SUPPLEMENTARY APPENDIX 1. Search strategies for literature reviews

- **Search Query**: Studies reporting "increased risk donor" criteria among donors included in reports of solid organ donor-derived HIV, HBV, or HCV

Search Strategy:

Database	Strategy	Run Date	Records
Pubmed 1991-	"HIV Infections"[Mesh] OR "Hepatitis B"[Mesh] OR "Hepatitis C"[Mesh]) AND "Organ Donors"[Mesh] Filters: Case Reports, Review, Systematic Reviews, Meta-Analysis	1/17/2019	645

Results: All titles and abstracts were evaluated, and 86 articles* that described transmission to recipients were reviewed in detail to ascertain donor risk factors for HIV, HBV, and HCV infections. None of the 86 articles identified donor criteria not already found from a review of Organ Procurement and Transplantation Network data or a previously known report on donor-derived HIV transmission resulting from hemodilution.

*References of 86 articles that described transmission to recipients were reviewed in detail to ascertain donor risk factors for HIV, HBV, and HCV infections:

1. (1991). "Deaths of two kidney transplant patients linked to AIDS-infected donor." Nephrol News Issues **5**(6): 12.
2. (2010). "HIV transmission through transfusion --- Missouri and Colorado, 2008." MMWR Morb Mortal Wkly Rep **59**(41): 1335-1339.
3. (2011). "Potential transmission of viral hepatitis through use of stored blood vessels as conduits in Organ Transplantation-Pennsylvania, 2009." Am J Transplant **11**(4): 863-865.
4. (2011). "Potential transmission of viral hepatitis through use of stored blood vessels as conduits in organ transplantation--Pennsylvania, 2009." MMWR Morb Mortal Wkly Rep **60**(6): 172-17
5. (2011). "Transmission of hepatitis C virus through transplanted organs and tissue--Kentucky and Massachusetts, 2011." MMWR Morb Mortal Wkly Rep **60**(50): 1697-1700.
6. Ahn, J. and S. M. Cohen (2008). "Transmission of human immunodeficiency virus and hepatitis C virus through liver transplantation." Liver Transpl **14**(11): 1603-1608.
7. Anthuber, M., et al. (1991). "Donor-transmitted infections in heart transplantation--HIV, CMV, and toxoplasmosis." Transplant Proc **23**(5): 2634-2635.
8. Aqel, B. A. and H. E. Vargas (2015). "Hepatitis C virus infection in nonliver solid organ transplant candidates and recipients." Curr Opin Organ Transplant **20**(3): 259-266.
9. Bain, V. G. (2000). "Hepatitis B in transplantation." Transpl Infect Dis **2**(4): 153-165.
10. Baltz, A. C. and J. F. Trotter (2003). "Living donor liver transplantation and hepatitis C." Clin Liver Dis **7**(3): 651-665, viii.
11. Bellandi, T., et al. (2010). "Unintended transplantation of three organs from an HIV-positive donor: report of the analysis of an adverse event in a regional health care service in Italy." Transplant Proc **42**(6): 2187-2189.
12. Blaich, A., et al. (2012). "Reactivation of hepatitis B virus with mutated hepatitis B surface antigen in a liver transplant recipient receiving a graft from an antibody to hepatitis B surface antigen- and antibody to hepatitis B core antigen-positive donor." Transfusion **52**(9): 1999-2006.
13. Borchi, B., et al. (2010). "Case report: HIV infection from a kidney transplant." Transplant Proc

