by then returned to Toledo.
7. Undergoes site review by the Ohio Department of Health, on behalf of the Centers for Medicare and Medicaid Services.
8. Modifies or implements new policies and procedures in the Operating Room Department:
    a. Enhanced hand-off communication position to position
    b. Room breakdown policy hard-wired
    c. Implements a dedicated donor kidney container, with a sealed top
    d. Implements a dedicated donor kidney tray, brightly colored and labeled
    e. Conducts staff-wide education on events and policy changes
    f. Case circulating nurse placed on paid administrative leave pending completion of the investigation
    g. Lunch-relief circulating nurse placed on paid administrative leave pending completion of the investigation
    h. Operating Room Administrative Director placed on paid administrative leave pending completion of the investigation
    i. Transplant Program Directorship reassigned pending completion of the investigation
    j. Formal communications on personnel changes and response to event with Operating Room Staff, Chiefs of Surgical Departments, Medical Executive Committee members, Board of Trustees
    k. Employee assistance/counseling offered to Operating Room and transplant Team staff
    l. Convened a task force to oversee implementation of the Corrective Action Plan (CAP) and regulatory response.

REVIEW PROCESS

Interviews were conducted in an administrative conference room of the University of Toledo Health Campus and a conference room in the Department of Urology at the University of Toledo Hospital with personnel listed below. The impression given was one of clear transparency to the events and processes and a genuine drive to program improvement. Additional records, documents, patient charts, and personnel were made available to us without hesitation. We were unequivocally instructed to take as much time as we needed, on this or any other subsequent visits, to be able to arrive at a sound impression of the events and program based upon our inquiry. At the end of the day an exit interview was conducted with senior leadership in which our preliminary conclusions were shared and questions answered.

One of us (MFL) has some familiarity with the transplant program, having made a previous detailed site visit in March of 2011 as part of an effort to improve clinical performance.

INDIVIDUALS INTERVIEWED

The following University of Toledo Medical Center personnel were interviewed, one-on-one or in groups:

1. Jeffrey P. Gold, M.D., Chancellor and Executive Vice President for Biosciences and Health Affairs, Dean of the College of Medicine and Life Sciences
2. Carl Sirio, M.D., Vice President for Medical Affairs/CMIO, Assoc. Dean for Clinical Affairs
3. Scott Scarborough, Ph.D., Senior Vice President and Executive Director/UTMC
4. Norma Tomlinson, Assoc. Vice President, Assoc. Executive Director/UTMC
5. Marge McFadden, Administrator/Hospital Development
6. Melissa Korb, Transplant Administrator
7. Michael Rees, M.D., Ph.D., Professor and Vice-Chair of Urology, Director of Renal Transplantation
8. Andrew Casabianca, M.D., Medical Director, Operating Room
9. Steven Selman, M.D., Chairman, Department of Urology
10. Gerald Zelenock, M.D., Chairman, Department of Surgery
11. Alan Marco, M.D., Chairman, Department of Anesthesiology
12. Tobin Klinger, Associate Vice-President, University Communications and Marketing
13. Vicki Huston, Operating Room Staff
14. Kim Munoz, Operating Room Staff

DOCUMENTS REVIEWED

The following documents were reviewed in detail:

1. Root Cause Analysis Draft Report
2. Policies and Procedures, Live-donor kidney transplantation
3. Operating Room policies and Procedures governing transplants
4. Representative Operating Room record, recent live-donor kidney transplant recipient
5. February 2012 OPTN/UNOS site visit report
6. March 2012 letter from OPTN/UNOS Membership and Professional Standards Committee Chair
7. OPTN/UNOS policy language re: key personnel change reporting requirement
8. CMS regulatory language re: key personnel change reporting requirement
9. Summary of transplant center actions taken in response to events
10. Transplant Quality/Assurance Process Improvement data and documents, calendar 2011
11. Scientific Registry of Transplant Recipients data release July 12 2012 (www.srtr.org) for OHCO (University of Toledo Medical Center) accessed 1 September 2012.

SUMMARY OF VISIT AND RECOMMENDATIONS

The OHCO program is a high-performing veteran program in existence for several decades, with seasoned and senior clinical and administrative leadership. In calendar 2011, 53 kidney transplants were performed (16 live-donor, 37 cadaveric). On 31 December 2011, 223 patients were on the kidney transplant waiting list. The program transplants at a higher than expected rate for cadaveric donors (O = 16.4, E = 10.9, statistically significant), indicating an aggressive clinical stance towards getting recipients transplanted. Survival statistics are robust, as indicated below:

	OBSERVED (%)	EXPECTED (%)
Deceased Donor (1 year) Graft Survival	96.3	92.04
Live Donor Graft Survival (1 year) Graft Survival	95.0	96.68
Patient Survival (1 year)	99.3	96.87

The OHCO program underwent a site visit by UNOS staff on behalf of the OPTN in February of 2012. The clinical score was 96 (passing threshold 90, the administrative score was 55 (passing threshold 90). The low administrative score was due to inaccurate/incomplete data on certain reporting forms, which have since been corrected. The program will undergo a desk audit (off site chart review) by UNOS staff 6 to 9 months from the most recent visit.

