

Where Do We Go from Here?

A look at donor-derived disease transmission

By Michael D. Green, M.D., M.P.H.

Organ transplantation provides life-saving therapy for tens of thousands of individuals. At any given time, there are around 60,000 patients on the active waiting list for deceased donor organs in the United States, and thousands more await organs from living donors.



In a typical year, about 30,000 individuals have a transplant in this country, but more than 6,000 others will die while waiting. Those numbers underscore not only the desperate need to increase the number of registered donors but also illustrate why the unnecessary loss of even a single donor is doubly tragic.

The urgent need for donors must be balanced, though, against the fact that there is a potential risk associated with any donor—living or deceased—and that our abilities to define those risks are far from perfect. Recognition that a donor could be a source of both malignancy and posttransplant infection in the recipient dates back to the early days of transplantation.

Over time, it became routine to screen for the most-common pathogens, such as cytomegalovirus (CMV). Unfortunately, some cases of donor-derived CMV infection are unavoidable. But being aware of the presence of CMV in the donor has served as the primary basis for prophylactic interventions and has led to OPTN policy that requires documentation of the donor's CMV status.

As early as 1994, the Centers for Disease Control and Prevention (CDC) published "Guidelines for preventing transmission of human immunodeficiency virus through transplantation of human tissue and organs," aimed at minimizing the risk of donor-derived transmission of HIV.

EVOLUTION OF OPTN POLICY

OPTN policy evolved to include both required assessment for the risk of HIV transmission as well as specific consent from recipients offered an organ from a donor identified as being at increased risk for HIV despite negative serologic screens.

Over the years, a number of widely publicized reports describing the unexpected transmission of high-profile pathogens, such as HIV, rabies and West Nile Virus, garnered the attention of the transplant community as well as the public. Those disease transmissions prompted additional efforts and further policy development aimed at enhancing our ability to identify donors at increased risk of transmitting pathogens or malignancies to organ recipients.

In the United States, growing concern for the problem of donor-derived disease transmission resulted in the formation of the OPTN/UNOS ad hoc disease transmission advisory

committee (DTAC). Current OPTN policy requires OPOs and transplant centers to notify each other and submit reports to the OPTN's "improving patient safety portal" when there is concern for a potential donor-derived disease transmission event.

DTAC is charged with reviewing those reports—with a goal of generating aggregate data that can be used to help provide education to the transplant community and develop or improve policy to enhance patient safety.

And, based upon DTAC data, we can now begin to quantify the burden of unexpected disease transmission. Between 2008 and 2011, 139 recipients of the total of 113,622 recipients during those years (0.1 percent) experienced a proven or probable donor-derived disease transmission; 29 of those 139 (0.03 percent) died of their unexpected donor-derived disease. While those numbers are low, the loss of even a single recipient to an unexpected disease transmission is tragic.

FURTHER REDUCING RISK

A number of efforts are under way to further reduce the likelihood of unexpected disease transmissions. DTAC continues to review its data to identify opportunities for policy improvement to enhance organ recipient safety. DTAC has reported on its reviews and prepared a number of guidance documents to increase awareness of potential disease transmission among OPOs, transplant centers and clinicians who evaluate potential donors and care for recipients.

In June, the Public Health Service (PHS) published its "Guideline for reducing human immunodeficiency virus, hepatitis B virus and hepatitis C virus transmission through organ transplantation," which updates the CDC's 1994 guideline, which focused only on HIV.

The new guideline is being reviewed by a joint subcommittee comprised of representatives from DTAC and the OPO, living donor, and operations and safety committees to determine whether policy changes are necessary as a result of the update.

Transplantation by its nature is associated with risk. No single effort or policy can completely eliminate the risk in general or the specific risk of unexpected disease transmission from an organ donor. DTAC's goal is to continue to work with the transplant community to reduce the risk of disease transmission and, through our collective efforts, to make transplantation as safe as possible. 

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Visit <http://www.publichealthreports.org> to read the Public Health Service's guideline for reducing HIV, HBV and HCV through transplantation (vol. 128, issue 4).