42(6): 2267-2269.
14. Calmy, A., et al. (2016). "HIV-Positive-to-HIV-Positive Liver Transplantation." Am J Transplant **16**(8): 2473-2478.
15. Carbone, M., et al. (2013). "Hepatitis C virus and nonliver solid organ transplantation." Transplantation **95**(6): 779-786.
16. Fabrizi, F., et al. (2003). "Transplantation of kidneys from HCV-positive donors: a safe strategy?" J Nephrol **16**(5): 617-625.
17. Gonzalez, S. A. and J. F. Trotter (2018). "The rise of the opioid epidemic and hepatitis C-positive organs: A new era in liver transplantation." Hepatology **67**(4): 1600-1608.
18. Ho, J. K., et al. (2006). "Utilization of a liver allograft from a hepatitis B surface antigen positive donor." Transplantation **81**(1): 129-131.
19. Hooi, L. S. (1993). "Human immunodeficiency virus infection in recipients of living unrelated donor renal transplants--a report of 4 cases." Med J Malaysia **48**(2): 232-235.
20. Hu, A., et al. (2012). "Living donor vs. deceased donor liver transplantation for patients with hepatitis C virus-related diseases." J Hepatol **57**(6): 1228-1243.
21. Khan, B., et al. (2017). "Successful Lung Transplantation From Hepatitis C Positive Donor to Seronegative Recipient."
22. Kobayashi, T., et al. (2003). "Living related renal transplantation for end-stage renal disease after liver transplantation from a brain-dead donor." Int J Urol **10**(11): 607-609.
23. Leiss, W., et al. (2008). "Men having sex with men donor deferral risk assessment: an analysis using risk management principles." Transfus Med Rev **22**(1): 35-57.
24. Li, C. Y., et al. (2015). "Retrospective observation of therapeutic effects of adult auxiliary partial living donor liver transplantation on postpartum acute liver failure: a case report." World J Gastroenterol **21**(9): 2840-2847.
25. Lin, C. C., et al. (2015). "Active vaccination to prevent de novo hepatitis B virus infection in liver transplantation." World J Gastroenterol **21**(39): 11112-11117.
26. Loggi, E., et al. (2016). "Liver grafts from hepatitis B surface antigen-positive donors: A review of the literature." World J Gastroenterol **22**(35): 8010-8016.
27. Magiorkinis, E., et al. (2013). "Renal transplantation from hepatitis B surface antigen (HBsAg)-positive donors to HBsAg-negative recipients: a case of post-transplant fulminant hepatitis associated with an extensively mutated hepatitis B virus strain and review of the current literature." Transpl Infect Dis **15**(4): 393-399.
28. Mahboobi, N., et al. (2012). "Renal grafts from anti-hepatitis B core-positive donors: a quantitative review of the literature." Transpl Infect Dis **14**(5): 445-451.
29. Muller, E. (2015). "Transplantation in resource-limited setting: using HIV-positive donors for HIV-positive patients." Clin Nephrol **83**(7 Suppl 1): 39-41.
30. Munoz, S. J. (2002). "Use of hepatitis B core antibody-positive donors for liver transplantation." Liver Transpl **8**(10 Suppl 1): S82-87.
31. Nampoory, M. R., et al. (1999). "Organ-transmitted HCV infection in kidney transplant recipients from an anti-HCV negative donor." Transplant Proc **31**(8): 3207-3208.
32. Natov, S. N. (2002). "Transmission of viral hepatitis by kidney transplantation: donor evaluation and transplant policies (Part 2: hepatitis C virus)." Transpl Infect Dis **4**(3): 124-131.
33. Natov, S. N. and B. J. Pereira (2002). "Transmission of viral hepatitis by kidney transplantation: donor evaluation and transplant policies (Part 1: hepatitis B virus)." Transpl Infect Dis **4**(3): 117-123.
34. Okamoto, M., et al. (1999). "Kidney transplantation from a hepatitis B surface antigen-positive donor to a HBSAG-negative recipient." Transplant Proc **31**(7): 2869.
35. Onoe, T., et al. (2016). "Prophylactic managements of hepatitis B viral infection in liver transplantation." World J Gastroenterol **22**(1): 165-175.

36. Ouseph, R., et al. (2010). "Review of the use of hepatitis B core antibody-positive kidney donors." Transplant Rev (Orlando) **24**(4): 167-171.
37. Papayannis, I. and P. Patel (2016). "Successful Treatment of a Hepatitis C-Positive Patient Who Received Kidney Transplant From a Hepatitis C-Positive Donor: A Case Report." Prog Transplant **26**(3): 238-240.
38. Patijn, G. A., et al. (1993). "Prevention of transmission of HIV by organ and tissue transplantation. HIV testing protocol and a proposal for recommendations concerning donor selection." Transpl Int **6**(3): 165-172.
39. Patwardhan, V. R. and M. P. Curry (2015). "Reappraisal of the hepatitis C virus-positive donor in solid organ transplantation." Curr Opin Organ Transplant **20**(3): 267-275.
40. Pereira, B. J. and A. S. Levey (1995). "Hepatitis C infection in cadaver organ donors: strategies to reduce transmission of infection and prevent organ waste." Pediatr Nephrol **9 Suppl**: S23-28.
41. Radomski, J. S., et al. (1996). "Hepatitis B transmission from a liver donor who tested negative for hepatitis B surface antigen and positive for hepatitis B core antibody." Liver Transpl Surg **2**(2): 130-131.
42. Rizzetto, M. (2001). "Transmission of hepatitis B infection from hepatitis B core antibody--positive livers: background and prevention." Liver Transpl **7**(6): 518-520.
43. Rogachev, B., et al. (2009). "Acute viral hepatitis (C - genotype 6a and B) acquired during kidney transplantation by two patients and review of the literature." Clin Nephrol **72**(6): 482-487.
44. Saberi, B., et al. (2018). "Utilization of hepatitis C virus RNA-positive donor liver for transplant to hepatitis C virus RNA-negative recipient." Liver Transpl **24**(1): 140-143.
45. Sawinski, D. (2017). "Kidney transplantation for HIV-positive patients." Transplant Rev (Orlando) **31**(1): 42-46.
46. Sawinski, D. and R. D. Bloom (2014). "Current status of kidney transplantation in HIV-infected patients." Curr Opin Nephrol Hypertens **23**(6): 619-624.
47. Schuch, D. R., et al. (1992). "Hepatitis C--importance of screening the organ donor preoperatively." J Thorac Cardiovasc Surg **104**(4): 1174-1175.
48. Seki, T., et al. (1998). "Kidney transplantation in a child with posterior urethral valve from a hepatitis B virus-carrier mother. Report of a case with special reference to urinary tract reconstruction for dysfunctionalized uropathies and seroimmunological preparation against viral transmission." Urol Int **61**(4): 237-239.
49. Shapira, R., et al. (2001). "Efficacy of lamivudine for the treatment of hepatitis B virus infection after liver transplantation in children." Transplantation **72**(2): 333-336.
50. Simonds, R. J., et al. (1992). "Transmission of human immunodeficiency virus type 1 from a seronegative organ and tissue donor." N Engl J Med **326**(11): 726-732.
51. Singer, A. L., et al. (2008). "The high-risk donor: viral infections in solid organ transplantation." Curr Opin Organ Transplant **13**(4): 400-404.
52. Soejima, Y., et al. (2007). "Successful living donor liver transplantation using a graft from a hepatitis B surface antigen-positive donor." Liver Int **27**(9): 1282-1286.
53. Suryaprasad, A., et al. (2015). "Transmission of Hepatitis C Virus From Organ Donors Despite Nucleic Acid Test Screening." Am J Transplant **15**(7): 1827-1835.
54. Suzuki, T., et al. (1998). "Hepatitis virus infection after living related liver transplantation: a report of 2 cases." Transplant Proc **30**(7): 3312-3313.
55. Taege, A. J. (2018). "Human Immunodeficiency Virus Organ Transplantation." Infect Dis Clin North Am **32**(3): 615-634.
56. Takada, Y. and S. Uemoto (2013). "Living donor liver transplantation for hepatitis C." Surg Today **43**(7): 709-714.
57. Torres, H. A., et al. (2015). "Hepatitis C Virus Infection among Hematopoietic Cell Transplant Donors and Recipients: American Society for Blood and Marrow Transplantation Task Force

