

Infectious Disease Verification to Enhance Patient Safety

OPTN/UNOS Operations and Safety Committee

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Infectious Disease Verification to Enhance Patient Safety

Affected Policies: 2.15.B (Pre-Recovery Verification), 5.8 (Pre-Transplant Verification), 14.7 (Living Donor Pre-Recovery Verification), and 14.11 (Living Donor Pre-Transplant Verification)

Sponsoring Committee: Operations and Safety

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Executive Summary

This proposal will require that OPOs, transplant hospitals, and living donor recovery hospitals conduct pre-recovery and pre-transplant verifications of infectious disease results for HIV, hepatitis B (HBV), and hepatitis C (HCV). Intestine recoveries and transplants will also require verification of cytomegalovirus (CMV) testing results.

This issue was referred to the Operations and Safety Committee (hereafter referred to as the Committee) from the Membership and Professional Standards Committee (MPSC) and Health Resources and Services Administration (HRSA) in 2014. Three living donor events had occurred where either a near miss or actual accidental disease transmission of HCV took place despite testing being completed.

In addition, the HIV Organ Policy Equity (HOPE) Act work group recommended that Operations and Safety continue its work on the infectious disease verification process to prevent inadvertent transmission of HIV from positive donors into negative recipients. The HOPE Act (effective November 19, 2015) allows special variances for research transplantation of HIV positive donor organs into HIV positive recipients. Another timely reason to adopt this proposal is an emerging practice of transplanting HCV positive organs into HCV negative recipients and then treating for HCV as new effective therapies have become available. As use of positive organs expands, verifications are needed to ensure that only willing recipients receive infected organs and to prevent accidental disease transmission.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

The Committee is seeking specific feedback regarding the area where the verification can take place. There has been debate on whether the pre-operative area would be an acceptable place. Part of this issue is developing a working definition of the pre-operative area. Draft Centers for Medicaid and Medicare Services (CMS) Interpretive Guidelines (IGs) for the Organ Transplant Conditions of Participation at 42 CFR §§ 482.68 through 482.104 would require living donor ABO verification to take place in the operating room.¹ The Committee is sensitive to remaining aligned where possible with CMS. CMS, however, does not require infectious disease verification prior to recovery or prior to transplant.

The Committee seeks feedback on:

- Pros and cons of allowing verifications to take place in the pre-operative area
- Suggestions for a working definition of the pre-operative area

¹ CMS, Provider: Enrollment, Survey and Certification Information.

What problem will this proposal solve?

While there is a clear process for ABO verification to prevent unintentional transplant of incompatible blood types, there is no similar process of verification related to infectious disease. The need to develop policy surrounding infectious disease verification was referred to the Operations and Safety Committee from the Membership and Professional Standards Committee (MPSC) and Health Resources and Services Administration (HRSA) in 2014. Three living donor events had occurred where either a near miss or actual accidental disease transmission of HCV took place despite testing being completed. These incidents stemmed from human error and/or lack of process to prevent downstream issues that can occur when infectious disease tests indicate possible infection.

In addition, the HIV Organ Policy Equity (HOPE) Act work group recommended that Operations and Safety develop an infectious disease verification process to prevent inadvertent transmission of HIV from positive donors into negative recipients. The HOPE Act (effective November 19, 2015) allows special variances for research transplantation of HIV positive donor organs into HIV positive recipients.

It has become more common to use HCV positive organs for HCV positive recipients. More recently, research on transplanting HCV positive organs into HCV negative recipients has begun as new effective therapies to treat HCV have become available. The use of infected or positive organs helps increase the number of candidates receiving life-saving organs. OPTN policy (15.3 Informed Consent of Transmissible Disease Risk) requires specific informed consent for when a donor has a known condition that may be transmissible to the recipient.

It is important, however, to ensure that a process is in place to prevent transplantation of these organs into the “wrong” recipient or into a recipient who has not consented to receive an infected organ. The proposed infectious disease verifications will help prevent unintentional disease transmission. By requiring verification of donor results and their acceptability for the intended recipient, process issues which might lead to results not being reviewed or properly acted upon will be avoided.

