



# Potential Transmission of Viral Hepatitis Through Use of Stored Blood Vessels as Conduits in Organ Transplantation— Pennsylvania, 2009

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Solid organ transplantation sometimes requires the use of blood vessels from a deceased donor as conduits to connect transplanted organ vessels to recipient vessels. Vessels not immediately used are sometimes stored for later use, including vessels collected from hepatitis B virus (HBV) and hepatitis C virus (HCV) seropositive donors; HBV and HCV seropositive vessels can be stored for use in seropositive recipients. In May 2009, HCV was transmitted when a transplant facility inadvertently used a blood vessel conduit from an HCV-seropositive donor in a seronegative recipient. In November 2009, a second transplant facility, the University of Pittsburgh Medical Center (UPMC), identified two cases of potential hepatitis virus transmission from vessel conduits. In December 2009, CDC was asked to assist the local health department in conducting an investigation at UPMC. This report summarizes the results of that investigation, which determined that, although neither recipient of the vessel conduits at UPMC contracted hepatitis, these represented "near miss" incidents in which transmission could have occurred. The storage of vessels from hepatitis-seropositive donors at UPMC and its affiliated Department of Veterans Affairs (VA) hospital was not necessary; vessels from seropositive donors were infrequently used because adequate supplies of vessels from seronegative donors were available. UPMC's prohibition of the storage of vessels from hepatitis-seropositive donors has removed a documented risk factor for viral transmission while not substantially affecting the transplant centers' vessel conduit supply. Evaluation of available national data supports this prohibition. Therefore, CDC recommends that transplant centers discontinue the practice of storing vessel from donors with markers for viral hepatitis, including HBV surface antigen (HBsAg), HCV antibody (anti-HCV), and HBV or HCV detectable by nucleic acid tests.

## **Case Reports**

In September 2009, CDC was notified of an anti-HCV negative patient who, during liver transplantation 4 months earlier, had been given a vessel conduit inadvertently from an anti-HCV positive donor. The potential disease transmission was identified when the United Network for Organ Sharing (UNOS) retrospectively recognized the serologic discordance between the HCV-seronegative recipient and the HCV-seropositive vessel donor. The transplant facility subsequently reported HCV infection in the patient resulting from use of the seropositive vessel conduit.

As a result of this disease transmission, UNOS requested that all transplant centers review HBV and HCV vessel conduit use during May 2006–May 2008. In November 2009, a second transplant center (UPMC) identified two incidents of conduit transplantation from hepatitis-seropositive donors into seronegative recipients. The first was identified as a result of the UNOS inquiry, and the second as a result of an internal audit by UPMC of its vessel conduit use during June 2008–November 2009. CDC and the local health department subsequently were invited to investigate the cases at UPMC. A case was defined as transplantation of a vessel conduit from a hepatitis-seropositive donor into a seronegative recipient at UPMC during May 2006–November 2009.

Case 1. On May 21, 2008, a woman aged 65 years received a cadaveric left kidney transplant for end-stage renal disease secondary to diabetes and hypertension. Pretransplantation, both the kidney donor and kidney recipient were negative HBsAg, hepatitis B surface antibody (HBsAb), and hepatitis B core antibody (HBcAb). However, the donor of the vessel was positive for HBcAb. Laboratory tests on recipient specimens on November 18, 2009, included an HBV surface antibody, surface antigen, and core antibody that were all negative, an aspartate aminotransaminase (AST) of 13 U/dL (normal: 15-37 U/dL), and an alanine aminotransaminase (ALT) of 21 U/dL (normal: 30-65 U/dL). On December 14, 2009, HBV DNA was undetectable at <300 copies. After the error was discovered, hepatitis B vaccinations were administered, but antiviral therapy was not offered because of the lack of clinical or laboratory evidence of hepatitis transmission. More than 1 year after the transplant, the patient remained asymptomatic for infection, and serial testing for hepatitis B markers remained negative.

**Case 2.** On October 21, 2009, a man aged 64 years received a living donor kidney transplant for end-stage renal disease secondary to diabetes and hypertension. Pretransplantation, both the donor and recipient of the

kidney were negative for anti-HCV. The donor of the vessel, however, was positive for anti-HCV. Subsequent testing showed the kidney recipient's serum on November 10, 2009, was negative for anti-HCV and had undetectable (i.e., <30 IU/mL) HCV RNA on November 19. One year after transplantation, the recipient remained asymptomatic for infection, and serial testing for hepatitis C markers remained negative.

## **Public Health Investigation**

CDC assisted the local health department in investigating the events that resulted in transplantation of the two vessel conduits from hepatitis-seropositive donors into seronegative recipients at UPMC. In addition, the effect of discontinuing the storage of hepatitis-seropositive vessels on the availability of stored vessels for transplantation was evaluated.