Recommendations." Biol Blood Marrow Transplant **21**(11): 1870-1882.
58. Trullas, J. C., et al. (2011). "Renal transplantation in HIV-infected patients: 2010 update." Kidney Int **79**(8): 825-842.
59. Veroux, M., et al. (2016). "Kidney Transplantation From Donors with Hepatitis B." Med Sci Monit **22**: 1427-1434.
60. Veroux, M., et al. (2014). "Kidney transplantation from donors with hepatitis C infection." World J Gastroenterol **20**(11): 2801-2809.
61. Victer, T. N., et al. (2016). "Deceased tissue donor serology and molecular testing for HIV, hepatitis B and hepatitis C viruses: a lack of cadaveric validated tests." Cell Tissue Bank **17**(4): 543-553.
62. Wasiak, D., et al. (2016). "Delayed, Uncommon Recurrence of Hepatocellular Carcinoma After Liver Transplantation: A Case Report." Transplant Proc **48**(5): 1855-1857.
63. Wells, M., et al. (2014). "Comparing outcomes of donation after cardiac death versus donation after brain death in liver transplant recipients with hepatitis C: a systematic review and meta-analysis." Can J Gastroenterol Hepatol **28**(2): 103-108.
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65. Wright, T. L. (1993). "Hepatitis C virus infection and organ transplantation." Prog Liver Dis **11**: 215-230.
66. Yasar, D. G., et al. (2013). "Adefovir is effective to promote development of immunity to donor origin hepatitis B virus in an allogeneic transplant recipient: a case report." Transplant Proc **45**(2): 833-834.
67. Yen, R. D., et al. (2006). "Case report of lamivudine-resistant hepatitis B virus infection post liver transplantation from a hepatitis B core antibody donor." Am J Transplant **6**(5 Pt 1): 1077-1083.
68. Morita, K., et al. (2009). "De novo hepatocellular carcinoma in a liver graft with sustained hepatitis C virus clearance after living donor liver transplantation." Liver Transpl **15**(11): 1412-1416.
69. Ijichi, H., et al. (2013). "Recurrent hepatitis B following recurrence of hepatocellular carcinoma after living donor liver transplantation." Fukuoka Igaku Zasshi **104**(10): 376-382.
70. Ichikawa, T., et al. (2007). "Clearance of hepatitis C virus after living-donor liver transplantation in spite of residual viremia on end date of interferon therapy before transplantation." World J Gastroenterol **13**(30): 4149-4151.
71. Hwang, S., et al. (2006). "Five-year follow-up of a hepatitis B virus-positive recipient of hepatitis B surface antigen-positive living donor liver graft." Liver Transpl **12**(6): 993-997.
72. Humpe, A., et al. (2000). "Hepatitis C virus transmission through quarantine fresh-frozen plasma." Thromb Haemost **84**(5): 784-788.
73. Hu, A., et al. (2012). "Living donor vs. deceased donor liver transplantation for patients with hepatitis C virus-related diseases." J Hepatol **57**(6): 1228-1243.
74. Franchello, A., et al. (2005). "Transplantation of hepatitis B surface antigen-positive livers into hepatitis B virus-positive recipients and the role of hepatitis delta coinfection." Liver Transpl **11**(8): 922-928.
75. Forbes, R. C., et al. (2017). "A2 to B Blood Type Incompatible Deceased Donor Kidney Transplantation in a Recipient Infected with the Human Immunodeficiency Virus: A Case Report." Transplant Proc **49**(1): 206-209
76. Feng, A. C., et al. (2015). "A successful child-to-adult deceased donor liver transplantation: a case report and literature review." Ann Transplant **20**: 21-24.
77. Fabrizio, F., et al. (2002). "Transplanting kidneys from donors with prior hepatitis B infection: one response to the organ shortage." J Nephrol **15**(6): 605-613.
78. Dominguez-Gil, B., et al. (2011). "Should we be using kidneys from hepatitis C virus-infected donors?" Curr Opin Nephrol Hypertens **20**(6): 599-604.
79. Delmonico, F. L. (2000). "Cadaver donor screening for infectious agents in solid organ