Why should you support this proposal?

The solution of requiring infectious disease verification prior to organ recovery (deceased and living donors) and prior to transplant will introduce “hard stops” that will require examination of test results and their appropriateness for the recipient. This will institutionalize a set time and process to prevent overlooking of results or accidental transplantation of seropositive organs into recipients not willing or able to accept these types of organs.

Published HOPE Act criteria notes, “Prevention or management of inadvertent transmission of HIV or exposure of an HIV-negative recipient to organs or tissues from an HIV-positive donor due to identification error is paramount (Ison, 2009, 2011a, 2011b). The transplant community, with regulatory oversight at multiple levels, has been able to achieve a high level of safety through routine procedures and clinical practice. The precautions taken with ABO compatible donor-recipient pairs and HCV-infected donor organs in HCV-infected recipients (Morales, 2010; Kucirka, 2010; Mandal, 2000; Tector, 2006) are existing models.”² The proposed infectious disease verification would occur in tandem with certain ABO verifications that went into effect on June 23, 2016.

How was this proposal developed?

This issue was originally referred to the Operations and Safety Committee by the MPSC and HRSA in March 2014. The referral reads, “In light of continuing issues with infectious disease verification, the MPSC Chair, Vice Chair, and HRSA suggested it may be necessary to develop policy requiring the verification of serologies at two points during the living donation process. The first would occur during the donor selection process, and the second would occur prior to scheduling the donation surgery. (The Chair

² [Federal Register: Final HIV HOPE Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV.](#)

and Vice-Chair also recommend consideration of similar requirements for deceased donors.) Required 'time out' periods are already specified in policy for blood type and correct donor/recipient verification."³

A Transplant Pro article, "Potential Failure Point Identified in the Evaluation of Living Donors" was published to raise awareness within the transplant community.⁴

This proposal was developed using a work group comprised of representatives from multiple committees including: the OPO, Transplant Administrators, and Transplant Coordinators Committees. Several other related initiatives including ABO, PHS Increased Risk Guidelines, the HOPE Act and Re-Execute the Match Run (REMR) were followed to help assure complementary and not conflicting recommendations.

The HOPE Act work group provided advice and consultation. The HOPE Act safety subgroup and the full work group discussed the possibility of this requirement being introduced as part of HOPE Act policy changes. The HOPE Act work group ultimately recommended that the infectious disease verification process be developed by the Operations and Safety Committee due to the complexity of the issues in comparison to the statutory time constraints on the implementation of the HOPE Act.

The US Secretary of Health and Human Services (US HHS) published criteria for HOPE Act research to assess the safety and effectiveness of solid organ transplantation from donors with HIV infection to recipients with HIV infection that approved participating transplant hospitals must follow. These include that the transplant hospital must verify the HIV status of both the donor and the recipient, however, these guidelines did not address verification specifics. The guidelines also require that: "Each transplant hospital shall have an institutional biohazard plan for handling of HIV-positive organs—to include, for example, organ quarantine measures, electronic information capture on infectious disease testing results, communication protocols between OPOs and transplant hospitals—that is designed to prevent and/or manage inadvertent transmission of or exposure to HIV."⁵ The Committee was able to ensure that this proposal is consistent with federal guidelines that had not been formally published at the time of other OPTN HOPE Act policy changes.

The Ad Hoc Disease Transmission Advisory Committee (DTAC) was concurrently working on REMR policy with representatives from both the OPO and Operations and Safety Committees on that effort. This need for this policy arose after discovery of matches run without infectious disease results that were later found to be positive. This could be problematic because candidates that do not desire to receive organs positive for HCV, HBV, or CMV would not be screened from match runs. UNOS data from 2012-2013 showed that approximately 21% of match runs had pending Hepatitis B Core antibody or Hepatitis C results at the time of organ acceptance. Three voluntary patient safety situation reports were received showing that the match had not been rerun following a positive result. This policy also codified voluntary candidate screening off the match run for certain infectious disease test results. OPTN Policy 15.6 requires candidates that will be accepting these types of organs to provide informed consent for receiving the infected organ. Programming was put into place to lock the match and force a re-execution if certain results change to positive. Positive HIV results do trigger other programming rules consistent with the HOPE Act.

