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SUPPLEMENT ARTICLE

Clinical Vignettes: Donor-Derived Infections

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Patients undergoing solid organ transplantation (SOT) may acquire infections from the transplanted organ. Routine screening for common infections are an established part of the pretransplant evaluation of donors and recipients. Likewise, strategies exist for prophylaxis and surveillance for common donorassociated infections including hepatitis B, CMV and EBV. However, despite advances in diagnostic testing to evaluate the infectious risk of donors, unanticipated transmission of pathogens occurs, particularly when donors are asymptomatic or have subtle or unusual manifestations of a transmissible Infection. Infectious diseases (ID) providers play an integral role in donor and recipient risk assessment and can advise transplant centers on organ utilization and guide evaluation and management of the SOT recipient. Consideration of the donor cause of death and preceding clinical syndromes are important for characterizing the potential risk for recipient infection. This allows a more accurate analysis of the risk: benefit of accepting a life-saving organ and risk of infection. ID providers and transplant teams should work closely with organ procurement organizations (OPOs) to solicit additional donor information when a donor-derived infection is suspected so that reporting can be facilitated to ensure communication with the care-teams of other organ recipients from the same donors. National advisory committees work closely with federal agencies to provide oversight, guide policy development, and assess outcomes to assist with the prevention and management of donor-transmitted disease through organ transplantation. The clinical vignettes in this review highlight some of the complexities in the evaluation of potential donor transmission.

Organ transplant recipients can acquire latent or active infection from the transplanted organ(s) or systemic circulation of the donor(s). Potential donor-to-recipient transmission of some pathogens, such as cytomegalovirus (CMV) latent in white blood cells or hepatitis B virus (HBV) in the liver parenchyma, can be anticipated through routine screening of donors before organ harvest. However, unexpected transmission of infection (including *Mycobacterium tuberculosis* infection, histoplasmosis, West Nile virus, rabies, *Strongyloides* sp infection, and others) from donors to recipients has been reported [1, 2]. In many cases of unanticipated infectious transmission, donors are asymptomatic or have subtle symptoms rendering it difficult to identify a possible infectious concern, and routine screening of the donor might not detect a very recently acquired infection.

Infectious disease (ID) providers play an integral role in pretransplant risk assessments by providing recommendations for screening and guidance for posttransplant risk reduction for patients who will be listed for a solid organ transplant (SOT). Pretransplant ID evaluation is becoming a more routine component of transplant clinical care and provides the opportunity for providers to educate patients and their families about prophylaxis for latent infections, ensure optimal pretransplant immunization in recipients, and perform testing based on recipient-specific exposures. For example, screening for *Strongyloides* spp is recommended for transplant candidates from all areas of endemicity, including but not limited to those who live in the southeastern United States [3]. In addition to identifying and addressing infectious risks among SOT recipients, ID providers offer critical expertise in the peritransplant period to help mitigate the potential risk of donor-derived infections. ID physicians also can advise transplant surgeons regarding the risk of accepting an organ given clinical symptoms or known infection in a donor candidate and assist local organ-procurement organizations (OPOs) with case reviews and recommendations for additional testing of the donor.

Nationally, the Organ Procurement and Transplantation Network (OPTN) within the US Department of Health and Human Services is tasked with oversight, policy development, and outcomes assessment of SOT across the 11 geographic transplantation regions in the United States. In 2006, the Disease Transmission Advisory Group began to review potential donor-transmitted cases, and in 2008 the ad hoc Disease Transmission Advisory Committee (DTAC) was officially established as part of the OPTN patient safety program. The role of the DTAC is to examine unexpected potential donor-derived transmission events, primarily those that involve infection or malignancy. The DTAC reviews cases to determine whether they are donor derived and works with the Centers for Disease

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Control and Prevention (CDC) to assess selected cases of public health interest. In addition, the DTAC evaluates aggregate data of all transmission events to enhance patient safety by informing policy change and improving existing screening and notification processes. The DTAC serves as a resource for ongoing education within the transplant community [4, 5]. Although case reviews by the DTAC have been ongoing for more than a decade, with publication of guidance documents to advise providers regarding donor assessment and screening strategies, little is known about potential donor-derived transmission events from pediatric or adult donors to pediatric recipients. A systematic review of unanticipated pediatric-specific potential transmission events reported to the DTAC between 2008 and 2013 was conducted for donors and recipients aged 0 to 17 years [6]. In this study period, investigators identified 5238 deceased pediatric donors who accounted for 17 456 organ transplants that were given to adult and pediatric recipients. From these pediatric donors, 103 (2%) unexpected potential donor-derived transmission events were reported to the DTAC during the study period, and 15 (0.3%) of them were identified as a proven or probable event. Infections accounted for 13 of these 15 events, which resulted in infection transmission to 22 of 54 recipients of organs from these donors. Important to note is that this transmission of disease from donors to recipients resulted in 6 deaths, 5 of which were attributed to infection. The study highlighted key differences in risks between pediatric and adult donors. Pediatric donors were much more likely to transmit viral infection (46%) than were adult donors (19%, as reported from another large DTAC adult cohort), and infections in general were by far the primary transmission event type from pediatric donors to recipients [7].

