Achieving Consensus on Increased Risk Donors to Improve Access to Organ Transplantation
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Abstract

Background: To address the significant shortage of organs for transplantation, centers have been increasingly using organs from donors at increased risk for HIV, HBV and HCV. In response, the Organ Procurement and Transplantation Network (OPTN) and the Centers for Medicare and Medicaid Studies (CMS) have developed policies and guidance requiring special informed consent of recipients of these organs. Further, the US Public Health Service (PHS) has provided guidance about the evaluation and management of living and deceased donors at increased risk of transmitting HIV, HBV and HCV. There is limited data to support these policies and guidance.

Methods: We were funded (AHRQ 1R13HS021060-01) to conduct a consensus conference to review the existing evidence and identify gaps in knowledge with regard to:
1. To develop a consensus definition of donors at increased risk of transmission of HIV, HBV, and HCV
2. To define the optimal evaluation of living donors to mitigate against infectious disease transmission, with a focus on HIV, HBV, and HCV
3. To define the optimal timing, content, and method of informed consent of candidates considering accepting an organ from an increased risk donor
4. To develop consensus on the optimal evaluation of recipients of organs from an increased risk donors

Content experts from the transplant community were organized into 4 work groups and conducted conference calls and an in person meeting, held April 27, 2012 in Chicago, Illinois, to address these goals.

Results: Optimally risk factors that occur in less than 10% of the donor population, that represent a significant (>1:10,000 donors) and can be assessed reliably should be included in a definition for increased risk donors. All live donors, irrespective of risk status, should be screened within 30 days but preferably within 14 days prior to surgery by HIV NAT, HBsAg, and HCV NAT to detect acute infection prior to donation. Education about increased risk donors should be provided at the time of listing for organ transplantation and again at the time of the organ offer. The consent should be individualized to the specific donor-recipient pair and information should be provided in a comprehensible way, allowing the recipient to engage their social support (family, friends, and others) during the consent process. Finally, the consent process must be clearly documented in the medical record. Pre-transplant serology should be drawn on such individuals to establish a baseline. Post-transplant, diagnostic tests that directly detect the virus (i.e. nucleic acid tests (NAT) for HIV and HCV and either NAT or HbsAg for HBV) should be utilized. Testing should be conducted at 1 and 3 months post-transplant for HIV, HBV, and HCV and once at a later time point (between 6 and 12 months) for HBV alone.

Conclusions: There are limited data specific to organ donors to inform the definition of donors at increased risk of transmission of HIV, HBV and HCV, the yield of enhanced screening of live donors and the optimal timing of live donor screening, specific data related to informed consent for increased risk donors, and the optimal timing of recipients of an organ from an increased risk donor. Prospective studies are greatly needed, similar to the REDS study that was funded for blood transfusion, for the field of organ transplantation. Such studies should include live and deceased donors and inform the relative risks and benefits of proposed interventions.