In 2013, revised guidelines to identify those at increased risk for these conditions were released by the US Public Health Service. Subsequent changes in OPTN/UNOS policy codified NAT testing for all HCV donors and either NAT or combination antigen/antibody testing for HIV in increased risk donors. This has led to greater ability to evaluate and potentially use those testing positive. For example, a transplant hospital might indicate that they would be willing to accept a HCV NAT negative but antibody positive donor organ as it could indicate cleared infection. Previous candidate screening did not distinguish on test type. This complexity, however, means greater awareness and analysis of results.

The Committee's infectious disease verification work group consulted the DTAC on this proposal. The DTAC recommended to the Committee that the infectious disease verification policy use the same infectious agents that are named in policy as those affecting the match run (HIV, HBV, and HCV as well

³ Policy Department Referral. March 5, 2014.

⁴ UNOS. "Potential Failure Point Identified in the Evaluation of Living Donors" *Transplant Pro*. Published March 26, 2014. Accessed at [UNOS Transplant Pro: Potential Failure Point Identified in the Evaluation of Living Donors](#).

⁵ [Federal Register: Final HIV HOPE Act Safeguards and Research Criteria for Transplantation of Organs Infected with HIV](#).

as CMV for intestines only). The Committee agreed with the DTAC recommendations and limited the infectious disease verification proposal to these test results.

The Operations and Safety Committee had heard anecdotally that many organizations were doing some type of infectious disease verification process although policy did not require this. From a cursory review of uploaded DonorNet® forms, at least 17 OPOs had forms indicating some type of infectious disease verification at organ recovery. To gather further information, OPO Committee members were surveyed on their current practices. All respondents (n=9) indicated that they had an infectious disease verification process in place. All respondents indicated that some results would be available at the time of verification although one OPO indicated that NAT results would not be available. One OPO performed the verification prior to organ recovery. Others performed one at the time of DonorNet entry or prior to allocation. Five of the nine had a process for documenting that results had been received. All indicated that entry into DonorNet could be a proxy for when results were received.

There was also collaboration with TransNetsm development. Positive infectious disease results will be displayed upon organ check-in and at the pre-transplant verification scan with the organ and the recipient. The Committee has added use of TransNet, referred to as the organ tracking system in the proposed policy, as an acceptable source for verification where possible.

The work group thoughtfully developed this proposal to overlay with ABO policies. The most recently revised policies require pre-recovery (deceased and living donors) and pre-transplant verifications prior to surgery. In order to ease implementation efforts and ongoing compliance, the Committee developed a proposal that could be incorporated into these processes. The Committee considered double data entry and verification of infectious disease testing results into UNetsm. They decided not to include that process in this proposal due to manpower and timing issues as that could add double verification requirements for up to seven fields. An unintended consequence might then be an increase in match runs executed without infectious disease results that could in turn lead required rerunning of matches for changed positive results. These potential delays and subsequent downstream effects were the reason double verification of infectious disease results at UNet entry was not proposed.

It was concluded that a “hard stop” verification prior to recovery and prior to transplant would be the best solution to prevent unintended transplantation of organs infected with HIV, HBV, HCV, and/or CMV. To reduce member burden, the Committee proposed that if all results were available and were verified as negative at a pre-transplant verification prior to organ arrival, then the verification will not need to be repeated upon organ arrival. The work group also discussed what proof of burden would demonstrate that the recipient is willing to accept a positive organ. The HOPE Act has its own set of safeguards including double data entry for willingness to accept an HIV positive organ. This choice is programmed to be only possible at HOPE Act approved transplant hospitals. There are not similar programming rules for HBV, HCV, and CMV candidate screening. The work group considered and discarded the idea of requiring an actual consent to be reviewed at the verification. The recipient medical record or surgeon attestation that the organ is acceptable to the recipient according to OPTN policy are source options.