The program is under no regulatory sanction or non-routine review by either the OPTN or CMS, and is a member in good standing with the OPTN/UNOS.

Our review identified no systemic process or team culture which could have indicated the program was at risk of experiencing the noted discard. It does indeed seem to be an act of an experienced nurse who did not follow procedures or standard operating room behavior in her actions, and who was not able to explain her actions. We were not able to interview this nurse, as she had been placed on administrative leave. Her actions were indeed baffling. At several steps in the described events seemingly many opportunities would have arisen for her to question the unorthodox nature of the situation she had encountered (basin left in slush machine, usually indicative of the presence of the kidney; lap sponge left in the slush machine, also indicative of the presence of the kidney, presence of the transplanting surgeon still in the operating room of the donor, where he was completing the donor nephrectomy). We do note that she was not drug tested on the day of the event. We are also baffled that no other team member saw her dismantle the slush machine and remove the contents from the room.

None of our conversations/interviews could identify a pattern of behavior among team members which would predicate such a discard risk. We are not aware of any such similar discard previously reported by the transplant community. Yet we note that no hand-off was performed between the two circulating nurses, presumably because both were simultaneously in the room. We also note that the recovery surgeon sometimes takes the kidney to the recipient's room prior to completing the closure on the donor, sometimes leaves the kidney with him in the donor operating room, with no clear explanation as

to the circumstances that dictate one action or the other. We do think the enhanced communication steps and the added high-visibility donor kidney containers/trays detailed above are appropriate responses and will be helpful in preventing such situations in the future, as would eliminating any variability in *how* and *when* the donor kidney is handled/stored/transported to the recipient room, regardless of which surgeon is involved. We reviewed the draft report of the Root Cause Analysis in detail and are in general agreement with the findings and the recommended steps.

While we failed to identify a 'smoking gun' to explain this event, we do have some observations and recommendations that the OHCO leadership may wish to consider as they work to enhance the program:

1. *Work towards more specialization of the nursing/technical staff in the Operating Room.* Transplants is grouped with General Surgery and not a team onto its own. While the case volumes may preclude the creation and maintenance of a dedicated transplant team it would seem some higher degree of specialization is desired. We note that transplant proficiency is deemed to have been attained after a 6-month orientation/probationary period to the General Surgery there is no specific subsequent assessment of proficiency. We note that the nurse involved with this case was a part-time staff, and generally assigned to cystoscopy at that. With 16 live-donor cases a year and some 20 or so nurses on the General Surgery team who might be exposed to transplants it is very likely this nurse would see only one or two of these live donors in a year. With the easy access to sophisticated simulation modules at the University, it should be possible to assess regular (yearly?) competencies on specialized systems such as transplants.
2. *Enhance transplant specific education in the operating room.* We note that any on-going education related to transplants occurs on the Wednesday morning staff meeting. Late staff (11 to 11, for example) is to be educated on a Wednesday afternoon staff meeting, but this afternoon meeting is frequently cancelled due to work load. With the increasing scrutiny brought to bear on strict adherence to transplant regulations (ABO verification, UNOS ID verification, documentation of high risk donors, documentation of ECD donors, documentation of data verification *after* cross-clamp, for example) there is simply a zero tolerance policy on the part of the regulatory oversight, and transplant centers across the country must stay extremely vigilant and be current on all regulations. The administrative leadership of the Operating Room should ensure the educational structure is conducive to this vigilance.
3. *Maintain adequate staffing levels in the operating room.* While we were unable to independently verify these impressions, our visit with OR staff led us to believe several positions were open and that work load amongst the OR staff was high and placing a high degree of stress of stress on the staff.
4. *Strictly enforce hand-off procedures at the time of staff transition in and out of cases in the OR.* We note that this is a key component of the Root Cause Analysis and a corrective action plan, but here again note that the OR staff we interviewed felt that hand-off communication was occasionally lax in the OR.

5. *Provide ongoing support to Transplant administration*
   The Transplant Administrator of the program is relatively new to her position, having been promoted up from a long-standing transplant coordinator position. We note that she continues to have some clinical (occasional) responsibilities as a coordinator. The low administrative score on the recent OPTN/UNOS review is a reminder of the importance of expert and dedicated transplant administration. Availing herself of continuing education opportunities and networking through the OPTN/UNOS will be essential. Ongoing direct patient care by the administrator should be discouraged, as it will distract from the core mission of keeping the program functioning at a high level administratively and in good standing from a regulatory standpoint.
6. *Re-address Transplant team staffing levels*
   Staffing levels, particularly that of nurse coordinators (pre and post-transplants) was an area noted in need of more attention on our site visit in March of 2011. The ratio of patients followed to the number of coordinators continues to be significantly out of proportion to UNOS staffing benchmarks and creates an ongoing stressor to the clinical staff.