At UPMC, vessels are collected and stored in a sterile fashion and refrigerated individually in bags with an outer pocket. A donor sheet with ABO blood group and hepatitis serologies is kept in the pocket of each bag, and examination of this sheet before transplantation is the only way to ensure seroconcordance between the vessel donor and organ recipient. At the time the two cases occurred, hepatitis-seropositive vessels were stored alongside hepatitis-seronegative vessels. According to UPMC transplant surgeons, the donor sheet presumably was examined in both cases, but hepatitis serologies likely were overlooked, resulting in HBV and HCV seropositive vessel conduits being transplanted into seronegative recipients.

In a review of vessel conduit use at UPMC and its affiliated VA hospital from January 1, 2008, to December 31, 2009, only two (0.6%) of 331 stored vessels were found to be from hepatitis-seropositive donors at UPMC and only six (9.4%) of 64 at the VA hospital. Two of the vessels were from donors positive for HBsAq, five were from donors positive for anti-HCV, and one was from a donor positive for both HBsAg and anti-HCV. UNOS collects information from all U.S. transplant centers on donor serologic markers for all vessel conduits recovered. According to these data, of 14,144 vessel conduits recovered nationally in 2008 and 2009, 367 (2.6%) were from donors with unknown or positive anti-HCV status, 30 (0.2%) were from donors with unknown or positive HBsAg status, and 644 (4.6%) were from donors of unknown, indeterminate, or seropositive HBcAb status. Even if no overlap of positive hepatitis markers among donors of these stored vessels existed, vessels from seropositive donors would account for only 7.4% of stored vessels nationally.

In addition to vessels from seropositive donors comprising a small proportion of stored vessels, UNOS data indicate that only a small proportion of these stored vessels are actually used. During 2008–2009, a total of 4,946 (72.2%) of 6,852 stored vessels with a documented disposition were not used for transplantations and eventually were discarded. During the same period at UPMC and its affiliated VA hospital, 275 (83.1%) of 331 and 61 (95.3%) of 64 stored vessels, respectively, were stored but not used.

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## **Editorial Note**

This investigation was triggered by the report of HCV transmission through use of a vessel conduit from an HCV-seropositive donor during liver transplantation. Al-though hepatitis transmission did not occur in the two cases described in this report, the error of transplanting a vessel from a seropositive donor into a seronegative recipient was the same in these cases as it was in the case where transmission did occur; the error occurred despite appropriate labeling of vessel seropositivity. These are thus considered important "near miss" incidents in which transmission could have occurred despite appropriate safeguards being in place. Although vessel conduits commonly are considered safe and reliable in transplant surgeries (1–3), they have been linked to disease transmission, resulting in severe illness and death (4).

Current policy regulating the storage and use of vessels is set by the Organ Procurement and Transplantation Network (OPTN) (1),\* which is overseen by UNOS through a contract with the Health Resources and Services Administration. Vessels can be stored for up to 14 days and used when surgical complications arise in recipients who received an organ from the vessel donor or to facilitate transplant in another organ recipient. Vessels designated for organ transplant are only available for organ transplant procedures and are not used for other vascular procedures.

OPTN permits recovery and storage of vessels from hepatitis-seropositive donors because many transplantations occur in patients with markers for hepatitis infection. However, CDC regards this practice as placing seronegative transplant recipients at an unnecessary risk for exposure to viral hepatitis. Based on the investigation of vessel conduit use at UPMC and review of available national data from UNOS, CDC found that vessels from seropositive donors rarely were stored, and removal of these vessels from storage would not result in lack of vessel conduit availability. In fact, several transplant centers nationwide do not store vessels from hepatitis-seropositive donors and have not

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reported vessel shortages from this practice. Some transplant centers might remain concerned about the potential for vessel shortages, particularly in the case of surgical complications that arise in the recipient of the accompanying organ. However, several acceptable alternatives to stored vessel use exist, including use of a recipient blood vessel procured at the time of surgery, and these may be considered if such a situation occurs. Since November 2009, UPMC has prohibited storage of vessels from donors positive for anti-HCV, HBsAg, and HbcAb, and no problems related to vessel availability have been noted.

Based on this investigation, CDC recommends that transplant centers discontinue the practice of storing vessels from donors with viral hepatitis markers. These markers include HBsAg, anti-HCV, or HBV or HCV detectable by nucleic acid tests. This discontinuation would apply to storage of vessels from donors seropositive or nucleic acid–positive, even if their storage was designated for use only with the original organ, because this practice still would not remove the potential for human error resulting in inadvertent use in a seronegative recipient. OPTN currently is considering a binding policy prohibiting storage of hepatitis-seropositive vessels at transplant centers.

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\*Additional information available at http://optn.transplant.hrsa.gov/policiesandbylaws/policies.asp

#### What is already known on this topic?

Donated blood vessels are considered safe and reliable for use as conduits in organ transplantation, but they have been linked in rare instances to disease transmission.

#### What is added by this report?

Current procedures that permit the collection and storage of potentially infectious vessels put patients at risk for hepatitis B and C infection. This risk is avoidable by discontinuing the practice of storing vessels from seropositive donors.

#### What are the implications for public health practice?

By discontinuing the storage of these potentially infectious vessels, the potential for viral hepatitis transmission is reduced greatly without affecting the availability of vessel conduits needed for organ transplantation.