OPTN policies have been established for infectious risk assessment of potential donors. The medical, travel, and social history of the donor, including data from the medical care of the patient at the donor hospital, is considered. It is important to recognize the limitations of the history often provided by donor family members who might not be aware of all medical information or risk factors, particularly in older children or teenagers. The CDC expanded its criteria in 2013 for the identification and disclosure of information regarding donors with increased risk of human immunodeficiency virus (HIV), HBV, or hepatitis C virus (HCV) infection to reduce the risks of transmitting these infections through organ transplantation [8]. The OPTN mandates testing for all potential donors (Table 1). The HCV nucleic acid test (NAT) is mandated for all donors to detect acute infection in the setting of negative serology results. Donors who are considered US Public Health Service (PHS) Increased Risk Donors (IRD) also must undergo the HIV NAT; the HIV NAT is performed routinely in some donor service areas in which a greater prevalence of HIV exists, including areas such as New York and Los Angeles (Table 2). Additional donor-specific testing or screening/prophylaxis based on travel to areas of endemicity (eg, for *Trypanosoma cruzi* [Chagas disease], *Strongyloides* spp, endemic fungi [such as coccidiomycosis], tuberculosis, and malaria) might be recommended.

ID providers are often asked to provide guidance regarding acceptance of organs or recipient management in the setting of known or suspected donor infection. Consideration is given not only to the transmissibility and consequences of a particular infection in a transplant recipient who will be immunosuppressed but also to balancing the risk of declining a scarce organ that might be life-saving for the recipient. Guidance given by ID providers can be informal or more structured, depending on individual institutional and regional policies, and decisions regarding specific donors and circumstances often must be made on a case-by-case basis. One example of a structured systems-based process for identifying cases that warrant ID provider review is the Infectious Diseases Working Group (IDWG), established by the Medical Advisory Board of the New York Organ Donor Network (LiveOnNY) [9]. The IDWG

Table 1. OPTN/UNOS-Required Deceased-Donor Infectious Disease Testing in the United States

Test	Methodology	Comment
Blood bacteriology	Culture	Yeasts, such as *Candida* spp, can also be identified with standard culture techniques
Urine bacteriology	Culture	Yeasts, such as *Candida* spp, can also be identified with standard culture techniques
HBV	HBsAg, HBcAb	Some experts in recent years have questioned the value of HBcAb testing for recipients other than for those undergoing liver transplantation
HCV	HCV antibody, HCV DNA (NAT)	HCV NAT was added after publication of the 2013 PHS guideline
CMV	CMV antibody	Although the serology type is not specified, it is most important to assess IgG levels if the donor is latently infected; donors aged <1 year are recognized as potentially having passive antibody [31]
EBV	EBV antibody	Although the serology type is not specified, it is most important to assess IgG levels against viral capsid antigen if the donor is latently infected; donors aged <1 year are recognized as potentially having passive antibody [31].
Syphilis	Syphilis FTA screen or RPR or VDRL titer	
Toxoplasma gondii	IgG antibody	This requirement for all organs was added in 2017; although IgM antibody levels can be obtained, the test is discouraged because of the high false-positive rate

Abbreviations: CMV, cytomegalovirus; EBV, Epstein–Barr virus; HBsAg, hepatitis B surface antigen; HBV, hepatitis B virus; HBcAb, hepatitis B core antibody; HCV, hepatitis C virus; FTA, fluorescent treponemal antibody absorption; IgG, immunoglobulin G; IgM, immunoglobulin M; NAT, nucleic acid testing; OPTN/UNOS, Organ Procurement and Transplantation Network/United Network for Organ Sharing; PHS, US Public Health Service; RPR, rapid plasma reagin; VDRL, Venereal Disease Research Laboratory.