transplantation." Clin Infect Dis **31**(3): 781-786.
80. Chung, C. W., et al. (2001). "Human immunodeficiency virus p24 antigen testing in cornea donors." Cornea **20**(3): 277-280.
81. Chopra, A., et al. (2014). "Nucleic acid testing to screen potential kidney donors for hepatitis C virus: is a universal statement possible soon?" Am J Kidney Dis **63**(3): 541.
82. Chin, J. L., et al. (2012). "Spontaneous clearance of hepatitis C infection after liver transplantation from IL28B rs12979860 CC donors." Eur J Gastroenterol Hepatol **24**(9): 1110-1112.
83. Genzini, T., et al. (2010). "Simultaneous pancreas-kidney transplantation in a human immunodeficiency virus-positive recipient: a case report." Transplant Proc **42**(2): 591-593.
84. Glassy, C. M., et al. (2012). "Tattooing: medical uses and problems." Cleve Clin J Med **79**(11): 761-770.
85. Goldman, M. and S. F. O'Brien (2016). "Donor deferral policies for men who have sex with men: where are we today?" Curr Opin Hematol **23**(6): 568-572.
86. Wilson, K., et al. (2014). "Three decades of MSM donor deferral policies. What have we learned?" Int J Infect Dis **18**: 1-3.

Search Query: Studies on risk of acute HIV infection if the person (excluding MSM) has an STI diagnosed in the previous one month or three months of infection.

Search Strategy:

Database	Strategy	Run Date	Records
Medline (OVID) 1946-	(*HIV Infections/ AND *Risk Factors/) OR ((Risk OR diagnosis) ADJ3 (HIV* OR human immunodeficiency virus*)).ti,ab. AND ((recent* OR prior* OR previous* OR within month* OR one month OR two months* OR three months* OR following) ADJ5 (sexually transmitted OR STD* OR STI OR syphilis OR gonorrhea)).ti,ab. NOT (Homosexuality, Male/ OR (Men who have sex with men OR MSM OR gay men).ti,ab.) NOT (heterosexual* OR non-MSM)	2/25/2019	261
Embase (OVID) 1988-	(*human immunodeficiency virus infection/ AND *Risk Factors/) OR ((Risk OR diagnosis) ADJ3 (HIV* OR human immunodeficiency virus*)).ti,ab. AND ((recent* OR prior* OR previous* OR within month* OR one month OR two months* OR three months* OR following) ADJ5 (sexually transmitted OR STD* OR STI OR syphilis OR gonorrhea)).ti,ab. NOT (Homosexuality, Male/ OR (Men who have sex with men OR MSM OR gay men).ti,ab.) NOT (heterosexual* OR non-MSM)	2/25/2019	305 -195 duplicates =110 unique items

Global Health (OVID) 1973-	((Risk OR diagnosis) ADJ3 (HIV* OR human immunodeficiency virus*)).ti,ab. AND ((recent* OR prior* OR previous* OR within month* OR one month OR two months* OR three months* OR following) ADJ5 (sexually transmitted OR STD* OR STI OR syphilis OR gonorrhea)).ti,ab. NOT (Homosexuality, Male/ OR (Men who have sex with men OR MSM OR gay men).ti,ab.) NOT (heterosexual* OR non-MSM)	2/25/2019	162 -142 duplicates =20 unique items
CINAHL (Ebsco)	((MJ "HIV Infections") AND (MJ "Risk Factors")) OR ((Risk OR diagnosis) N3 (HIV* OR "human immunodeficiency virus")) AND ((recent* OR prior* OR previous* OR "within month*" OR "one month" OR "two month*" OR "three month*" OR following) N5 ("sexually transmitted" OR STD* OR STI OR syphilis OR gonorrhea)) NOT ((MH "Homosexuality, Male") OR ("Men who have sex with men" OR MSM OR "gay men")) NOT (heterosexual* OR non-MSM) *Exclude Medline records*	2/25/2019	38 -9 duplicates =29 unique items

Results: Four articles were identified that were based in the United States and either measured the incidence of acquiring HIV following a diagnosis of a syphilis, gonorrhea, or chlamydia with at least 10,000 patients (references 1-3) or were a systematic review of the relative risk of HIV acquisition among persons with a positive herpes simplex virus 2 serology versus seronegative persons (reference 4).

