Duke's letter about transplant error

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Ms. Deanna Sampson
Director, UNOS Policy Compliance Department
United Network for Organ Sharing
Post Office Box 2484
Richmond, Virginia 23218

Dear Ms. Sampson:

Duke University Hospital has completed the initial phase review of the events related to the heart/lung transplant from donor _____. We provide the following to promote our joint efforts in the peer review of this incident and for the purpose of performance improvement. We have concluded that human error occurred at several points in the organ placement process that had no structured redundancy. The critical failure was absence of positive confirmation of ABO compatibility of the donor organs and the identified recipient patient. The transplant surgeon does not recall receiving or requesting information regarding the donor's ABO type from the procurement coordinator, who released the organs for the specific recipient.

Jesica Santillan is a 17 y/o female with restrictive cardiomyopathy and secondary nonreactive pulmonary hypertension. She had been listed [with] UNOS for heart transplant in January 2002, but following a cardiac catheterization that showed nonreactive pulmonary hypertension and a CT scan that showed no intrinsic lung disease, she was then listed for heart/lung transplantation in May 2002. Patient had a progression of symptoms with frequent syncope with any exertion.

An offering from Carolina Donor Services (CDS) of organs was made in the evening on 2/6/03. The organs were offered to Dr. Milano, the adult heart transplant surgeon on call, for a pediatric heart transplant recipient. Because the potential recipient was a pediatric patient Dr. Milano referred CDS to Dr. Jaggers, the pediatric heart transplant surgeon on call. Dr. Jaggers declined for the specified patient because that patient was not ready for transplant. Dr. Jaggers inquired about hear/lung availability for Jesica Santillan, specifying the patient by name. Dr. Jaggers inquired about the status of the lungs. The organ procurement coordinator stated that he would check this and call back. On the return call, Dr. Davis, the lung and heart/lung adult transplant surgeon on call, then was offered a heart/lung block from this donor for an adult recipient. He declined due to size incompatibility. The organs were then offered by CDS to Dr. Jaggers for Jesica Santillan. Dr. Jaggers accepted the offer. He does not recall ABO typing being discussed with CDS but does recall a discussion of height, weight and cause of death. Arrangements were made for Jesica Santillan to be admitted to the Pediatric ICU and for the harvest team to travel to the donor site to retrieve the organs.

On arrival at the donor site, the harvesting physician, Dr. Lin, examined the organs of the donor and reviewed the donor packet. Dr. Lin judged the organs to be of good quality. He called Dr.

Jaggers and reported the condition of the organs and was directed to harvest the heart and lungs. The organs were transported back to Duke University Hospital a delay due to bad weather.

Once the organs arrived at the Duke University Hospital operating room #7 the recipient's heart and lungs were removed and the donor organs were implanted. Total ischemic time was six hours. This included 30 minutes of warm ischemic time. The organs functioned well for approximately 30-40 minutes after she was removed from bypass. Then the organ function deteriorated and the patient was placed back on cardiopulmonary bypass. Moments later, the OR received a call from the Duke University Hospital Clinical Transplant Immunology Laboratory reporting the transplant was ABO incompatible with the recipient. The team was able to stabilize cardiopulmonary function and again separate from bypass. The patient was closed and transported to the Pediatric Intensive Care Unit.

In response, Duke University Hospital has conducted a thorough root cause analysis of the event and the organ procurement process followed in the pediatric thoracic transplant program. During that review the lack of redundancy was recognized as a weakness. Validation of the ABO compatibility and other key data elements regarding the donor and recipient will now be performed by:
--the transplant surgeon
--the transplant coordinator, and
--the procuring surgeon.

The transplant surgeon will actively confirm the donor and recipient key data elements verbally. During the notification call to the transplant surgeon, the donor key data elements will be communicated. These data elements will be compared to the information in the transplant program's database to confirm blood type compatibility, size compatibility and if there are issues regarding anti-HLA antibodies.

An additional verification will be accomplished via telephone contact with the organ procurement organization placement coordinator by the transplant coordinator.

The procuring surgeon will receive information including but not limited to the ABO type and size about the intended recipient. In the review of the donor packet, the procuring surgeon will verify the ABO compatibility as well as other key elements used to evaluate the suitability of the donor and the organs for the targeted recipient. In addition, the procuring surgeon will complete a verbal verification of the ABO compatibility with the transplant surgeon. This call will be placed, as per current standard, prior to the organ procurement.

The verification processes outlined above were effectively implemented during the re-transplant of the recipient of donor _____'s organs on February 20, 2003.

In addition to the redundant validation put in place, Duke University Hospital is evaluating the information technology supporting access to recipient information. Should that evaluation reveal a need for additional support, resources will be dedicated to meet those needs.

We will continue to examine the organ procurement process for opportunities for additional safeguards. We will monitor the effectiveness of the process changes through our performance improvement program. We believe that the changes we have put in place enhance the safety of the procurement process and should be considered as a national guideline.

Should you require additional information please do not hesitate to contact us.

Sincerely,
William J. Fulkerson, MD
R. Duane Davis, MD