

Perspectives on Creating a Balanced Approach to Organ Transplantation Safety and Availability

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As the Assistant Secretary for Health, I have the honor of advancing a broad portfolio of public health issues on behalf of the Department of Health and Human Services. Organ transplantation safety and availability has been a priority for several decades. In 1984, Congress passed the National Organ Transplant Act to establish the public health infrastructure for organ transplantation in the United States.¹ Since then, advances in the organ transplantation field have improved outcomes, increasing survival for many.² Critical to this entire process is the willingness of individuals to be organ donors. Transplantation for those in need depends upon the altruism of individuals and families of deceased donors to consider organ donation. The accompanying commentary by Kenneth Moritsugu³ in this issue represents one extraordinary example of such generosity and courage.

Organ transplantation should be safe, with the associated transmission of infectious diseases kept as low as possible. This theme gained prominence in the early 1980s when the epidemic of human immunodeficiency virus (HIV) became a significant public health challenge. The U.S. Public Health Service (PHS) then published recommendations to test potential organ and tissue donors for the antibody to HIV in 1985, the same year the test became available in the U.S.⁴ This action dramatically decreased the transmission of HIV through organ and tissue transplantation.

In 1994, prompted by HIV transmission to four organ recipients and three tissue recipients from a common donor,⁵ PHS agencies, representatives from the transplant community, and other interested stakeholders published guidelines that contained recommendations to exclude potential organ and tissue donors who had risk factors for HIV, unless the transplant center determined that the risk of not performing the transplant outweighed the potential risk of HIV transmission. In circumstances involving the consideration of a high-risk donor organ, the guidelines recommended obtaining informed consent from the transplant candidate. The guidelines also recommended testing all recipients for HIV at three months posttransplant.⁶

Two years later, a clarification to the 1994 PHS guidelines was provided in response to concerns that many potential donors who had risk factors for HIV but negative laboratory tests for antibodies to HIV were being unnecessarily

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excluded from donating organs. The updated guidance encouraged transplant centers to consider organs from such donors for transplantation, following an informed discussion of the risks and benefits with the transplant candidate and/or his or her family.⁷

The high demand for organs with little change in availability has now resulted in increasing acceptance of donors with risk factors for HIV, hepatitis B virus (HBV), and hepatitis C virus (HCV), as well as donors who are known to be infected with HBV or HCV. In 2012, organs were recovered from 14,014 donors (living and deceased), with 28,052 transplants performed. However, a considerable number of patients die each year while waiting for an organ. Nearly 118,000 patients are currently on the organ transplant wait list (Unpublished data, Organ Procurement and Transplantation Network, April 2013).

Increasingly, given the overlap of associated risk, organ procurement organizations have used the risk factors listed in the 1994 PHS guidelines to identify donors who are at risk for HBV and HCV infection, in addition to HIV. During the last 20 years, the understanding of the epidemiology of HIV and hepatitis has improved, leading to better identification of risk factors. Laboratory testing has improved along with advancements in technology. In 2008, recognizing the need to update and expand recommendations, the Association of Organ Procurement Organizations requested that the Centers for Disease Control and Prevention take the lead for PHS to revise the 1994 PHS guidelines, including updating the definition of “high-risk donors” and expanding the guidelines to address other infectious diseases. Similar letters of support followed from the United Network for Organ Sharing and the American Society of Transplant Surgeons. The revised guideline that appears in this special issue of *Public Health Reports* represents the best efforts of the PHS agencies, with valuable input from the transplant community.⁸

The PHS guideline in this issue, which is limited to solid organs and blood vessel conduits recovered for transplantation, contains recommendations addressing living and deceased donors, transplant candidates, and

recipients. It focuses on risk factors for HIV, HBV, and HCV infection; laboratory testing of donors, transplant candidates, and recipients; informed consent discussions; collection and storage of donor and recipient specimens; and tracking and reporting suspected or unexpected HIV, HBV, or HCV infections transmitted through transplantation. A section on recommendations for further study outlines gaps in knowledge identified during the systematic review of literature. Addressing these gaps would lead to better analysis of the risks of transmission, the risk and benefits of measures for reducing these risks, and increased early recognition of unexpected transmissions.

The 1994 PHS guidelines have already created a benchmark for patient safety. This updated PHS guideline represents another milestone in that regard. Organ safety and availability should be balanced and carefully considered. The goal should be to reduce the risk of disease transmission as much as is feasible while preserving the availability of the highest-quality organs. Providing the best available information for transplant teams and their patients can guide informed decisions that can save lives as well as improve the quality of life for many.

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