Table 2. Window Phase According to Donor Serologic and NAT Result[a]

Test	Window Phase (days)[b]		
	HIV	HBV	HCV
Serology	17–22	35–44	~66
Fourth–fifth-generation Ag/Ab	~5–16	NA	40–50
NAT	5–9	20–22	3–7

Abbreviations: Ab, antibody; Ag, antigen; HIV, human immunodeficiency virus; HBV, hepatitis B virus; HCV, hepatitis C virus; NA, not applicable; NAT, nucleic acid testing.
[a]Adapted from reference 26.
[b]Window phase refers to the period from time of infection to time of detection of infection by specific testing methods.

includes transplant ID physicians who provide telephone consultation for potential donors when an infectious concern has been identified. The initial experiences of this group led to the development of a list of red-flag conditions, such as acute disseminated encephalomyelitis, that alert the LiveOnNY coordinators to request an IDWG consultation. The IDWG consultant provides advice regarding infectious transmission risk, need for additional testing, and recommendations for prophylaxis in recipients. The IDWG also provides recommendations regarding emerging infections, such as the need to screen for West Nile or Zika virus. Although such formal programs for ID evaluation and assessment of cases do not exist in all institutions and regions, this experience highlights the value of ensuring routine communication and collaboration between transplant centers and transplant ID teams.

The following cases illustrate typical scenarios in which ID providers must evaluate and assist with recommendations for organ procurement in the setting of a possible donor infection.

CASE 1

The organ procurement team calls for advice regarding the infectious risks of procuring and offering organs from a 2-month-old infant who presented to a community hospital with a 1-day history of fever (T_{max}, 39.4°C) and seizures. No prodrome history of rhinorrhea, cough, respiratory distress, vomiting, diarrhea, or rash was reported. An 8-year-old sibling who lives in the home has had 2 days of runny nose and cough. No one else in the family is sick, and no recent travel outside the United States was reported. The infant has deteriorated rapidly with the appearance of uncontrollable seizure activity, and computed tomography of the brain revealed multiple areas of infarction. Pertinent laboratory results include a respiratory virus multiplex polymerase chain reaction (PCR) panel positive for influenza A and coronavirus and negative blood and urine culture results. Cerebrospinal fluid (CSF) was not obtained. Other laboratory results include a prothrombin time of 20.8 seconds, a partial thromboplastin time of 43 seconds, an alanine aminotransferase concentration of 319 u/L, an aspartate aminotransferase concentration of 709 u/L, and an albumin concentration of 2.7 g/dL. The patient has been treated for 48 hours empirically with vancomycin, cefotaxime, and acyclovir (20 mg/kg body weight per dose every 8 hours).

DISCUSSION

The ID differential diagnosis for this infant includes influenza-associated encephalitis, herpes simplex virus (HSV), other viruses, and bacterial disease. From the perspective of evaluating potential infectious risk from this donor, bacterial etiologies are less of a concern, because the blood culture result was negative, and the patient has received >48 hours of antibiotic therapy. Furthermore, several studies have documented the safety of transplanting organs from donors with treated bacteremia, including bacterial meningitis [10–13]. Acute influenza-associated encephalitis syndrome is the leading diagnosis given the results of the respiratory virus panel and the 8-year-old sibling at home with possible influenza infection. Influenza-associated encephalitis is uncommon but well described, and it is associated with a poor outcome. For example, in the Australian Childhood Encephalitis Study 2013–2015 database, 13 patients with influenza-associated encephalitis were identified, and death or significant morbidity occurred in 7 of them [14]. However, the results of the respiratory virus multiplex PCR panel also could represent colonization or resolved infection and not be the cause of the encephalitis. HSV is clearly a potential cause of the infant's illness and is consistent with the elevated liver transaminase levels, low albumin level, and coagulopathy.

The initial recommendations to the OPO were to perform a PCR assay for HSV from serum and, if possible, to obtain CSF for HSV and influenza PCR testing. Because this infant donor was in New York, the OPO also recommended the New York State encephalitis panel for testing, although the results of that panel would not be available before transplantation. The New York State encephalitis panel includes real-time PCR for adenovirus, CMV, Epstein–Barr virus, enteroviruses, HSV types 1 and 2, human herpesvirus type 6, and varicella-zoster virus. Testing for arboviruses such as Eastern Equine or West Nile virus is included also but available only in the summer [15]. It was recommended that antibiotics and acyclovir be continued and oseltamivir added. The result of a blood HSV PCR was negative; CSF was not obtained. The infant's heart was donated, and the recipient underwent oseltamivir prophylaxis. No infectious complications were reported.

The risk/benefit ratio for each organ should be considered individually. Influenza and other respiratory virus infections, including those from coronavirus, have the potential to cause significant morbidity in SOT recipients, particularly in lung and, to a lesser extent, intestine recipients. Current guidelines recommend that potential lung and intestine donors who have been diagnosed with influenza within the previous 2 weeks be disqualified from donations. However, this recommendation might be tailored if the donor has received 5 days of antiviral

therapy. Other organs (heart, liver, kidneys) can be accepted in the absence of completing an antiviral treatment course if additional consent is obtained and the donor and recipient undergo anti-influenza treatment and prophylaxis, respectively. Oseltamivir-resistant influenza should generally preclude donation, although susceptibility testing is not typically performed or readily available [16–18].

