Transplant error finds more at fault

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By Sean D. Hamill / Pittsburgh Post-Gazette

The results of a positive hepatitis C test sat in a living donor's medical record at UPMC for more than two months before her kidney was transplanted into a man who did not have the virus, according to the findings of a federal investigation into the case.

But despite at least six chances to review the test result and possibly stop the transplant because of the potentially lethal hepatitis C infecting the donor, none of the doctors or nurses involved in the case did so, according to the Centers for Medicare and Medicaid Services (CMS) investigation.

Though UPMC has pegged the blame for the bungled transplant on the lead surgeon, who was demoted, and the transplant coordinator, who was suspended, CMS investigators say the transplant nephrologist, who reviewed the donor's condition prior to surgery, also was at fault. It is not known if the nephrologist was also disciplined.

CMS's investigation found UPMC committed two violations that are "condition" level, which is the most serious level and require that CMS do a follow-up with the hospital to ensure it has corrected the problems. CMS also found six lesser violations -- two of them "standard" level and four "element" level.
In the report, UPMC detailed its plan of correction and the various steps it has taken to ensure such a mistake doesn't occur again, most of which included adding additional people and checks and balances.

Dr. Abhinav Humar, UPMC's transplant chief, said Monday in emailed responses to questions: "We are however confident that our plan of correction is sound as it was approved by UNOS."

UNOS is the United Network for Organ Sharing, which oversees the nation's transplant centers and on Thursday gave UPMC to go-ahead to restart its kidney program. It had been closed since May 6, when UPMC voluntarily shut down the program because of the medical error.

The investigation's findings were made following CMS's on-site investigation June 7 and 8 at UPMC Presbyterian-Shadyside hospital -- which is how CMS in its report described the location of the transplant center.

CMS did not have the power to decide if UPMC could continue to do transplants or not. But it does have the power to decide if transplant centers like UPMC's get Medicare funding for surgeries -- a financial blow that could shut down most kidney transplant programs since more than 50 percent of kidney transplants are funded by Medicare.

CMS's investigation found that the donor, a woman who did not know that she was hepatitis C positive, was tested the morning of Jan. 26 and the positive hepatitis C test results came back the same day "with recommended follow-up testing to be completed," according to CMS's report.
That information was found in the donor's medical record. But the report does not indicate if the test was done in-house, when UPMC received the report, or whether the results were returned in a paper form or sent electronically to UPMC's computers.

"From our perspective, it's really irrelevant whether it's from a printout from a computer or written in ink," said CMS spokesman Martin Kennedy.

CMS's mandate is to follow Medicare rules for the standard of care for patients, and the standard of care does not consider what role paper or electronic records played in a medical error, Mr. Kennedy said, just whether the information was documented.

CMS also does not dwell on why something happened, so the report also does not indicate what excuses, if any, the doctors and nurse gave investigators for why they missed the results.

Dr. Humar said Monday in his statements that there was no other explanation for why everyone missed the test result.

Last week, Dr. Humar said that despite UPMC having one of the nation's most celebrated electronic records system, the surgeon and nurse in the case missed the result in the paper record. The paper test result was scanned in and was part of the electronic medical record, he said, but it also was not checked.

Sources have said that there was a highlight on the hepatitis C test result when it was put into UPMC's electronic medical record system but that everyone involved in the case missed it.
After the test result came in Jan. 26, there were two forms in the medical record that should have included the hepatitis C result, but it was never included on them, CMS reported.

There were then two meetings -- Feb. 17 and March 23 -- of the multidisciplinary selection committee to review the donor's status, but she was given final approval at the March 23 meeting, with no documentation of her hepatic C status.

Then on April 1, the lead surgeon in the case -- whom sources say was nationally known laprascopic nephrectomy expert Henkie Tan -- completed a "Transplant Surgery Consultation" note, but he showed no documentation of evidence of a possible hepatitis C result.

The woman's kidney was then removed April 6 and transplanted into the man. The woman and the man are a couple who live together. It is not known if he has been infected with the virus.

UPMC discovered the woman was hepatitis C positive after a follow-up test on April 22 came back on May 2. Four days later, the living donor kidney program was shut down.

Sometime early in the process, the transplant nephrologist met with the patient for an evaluation. UPMC's own policies required the nephrologist to take part so that the donor is "screened and evaluated ... with a complete history and physical examination."

In an interview by CMS investigators, the unnamed nephrologist said he "did not see the living donor patient or review the medical record after the initial visit."
CMS found that this was an element level violation on par with the errors by Dr. Tan and the nurse -- whom sources say is nationally known transplant coordinator Mimi Funovits.

But Dr. Humar said in an email reply to a question that UPMC's practice was for the nephrologist "to review the patient and the results that were available at the time of the initial evaluation. The donor surgeon and coordinator would review the labs that came back later, before verbally presenting it to the committee."

Dr. Humar wrote, "our protocol now has the coordinator, nephrologist and surgeon independently review all the tests when they are back before the patient is presented to the committee."

CMS will make an unannounced return visit to UPMC sometime within the 60 days after the report was completed on June 24.

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