1. Peterman et al. Risk for HIV following a diagnosis of syphilis, gonorrhea or chlamydia: 328,456 women in Florida, 2000–2011. International Journal of STD & AIDS, 2014.
2. Peterman et al. High Risk for HIV following a diagnosis of syphilis, men living in Florida, 2000-2011. Public Health Reports, 2014.
3. Hanson et al. Assessment of sexually transmitted diseases as risk factors for HIV seroconversion in a New Orleans sexually transmitted disease clinic, 1990-1998. Annals of Epidemiology, 2005.
4. Freeman et al. Herpes simplex virus 2 infection increases HIV acquisition in men and women: systematic review and meta-analysis of longitudinal studies. AIDS, 2006.

SUPPLEMENTARY APPENDIX 2. Detailed comparison of 2013 and 2020 U.S. Public Health Service guideline recommendations

2013	2020
1. All living potential donors and individuals interviewed about deceased potential organ donors (e.g., next of kin, life partner, cohabitant, caretaker, friend, or primary treating physician) should be informed of the donor evaluation process, including the review of medical and behavioral history, physical examination, and laboratory tests to identify the presence of infectious agents or medical conditions that could be transmitted by organ transplantation. Organ procurement organizations (OPOs) and transplant centers adopted IRD designation for donors with these risk criteria.	• All living potential donors and persons contacted about deceased donors (e.g., next of kin, life partner, cohabitant, caretaker, friend, or primary treating physician) should be informed of the donor evaluation process, including the review of medical and social history, physical examination, and laboratory tests to identify the presence of infectious agents or medical conditions that could be transmitted by organ transplantation.
2. To ascertain whether potential organ donors are at increased risk for HIV, HBV, or HCV infection, living donors, or individuals contacted about deceased donors, should be interviewed in a confidential manner about behaviors that may have increased the potential donor's probability of having HIV, HBV, or HCV infection. Risk criteria (during the **12 months** prior to organ procurement): i. Sex with a person known or suspected to have HIV, HBV, or HCV infection ii. Drug injection for nonmedical reasons iii. Man who has had sex with another man iv. Incarceration (confinement in jail, prison, or juvenile correction facility) for >72 consecutive hours v. Sex in exchange for money or drugs vi. Sex with a person who injected drugs for nonmedical reasons vii. Unknown medical or social history at time of organ procurement viii. Child (≤18 months of age) born to a mother known to be infected with, or at increased risk for, HIV, HBV, or HCV infection ix. Child who has been breastfed by mother who is known to be infected with, or at increased risk for, HIV infection x. Sex with a person who had sex in exchange for money or drugs xi. Woman who has had sex with a man who has had sex with another man	• Organ procurement organizations (OPOs) should ascertain, in a confidential manner, whether any of the following exposures, which would put organ recipients at risk for acquiring HIV, HBV, and HCV infections, were present in potential organ donors within 30 days before organ procurement: ○ Sex (i.e., any method of sexual contact, including vaginal, anal, and oral) with a person known or suspected to have HIV, HBV, or HCV infection ○ Man who has had sex with another man ○ Sex in exchange for money or drugs ○ Sex with a person who had sex in exchange for money or drugs ○ Drug injection for nonmedical reasons ○ Sex with a person who injected drugs for nonmedical reasons ○ Incarceration (confinement in jail, prison, or juvenile correction facility) for ≥72 consecutive hours ○ Child breastfed by a mother with HIV infection ○ Child born to a mother with HIV, HBV, or HCV infection ○ Unknown medical or social history

xii. Newly diagnosed with, or have been treated for, syphilis, gonorrhea, Chlamydia, or genital ulcers xiii. Hemodialysis xiv. Hemodilution of the blood sample used for infectious disease testing	
3. Living potential donors with behaviors associated with an increased risk of acquiring HIV, HBV, or HCV identified during evaluation should receive individualized counseling on specific strategies to prevent exposure to these viruses during the time period prior to surgery. 4. If a potential donor is ≤18 months of age or has been breastfed within the preceding 12 months, the birth mother, if available, should be interviewed about behaviors that may have placed her at risk for HIV, HBV, or HCV infection.	• Living potential donors who have past or on-going risk of acquiring HIV, HBV, or HCV infection should receive individualized counseling on specific strategies to prevent exposure to these viruses during the time period prior to surgery • Remove any specific label (e.g., "increased risk donor") to describe donors with risk factors for acute HIV, HBV, or HCV infection
5. When a deceased potential organ donor's medical/behavioral history cannot be obtained or risk factors cannot be determined, the donor should be considered at increased risk for HIV, HBV, and HCV infection because the donor's risk for infection is unknown. 6. All living potential donors should be tested for HIV, HBV, and HCV as close as possible to the date of the organ recovery operation, but at least within the 28-day time period prior to surgery. 7. All potential organ donors (living or deceased) should be tested for antibodies to HIV (i.e., anti-HIV 1/2 or HIV antigen/antibody [Ag/Ab] combination assay). All potential organ donors identified as being at increased risk for HIV infection should also be tested for HIV ribonucleic acid (RNA) by NAT or HIV antigen (e.g., HIV Ag/Ab combination assay). Donor blood specimens should be obtained before procurement. Ab or Ag/Ab test results should be made available before transplantation. 8. All potential organ donors (living or deceased) should be tested for both anti-HCV and for HCV RNA by NAT. Donor blood specimens should be obtained before procurement. Ab test results should be made available before transplantation. 9. All potential organ donors (living or deceased) should be tested for anti-HBc and for HBsAg. Donor blood specimens should be	• Test all potential organ donors for HIV, HBV, and HCV infections using serological tests (including anti-HIV antibody, total anti-HBc, HBsAg, and anti-HCV) in addition to NAT for all three viruses, regardless of the risk criteria identified during screening using assays licensed, approved, or cleared by FDA for donor screening. ○ For living potential donors, testing should continue to be performed as close as possible to the surgery, but at least within the 28-day time period prior to organ procurement. ○ For deceased potential donors, the donor specimen should be collected within 96 hours prior to organ procurement with results of these screening tests available at the time of organ procurement.