The original referral requested two verifications for living donors. To reduce member burden and ensure that the most recent results are taken into consideration, the Committee only proposed the pre-recovery verification on the day of living donor surgery.

The Committee recognizes the community’s significant efforts that have gone into implementing ABO policy changes. The Committee deliberately delayed releasing the proposal for public comment until after ABO implementation. The Committee is sensitive to the perception of increased burden particularly given comments during ABO public comment. It was decided to allow time for organizations to develop and practice their revised verification practices to meet ABO requirements before proposing additional requirements. The Committee hoped that once the community was comfortable with revised ABO processes that adding infectious disease elements would be less burdensome. The Committee has chosen to move forward at this time to get relevant feedback gained during ABO implementation and to address the proposal’s growing need as increasing numbers of seropositive organs are being transplanted.

How well does this proposal address the problem statement?

The problem of clinically relevant data not being used effectively to avoid preventable morbidity and mortality is well documented in health care as well as within the transplant community. This proposal specifically puts into place process requirements for both donors and recipients to minimize the chances that clinically relevant data, specifically pertinent infectious disease results, will be appropriately reviewed and considered prior to transplant.

Human factors and communication have been among the top three root causes for sentinel events reported to The Joint Commission since 2012.⁶ Handover error is recognized as a potential hazard in patient care and the information error rate has been estimated at 13%. Studies suggest that discontinuity results from poor information transfer and faulty communication, which in turn may cause avoidable adverse events.⁷

The concept of effectively communicating and verifying critical data has become a widely accepted safety practice and promoted by various health care organizations such as The Joint Commission. Relevant 2016 Joint Commission hospital national patient safety goals (NPSG) include:

- Improve staff communication: Get important test results to the right staff person on time (NPSG.02.03.01)
- Prevent mistakes in surgery: Make sure that the correct surgery is done on the correct patient (UP.01.01.01) and Pause before the surgery to make sure that a mistake is not being made (UP.01.01.03)⁸

These steps were developed to prevent wrong-patient/wrong-site/wrong-procedure events that have consistently been one of the top commonly reported sentinel events (n=1,215) to The Joint Commission between 2004- 2015.⁹ This issue was the most frequently reviewed sentinel event in 2015.¹⁰ The most common root causes for this error were leadership (n=1,656), human factors (n=1,335), and communication (n=1,319). They note that most events have multiple root causes.¹¹ Common factors identified in wrong-site surgery include the involvement of multiple surgeons on a case, the performance of multiple procedures during a single trip to the operating room, unusual time constraints, and unusual anatomy or patient characteristics, such as physical deformity or morbid obesity.¹² The Joint Commission does note that reporting is voluntary and represents only a small proportion of actual events and no conclusions should be drawn about the actual relative frequency of events or trends in events over time.¹³

Inadequate test result reporting and follow-up is the fifth highest patient safety concern in 2016 according to the ECRI institute. The ranking is based on a routine review of events in their patient safety organization (PSO) database containing more than 1.2 million events, PSO members' root-cause analyses and research requests, healthcare risk alert topics, and voting by a panel of experts from inside and outside ECRI Institute. Failing to report and follow up on significant test results can result in patient harm. ECRI cites that among the many challenges to effective, timely reporting and follow-up is

⁶ The Joint Commission. Sentinel Event Data Summary and Sentinel Event Statistics Data - Root Causes by Event Type (2004 - 2015) Accessed at http://www.jointcommission.org/sentinel_event.aspx.

⁷ Agency for Health Care Quality and Research. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. 2001.

⁸ The Joint Commission. Hospital: 2016 National Patient Safety Goals. Accessed at https://www.jointcommission.org/hap_2016_npsgs/.

⁹ The Joint Commission. Sentinel Event Data Summary. Accessed at: https://www.jointcommission.org/assets/1/18/2004-2015_SE_Stats_Summary.pdf.