Current guidelines also suggest that allografts from patients with suspected viral encephalitis not be accepted because of the risk of transmission of West Nile virus, lymphocytic choriomeningitis virus, and HSV [19–21]. However, this recommendation must be made after considering the risk and potential benefit. In the absence of viremia, HSV is not likely to be transmitted via heart transplant, but the virus can be present in liver and kidneys. In the authors' experience, transplantation of hearts from donors with HSV encephalitis who were treated with acyclovir and had a negative serum PCR result have been performed successfully.

CASE 2

A 26-year-old young man was found pulseless in a bathroom with a needle beside him. The emergency medical service administered naloxone (which resulted in no response), started chest compressions, and intubated the patient. Despite intensive care, he had fixed and dilated pupils and was declared brain dead 3 days after admission. The medical and social history obtained from the patient's wife revealed that he had been using heroin off and on for 2 years. His family agreed to organ donation. Blood test results for HIV, HCV, and HBV were negative according to an NAT and serologic analysis. You are called by the liver transplant team to assist in assessing the risk of donor transmission despite negative test results.

DISCUSSION

In 2015, more than 20% of all deceased donors were considered a PHS IRD because of their risky behavior or hemodiluted screening specimens [22]. By law, potential recipients must be counseled for and consent to the use of a PHS IRD organ at the time of listing [8]. If a patient does not provide consent, an IRD organ will not be offered to him or her. The growing opioid epidemic continues to increase the number of previously healthy young people becoming donors with the risk factors noted above. Therefore, it is important to understand the testing procedures and the window or eclipse period to help assess the true risk of transmission. The chance of an NAT result being falsely negative in this scenario is influenced by the window period for each virus, sensitivity of the screening test, and the risk of the donor having acquired one of these viruses in the recent past. The risk of missing an infection during the window period depends on the assay used. HIV would be missed in 12 of 10 000 intravenous drug donors using serology compared to 5 of 10 000 using NAT, and for HCV, the decrease is more dramatic, from 300 missed HCV cases with serology compared to 32 with NAT [23–25]. In a more recent article, the CDC performed mathematical modeling for the United States and found the overall risk to be low and to decrease even more the longer the donor testing was from the time of the last potential exposure. The risk of an NAT result being inaccurate is estimated to be, at most, 2.5%, and for HCV, the risk is almost zero if testing is performed at least 10 days after exposure [26].

For recipients, the risk of missing a transmissible infection must be countered by the risk of not taking the organ and remaining on the waiting list. For a child in fulminant hepatic failure in an intensive care unit, the risk of dying in the next few days might be substantially greater than the minimal risk of the donor being in the window period. In contrast, a stable child at home might be able to wait for another organ offer rather than accept the possible risk of an unidentified infection. Counseling should reflect this balance.

It is important also to consider the potential of treating a recipient should transmission of HCV, HBV, or HIV occur. For example, current studies are examining the deliberate use of HCV-positive donors in seronegative adult recipients [27]. As part of PHS guidelines and OPTN/United Network for Organ Sharing policies, each institution should have a protocol in place for assessing the potential of transmission after transplantation at predetermined intervals if a patient receives a PHS IRD organ. It is essential to note, however, that despite the testing and risk considerations for IRD organs, studies in renal transplant recipients have found good graft outcomes and overall minimal ID transmission [28–30].

SUMMARY

Infections remain a significant cause of morbidity and death among transplant recipients. Advances in screening practices for donors, testing strategies, and the development of broader consensus guidelines for the evaluation and management of infectious risks have been instrumental in reducing donor-derived infections and their associated complications among recipients. Although many potential donor infections can be identified through risk assessment and screening in the pretransplant and peritransplant periods, other infections might not be recognized until the immediate posttransplant period, after results become available. ID providers will be called on to evaluate recipients in this setting and offer recommendations regarding management of recipient exposures or infection. Communication with OPOs regarding exposures or infections that are identified in the posttransplant period remains critical for alerting recipients of other organs from the same donor.

Emerging and previously unknown infections, such as those caused by Zika virus, that might be transmissible from a donor to the recipient(s) are also an area in which ID providers can contribute valuable expertise. Improved testing methods, such as molecular testing and gene sequencing, enable the identification of infections that might not have been detected previously and for which the clinical implications might be unclear. Multidrug-resistant organisms in a donor might necessitate complicated management strategies to be used for recipients. ID providers will continue to have an important role in providing guidance regarding these issues to help ensure optimal outcomes.

Note

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