obtained before procurement. Ab/Ag test results should be made available before transplantation.	
10. An informed consent process discussion between the transplant candidate, or medical decision maker, and the listing clinician should start before the patient is placed on the transplant wait list. Patients should be counseled to consider potential risks of both accepting and rejecting organs from donors known to be infected with HBV or HCV, or donors at increased risk for HBV, HCV, or HIV infection. 11. The transplant candidate, or medical decision maker, should have opportunities to discuss with clinicians issues related to the associated risk of HIV, HBV, or HCV transmission with organ acceptance while the patient is on the transplant wait list. 12. At the time of the organ offer, if a donor is identified as being at increased risk for HIV, HBV, or HCV infection, the transplant center team primarily responsible for the patient's care should include this risk information in the informed consent discussion with the transplant candidate or medical decision maker. 13. If prior to transplantation or repair of a transplanted organ it is known or anticipated that stored blood vessel conduits (from a donor who is different from the donor of the primary organ being transplanted or repaired) may be used, and the donor is identified as being at increased risk for HIV, HBV, or HCV infection, then the transplant center team should include this risk information in the informed consent discussion. 14. When organs from HBV- or HCV-infected donors will be used, the transplant center team primarily responsible for the patient's care should have an informed consent discussion with the transplant candidate, or medical decision maker, prior to transplantation regarding the risks related to disease transmission. 15. Transplant candidates should be informed that although all donors are screened for HIV, HBV, and HCV, donor screening has limitations and no screening question or laboratory test can completely eliminate the risk for transmitting these infections (or any other infection).	• An informed consent process discussion between the transplant candidate, or medical decision maker, and the listing clinician should be initiated prior to placement of a patient on a transplant wait list. This discussion should include opportunities to address concerns related to the risk of HIV, HBV, or HCV transmission via organ transplantation. • When donors with one or more of the risk criteria specified under Risk Assessment of Living and Deceased Donors are identified, OPOs should communicate this information to the appropriate transplant centers. Transplant centers should include this information in informed consent discussions with transplant candidates or their medical decision-makers. No separate, specific informed consent is recommended. Transplant centers should make efforts to contextualize these discussions and should include the following: ○ The risk of undetected HIV, HBV, or HCV infection is very low, but not zero.* ○ Recipients will be tested for HIV, HBV, and HCV infections after transplantation and should transmission occur, effective therapies are available.† ○ Transplant candidates might have a higher chance of survival by accepting organs from donors with risk factors for HIV, HBV, and HCV infections compared with waiting for an organ from a donor without recognized risk factor.§ • If before transplantation or repair of a transplanted organ the transplant center team knows or anticipates that stored blood vessel conduits (from a donor who is different from the donor of the primary organ being transplanted or repaired) may be used, and the blood vessel donor meets risk criteria listed under Risk Assessment of Living and Deceased Donors, then the transplant center team should include this risk information in the informed consent discussion.