¹⁰ The Joint Commission. Sentinel Event Data General Information. Accessed at: https://www.jointcommission.org/assets/1/18/General_Information_1995-2015.pdf.

¹¹ The Joint Commission. Sentinel Event Statistics Data - Root Causes by Event Type (2004 - 2015) Accessed at: https://www.jointcommission.org/assets/1/18/Root_Causes_by_Event_Type_2004-2015.pdf.

¹² Mulloy DF, Hughes RG. Wrong-Site Surgery: A Preventable Medical Error. In: Hughes RG, editor. Patient Safety and Quality: An Evidence-Based Handbook for Nurses. Rockville (MD): Agency for Healthcare Research and Quality (US); 2008 Apr. Chapter 36. Available from: <http://www.ncbi.nlm.nih.gov/books/NBK2678/>.

¹³ Agency for Health Care Quality and Research. Making Health Care Safer: A Critical Analysis of Patient Safety Practices. 2001.

inadequate communication among providers. Because there are so many gaps, a key improvement strategy is to “analyze the whole test-result reporting and follow-up system.”¹⁴

The transplant community is not immune from these issues identified in the broader healthcare community. Research more specific to the transplant community notes, “The detection and management of potential donor derived infections is challenging, in part due to complexity in communications among diverse labs, OPOs, and recipient transplant hospitals.” In addition, the researchers find, “...a significant association between having a proven/probable transmission or not, and the presence or absence of a communication gap present ($x^2/1 = 13.13$, $p = 0.0003$)...Conversely, effective communication was associated with minimized or averted infection in transplant recipients through the implementation of preventive or preemptive treatment strategies.” Gaps were found in several areas including the transplant hospital delaying contact with OPO or OPTN, the laboratory failing to relay donor results, clerical errors in reporting donor viral serologies, incomplete communication of test results by the OPO to transplant centers, and OPO delay in contacting the OPTN or transplant centers. All three infection events related to HCV or CMV in the study were found to have communication gaps.¹⁵

In one targeted study, 54 HCV cases reported from January 2008 through October 2013 and reviewed by DTAC were analyzed. Eight (15%) donor cases were decided to be proven or probable transmission of HCV affecting 12 recipients. Only one donor was identified as increased risk. Of the eight donors, three donor cases (38%) had resulting transmissions due to human error. This highlights the frequency with which human error may contribute to unintended disease transmission.

Process issues identified with near-miss or unintended disease transmission have also included:

- Mistake in data entry (entered as negative when should have been positive)
- Not examining the most recent test result data. Multiple tests with different results (both reactive and non-reactive test results for same virus/same patient) conducted with the most recent test reactive but overlooked.
- Not reviewing or acting upon positive results. Positive result in chart but not discovered until post-transplant

Management of viral hepatitis in transplant candidates and recipients is complex and highly depends on the organ transplanted, particularly for HBV and HCV, and the donor/recipient status.¹⁶ The landscape for detecting and using organs infected with HBV, HCV, and HIV has been significantly changing in the past several years. The enactment of the federal HOPE Act and subsequent OPTN HOPE Act variance policy marks the crossing of a line that had been in place for nearly thirty years. New advances for the treatment of HCV appear to be driving increases in potential use of positive organs into negative recipients. Data below describe some of these trends that underscore the need for having an infectious disease verification due to increased use and willingness to use organs positive for HBV, HCV and HIV.

Use of organs with positive HBV test results:

The American Society of Transplantation (AST) Infectious Diseases Community of Practice notes that HBV core antibody positive donors have been increasingly used to expand the donor pool, although without prophylaxis they pose a 34–86% risk of transmitting HBV infection to unexposed (HBV surface antigen negative) liver recipients. This group has also recommended that consideration may be given to using organs from HBV surface antigen positive donors, particularly for a lifesaving transplant (non-renal) with prophylaxis and informed consent. They note that HBV reactivation rates without treatment range from 50 to 94%.¹⁷

¹⁴ ECRI Institute. “Top 10 Patient Safety Concerns for Healthcare Organizations” available at <https://www.ecri.org/Pages/Top-10-Patient-Safety-Concerns.aspx>.

¹⁵ R Miller et al., 261-263.

¹⁶ J. Levitskya, K. Doucette, and the AST Infectious Diseases Community of Practice. “Viral Hepatitis in Solid Organ Transplantation”. *American Journal of Transplantation* 2013; 13: 147–168. doi: 10.1111/ajt.12108 accessed at <http://onlinelibrary.wiley.com/doi/10.1111/ajt.12108/pdf>.

¹⁷ J. Levitskya, K. Doucette, and the AST Infectious Diseases Community of Practice, page 150.

Recent studies also note more widespread use of HBV core antibody positive organs and call for use of HBV surface antigen positive organs when other options are unavailable even for HBV negative recipients (with adequate anti-viral protection) as well as for HBV core antibody positive and or HBV surface antigen positive patients with liver failure.¹⁸ Hepatitis core antibody positive donor grafts have better outcomes when transplanted into HBV surface antigen positive than when transplanted into HBV surface antigen negative recipients. These findings suggest that more stringent allocation strategies might be needed.¹⁹ Using HBV surface antigen positive liver grafts seems not to increase postoperative morbidity and mortality. It is viewed as a safe way to expand the donor pool when no other suitable donor is available.²⁰

Following 2015 changes to OPTN candidate screening criteria choices, data showed that 2,319 or 2% of kidney and/or pancreas (K/P) candidates indicated a willingness to accept a HBV positive NAT organ. For liver and/or intestine (L/I) candidates the percentage was higher at 12%. A higher percentage of both types of candidates (K/P = 57% and L/I = 74%) were listed as willing to accept a HBV core antibody positive organ. Currently, there is not a screening choice regarding HBV surface antigen status. Other OPTN data studies indicate that 4.1% of donors (with extra vessels recovered) were HBV core antibody positive and 0.1% were HBV surface antigen positive (2008 through June 2014). Of 2,300 deceased donors recovered between April 1, 2015 and June 30, 2015, 2,226 (96.8%) had HBV NAT performed and four (0.2%) deceased donors had a positive HBV NAT result.

Use of organs with positive HCV test results:

AST recommendations published in 2013 noted that transplantation of an HCV positive organ into an HCV negative recipient results in near universal transmission and a high risk of death. They also note mixed outcomes for HCV positive donors to HCV positive recipients but that this type of transplant provides an overall survival advantage in kidney transplants versus remaining on dialysis. They note that HCV positive kidneys continue to be underutilized. The authors state, "Given the current era of organ shortage and risk of death on the waitlist, an HCV-positive organ should be considered for transplantation, with informed consent, into an HCV-positive recipient (II-2)...The use of HCV-positive organs into HCV-negative recipients should be avoided due to poor outcomes; however this may be considered with strict informed consent in critically ill patients awaiting a life-sustaining transplant (III)."²¹

More recently, highly effective treatments for HCV have come into the market. Studies started in spring 2016 where deceased donor kidneys with HCV will be transplanted into HCV negative recipients who will then receive antiviral therapy "in the hopes that they will emerge infection-free." Between 2005 and 2014, only 37% of HCV positive kidneys were used. This research estimates that an average of 400 HCV positive kidneys have been discarded annually. With the new and highly successful HCV treatments available, this may lead to an increase in utilization of these organs.^{22, 23}

Another author says that with the rapid advances in therapy using direct acting antivirals (DAAs), "...it is easy to imagine an era on the horizon where HCV in donors will be approached in a manner similar to a donor with positive blood cultures; there may be a slightly increased risk of donor derived transmission of infection, but with safe effective therapy, this risk could be effectively mitigated and the donor pool further

¹⁸ Daniel Shouval. "Expanding the donor pool for liver transplant recipients using HBsAg positive grafts". *Journal of Hepatology*, Volume 61, Issue 4, October 2014, Pages 717-719. Accessed at <http://www.sciencedirect.com/science/article/pii/S0168827814004784>.