16. Pre-transplant testing of transplant candidates for HIV, HBV, and HCV should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HIV, HBV, and HCV infection (Note: If the donor is only identified as being at risk for HCV infection due to hemodialysis in the preceding 12 months, then testing for HCV only is recommended); (2) screening specimens are hemodiluted; or (3) the medical/behavioral history is unavailable. When the donor meets any of the three conditions, transplant candidate testing should occur during hospital admission for the organ transplant but prior to implantation of the organ, unless the transplant candidate is known through prior testing to be infected. 17. Pre-transplant testing of transplant candidates for HBV or HCV should be conducted when the donor (living or deceased) is known to be infected with HBV or HCV. Transplant candidate testing should occur during hospital admission for the organ transplant but prior to organ implantation, unless the transplant candidate is known through prior testing to be infected. 18. Posttransplant HBV testing of recipients should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HBV infection, (2) screening specimens are hemodiluted, (3) the medical/behavioral history is unavailable, or (4) the donor is infected with HBV. Recipient testing should be performed sometime between one and three months posttransplant to include HBV NAT and HBsAg, and at 12 months posttransplant to include antibody to hepatitis B surface antigen (anti-HBs), anti-HBc, and either HBV NAT or HBsAg (unless infection was documented pre-transplant). 19. Posttransplant HIV testing of recipients should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HIV infection, (2) screening specimens are hemodiluted, or (3) the medical/behavioral history is unavailable. Recipient testing should be performed sometime between one and three months posttransplant to include HIV NAT or an HIV Ag/Ab combination assay (unless infection	• Regardless of donor risk profile for HIV, HBV, or HCV infections, transplant programs should test all organ recipients using assays licensed, approved, or cleared by FDA for diagnosis. ○ Before transplantation, HIV testing should be performed using a recommended laboratory HIV testing algorithm[¶]; hepatitis B testing should be performed using total anti-HBc, HBsAg, and hepatitis B surface antibody (anti-HBs); and hepatitis C testing should be performed using anti-HCV antibody and HCV NAT. Blood samples should be obtained from the transplant candidate during hospital admission for the organ transplant but prior to implantation of the organ, unless the transplant candidate is known through prior testing to be infected. Results of transplant candidate testing do not have to be available at the time of transplantation. ○ At 4-6 weeks following transplantation, transplant centers should test recipients for HIV, HBV, and HCV infections using NAT. ○ Clinicians caring for liver recipients should maintain heightened awareness of the potential for delayed appearance of HBV infection and consider additional testing using HBV NAT at one year. ○ Recipients who develop signs or symptoms of liver injury (e.g., jaundice or elevated liver function tests) after transplantation, should be tested for viral hepatitis, even if previous hepatitis B or hepatitis C testing was negative.

was documented pre-transplant). NAT or an Ag/Ab combination assay for HIV detection is important as infected recipients may remain Ab-negative due to immunosuppression. 20. Posttransplant HCV testing of recipients should be conducted when the donor (living or deceased) meets any of the following conditions: (1) identified as being at increased risk for HCV infection, (2) screening specimens are hemodiluted, (3) the medical/behavioral history is unavailable, or (4) the donor is infected with HCV. Recipient testing should be performed sometime between one and three months posttransplant to include HCV NAT (unless infection was documented pre-transplant). NAT is important for HCV detection as infected recipients may remain Ab-negative due to immunosuppression.	
	• All organ transplant candidates should be vaccinated against Hepatitis B virus infection.
21. For deceased donors, the OPO should consider collecting two blood specimens, when possible, for HIV, HBV, and HCV real-time testing (i.e., prior to organ recovery)—an ethylenediaminetetraacetic acid (EDTA) plasma specimen or serum specimen for serologic assays and a separate EDTA plasma specimen for NAT. Additionally, the OPO should consider collecting two blood specimens for archiving, when possible. If it is only feasible to collect one specimen, a plasma specimen collected in EDTA, rather than a serum specimen, is optimal. 22. The OPO should consider archiving blood specimens from deceased donors for at least 10 years. 23. For living donors, transplant candidates, and recipients, two blood specimens should be collected when HIV, HBV, or HCV testing is	• OPOs and living donor recovery centers should archive donor blood specimens for at least 10 years. These specimens should be collected within 24 hours before organ procurement. Two blood specimens should be collected for archiving: an ethylenediaminetetraacetic acid (EDTA) plasma specimen or serum specimen for serologic assays and a separate EDTA plasma specimen for NAT. If only feasible to collect one specimen, a plasma specimen collected in EDTA, rather than a serum specimen, is optimal. • For deceased donors, living donors, transplant candidates, and recipients, two blood specimens should be collected when HIV, HBV, or HCV infection testing is planned—an EDTA plasma specimen or serum specimen for serologic assays and a separate EDTA plasma specimen for NAT.