¹⁹ Mario Angelico et al., "Hepatitis B-core antibody positive donors in liver transplantation and their impact on graft survival: Evidence from the Liver Match cohort study". *Journal of Hepatology*. Volume 58, Issue 4, April 2013, Pages 715–723. Abstract accessed at <http://www.ncbi.nlm.nih.gov/pubmed/23201239>.

²⁰ Songfeng Yu et al., "Safe use of liver grafts from hepatitis B surface antigen positive donors in liver transplantation". *Journal of Hepatology*, Volume 61, Issue 4, October 2014, Pages 809-815. Abstract accessed at <http://www.sciencedirect.com/science/article/pii/S0168827814003122>.

²¹ J. Levitskya, K. Doucette, and the AST Infectious Diseases Community of Practice, pages 157-158.

²² E Dolgin. "In groundbreaking trials, surgeons to use infected kidneys for transplant" STAT. Published March 16, 2016. Accessed at: <https://www.statnews.com/2016/03/18/kidney-transplant-hepatitis-c/>.

²³ S Verma et al., "Kidney transplantation from an anti-hepatitis C virus antibody-positive donor into an anti-hepatitis C virus antibody-negative recipient: A case report". *Transplantation Reports*. Available online 3 June 2016.doi:10.1016/j.tpr.2016.05.001. Accessed at <http://www.sciencedirect.com/science/article/pii/S2451959616300014>.

expanded. This approach however will require further data before such recommendations can be made.”²⁴

Following 2015 changes to OPTN candidate screening criteria choices, data showed that 1,256 or 1% of K/P candidates and 3,101 or 20% of L/I candidates indicating a willingness to accept HCV positive NAT organs. For HCV positive serology, there were 1,621 or 1% of K/P candidates and 3,423 or 22% of L/I candidates willing to accept. The six-week post-production data do not reflect possible combination of results such as NAT negative and antibody positive, which might indicate recently cleared disease.

Since 2008, UNOS extra vessels data analysis show increases in HCV positive donors rising from 2.6% (2008-2010) to 3.9% (first half of 2014) when vessels were recovered (n=46,857). Other data show that 4.6% of deceased donors had a positive HCV NAT result. These data reflect analysis of all 2,300 deceased donors recovered between April 1, 2015 and June 30, 2015.

Use of organs with positive HIV test results:

The HOPE Act, permitting use of HIV infected donor organs into HIV infected recipients, went into effect on November 21, 2015. This allows research transplantation at OPTN member transplant hospitals with approved OPTN variances that are participating in IRB-approved studies following published US HHS guidelines. As of July 22, 2016, twelve transplant programs at eight transplant hospitals are participating. There are 57 waitlist candidates willing to accept HIV positive organs (50 kidney, 7 liver). The first HOPE Act transplants (kidney and liver) took place in March 2016 at John Hopkins University.²⁵ Since the HOPE Act went into effect, there have been ten transplants from four HIV positive donors.

Boyarsky et al. maintain that annually there are as many as 500-600 potential HIV positive deceased donors that could result in several hundred additional kidney and liver transplants each year.²⁶

Another study based on Philadelphia data estimated that there might be 356 potential HIV positive donors yielding 192 kidneys and 247 livers. This study also noted that they were more likely to be co-infected with HCV.²⁷

The strengths of this proposal are that it builds on existing policies and programming designed to prevent inadvertent transmission including candidate screening criteria, double verification of candidates willing to accept HIV positive organs, HOPE Act protocols, REMR requirements and programming, and approved policy requiring that all test results be uploaded to DonorNet (effective 9/1/2016). The policy extends the ABO verification process versus building a new stand-alone process. It provides some flexibility for not having to repeat the verification pre-transplant if all results are available, negative, and verified. It is important to note that neither the current nor the proposed policy requires that these results be completed prior to transplant. The proposal adds use of TransNet as a verification source. The UNetsm organ verification link built for ABO use, which has been widely used (over 6,000 views in the first month), will be another resource and have the infectious disease results added to assist members.