planned—an EDTA plasma specimen or serum specimen for serologic assays and a separate EDTA plasma specimen for NAT. 24. Infusion of crystalloid and colloid solutions and transfusion of blood products can cause hemodilution and produce false-negative results for HIV, HBV, and HCV testing. Therefore, the OPO should make an effort to collect a qualified (non-hemodiluted) specimen—that is, a specimen that is deemed acceptable for testing according to an appropriate hemodilution algorithm and calculation method, such as provided by the FDA. Furthermore, a hemodilution calculation should be performed on archived specimens of deceased donors to facilitate interpretation of test results. 25. All stored blood vessel conduits from a donor found to be infected with HIV, HBV, or HCV should be quarantined immediately and not released for clinical use unless the HBV- or HCV-infected vessel conduits are needed for the initial transplant procedure in the recipient. After completing the initial transplant procedure, any remaining vessel conduits should be disposed of in accordance with hospital policy to prevent inadvertent release from quarantine and unintentional use in other patients.	• All stored blood vessel conduits from a donor found to be infected with HIV, HBV, or HCV should be quarantined immediately and not released for clinical use unless the HIV-, HBV-, or HCV-infected vessel conduits are needed for the initial transplant procedure in the recipient. After completing the initial transplant procedure, any remaining vessel conduits should be disposed of in accordance with hospital policy to prevent inadvertent release from quarantine and unintentional use in other patients.
26. (A) When an OPO receives information before organ recovery that a deceased potential donor is at increased risk for or is infected with HIV, HBV, or HCV, the OPO should notify (1) the OPTN, (2) the transplant centers receiving organ offers, and (3) any institutions considering tissue and eye recovery. (B) The OPO should also notify the public health authorities where the potential donor is admitted, in accordance with state requirements for reporting notifiable infections, if the deceased potential donor is infected. 27. (A) When an OPO receives information after organ recovery that a deceased donor was infected with HIV, HBV, or HCV, or that an organ recipient infection with HIV, HBV, or HCV is suspected of being donor-derived, the OPO should notify (1) the OPTN, (2) the transplant centers that received organs and/or blood vessel conduits from the deceased donor, and (3) any institutions that recovered tissues and eyes from the donor. (B) The OPO should also notify public health authorities where the organ recovery took place,	• When an OPO, living donor recovery center, or transplant center receives information, including before organ recovery, that (1) an organ or blood vessel conduit donor meets ≥1 of the criteria as specified under recommendation #2; (2) the donor is infected with HIV, HBV, or HCV; or (3) that an organ recipient infection with HIV, HBV, or HCV is suspected of being donor-derived, they should contact other organizations involved with organs or tissue procured from the donor, including (1) the OPTN, (2) OPO or living donor recovery center, (3) transplant centers, and (4) any institutions considering tissue and eye recovery. Living donors who test positive for HIV, HBV, or HCV infections should be notified of the results. • An OPO, living donor recovery center, or transplant center should also notify the appropriate public health authorities if the deceased donor, living donor, or transplant recipient is infected with HIV, HBV, or HCV. • OPOs, in coordination with the OPTN, should have a system in place allowing tracking between a common deceased donor and (1) recovered

in accordance with state requirements for reporting notifiable infectious diseases, if the deceased donor was infected. 28. (A) When a transplant center receives information that a recipient of an organ or blood vessel conduit from any deceased donor is newly infected with HIV, HBV, or HCV posttransplant and the infection is suspected of being donor-derived, the transplant center should notify (1) the OPTN and (2) the OPO that procured the organs and any blood vessel conduits. (B) In accordance with state requirements for reporting notifiable infectious diseases, the transplant center where the transplant took place should also notify public health authorities of the recipient infection. 29. (A) When a living donor recovery center receives information before organ recovery that a living potential donor is infected with HIV, HBV, or HCV, the living donor recovery center should notify the transplant center intended to receive the organ. If the organ from an HBV- or HCV-infected donor is used for transplantation, the living donor recovery center should also notify the OPTN. (B) In accordance with state requirements for reporting notifiable infectious diseases, the living donor recovery center should also notify public health authorities where the potential donor lives of the potential living donor's infection. 30. (A) When a living donor recovery center receives information after organ recovery that a living donor is infected with HIV, HBV, or HCV, the living donor recovery center should notify (1) the OPTN and (2) the transplant center that received an organ from the living donor. Disclosure to the OPTN and transplant center should be in accordance with state requirements. (B) In accordance with state requirements for reporting notifiable infectious diseases, the living donor recovery center should also notify public health authorities where the organ recovery took place of the living donor's infection. 31. When a living donor recovery center receives information after organ recovery that an organ recipient infection with HIV, HBV, or HCV is suspected of being donor-derived, the living donor recovery center should notify the OPTN.	organs, (2) recovered associated blood vessel conduits, and (3) recovered tissues and eyes to facilitate notification when a donor-derived disease transmission is suspected. This system should include accurate records of the distribution and disposition of each organ and initial distribution of associated blood vessel conduits, along with procedures to facilitate the timely notification of transplant centers and tissue and eye recovery establishments when a donor-derived disease transmission is suspected. To facilitate notification by the OPO, transplant centers should keep accurate records of all organs and associated blood vessel conduits received and the disposition of each.

32. (A) When a transplant center receives information that a recipient of an organ from a living donor is newly infected with HIV, HBV, or HCV posttransplant and the infection is suspected of being donor-derived, the transplant center should notify (1) the OPTN and (2) the living donor recovery center that procured the organ. (B) In accordance with state requirements for reporting notifiable infectious diseases, the transplant center should also notify public health authorities where the transplant took place of the recipient's infection. 33. A living donor whose blood specimen is positive for HIV, HBV, or HCV when tested by the living donor recovery center should be notified by the living donor recovery center of his or her infectious disease status. 34. OPOs should have a system in place allowing tracking between a common deceased donor and (1) recovered organs, (2) recovered associated blood vessel conduits, and (3) recovered tissues and eyes to facilitate notification when a donor-derived disease transmission is suspected. This system should include accurate records of the distribution and disposition of each organ and initial distribution of associated blood vessel conduits, along with procedures to facilitate the timely notification of transplant centers and tissue and eye recovery establishments when a donor-derived disease transmission is suspected. To facilitate notification by the OPO, transplant centers should keep accurate records of all organs and associated blood vessel conduits received and the disposition of each.	