Because there is no requirement to have infectious disease testing completed and reported prior to transplant, it is necessary to have a verification hard stop prior to both recovery and transplant surgery. Some results are provided after transplant. Another strength is requiring documentation of outstanding results.

As seen in previously cited data, use of infected organs is likely to grow given the length of the waitlist and chance of waitlist mortality without a transplant. Should the HOPE Act be made permanent after the

²⁴S Belga and KE Doucette. "Hepatitis C in non-hepatic solid organ transplant candidates and recipients: A new horizon" *World Journal of Gastroenterology*. 2016 Jan 28; 22(4): 1650–1663. Published online 2016 Jan 28. doi: 10.3748/wjg.v22.i4.1650. Accessed at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4721996/>.

²⁵ Johns Hopkins performs first HIV-positive to HIV-positive organ transplants in U.S. <http://hub.jhu.edu/2016/03/31/first-kidney-liver-transplant-hiv-positive/>.

²⁶ B. Boyarsky et al. "Estimating the Potential Pool of HIV-Infected Deceased Organ Donors in the United States". *American Journal of Transplantation*, 2011; 1209–1217. doi: 10.1111/j.1600-6143.2011.03506.

²⁷ A. Richterman et al. "An Assessment of HIV-Infected Patients Dying in Care for Deceased Organ Donation in a United States Urban Center" *American Journal of Transplantation*. Volume 15, Issue 8, pages 2105–2116, August 2015. Abstract accessed at: <http://onlinelibrary.wiley.com/doi/10.1111/ajt.13308/abstract;jsessionid=3195D2C2772F2A34B1D8B5AB247CBA81.f01t02>.

research period, it will be imperative to have a verification process to maintain public trust. NAT testing has added a new dimension in interpreting results and options available. The complexity in what transplant hospitals can list candidate willingness to accept regarding infectious disease test results supports the requirement to confirm that the organ donor's infectious disease results are acceptable to the intended recipient. The consequences of accidentally transplanting infected organs can result in lifelong morbidity or mortality. The intended consequence of this proposal is to add process to prevent unintended transplantation of infected organs.

Some weaknesses may be the transplant community perceives that there is too much information to be verified or that the policy is becoming too complex. Unintended consequences could be building a process that the community feels they are not able to implement. The Committee plans to solicit and respond to feedback for both this proposal as well as the recently implemented ABO proposal. The Committee will also consider modifications as needed to reduce complexity. The Committee is also working towards a paperless, electronic solution with TransNet.

Which populations are impacted by this proposal?

This proposal will impact all donors (both deceased and living) and candidates. In 2015, there were 9,079 deceased donors and 5,989 living donors. That same year there were 30,969 recipients.

All 58 OPOs, 249 transplant hospitals and living donor recovery hospitals will be impacted and will be required to add certain infectious diseases to their verification processes. For those organizations who currently conduct infectious disease verifications, it might not have as a significant of an impact and some might be meeting proposed policy requirements already.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* This proposal supports Goal 4 by requiring processes to verify infectious disease results prior to recovery and prior to transplant for both deceased and living donors. This will help prevent inadvertent transmission of disease and subsequent organ loss, recipient morbidity, and recipient mortality.
5. *Promote the efficient management of the OPTN:* There is no impact to this goal.

How will the OPTN implement this proposal?

Implementation of this proposal will require communication and educational efforts. Research will conduct evaluation of the policy. Member quality will incorporate elements into compliance monitoring. The Organ Center may be asked to help with verifying information for intended recipients not appearing on a match run. Instructional Innovations will provide additional educational efforts.

This proposal will require programming in UNetSM. It will add certain infectious disease testing fields to the organ verification link (OVL) page released as part of ABO programming on June 23, 2016. This is expected to be a small effort.

How will members implement this proposal?

Members will need to familiarize themselves with policy changes related to infectious disease verification. Members will need to update their protocols in these areas.

Transplant Hospitals

Transplant hospitals must add verification of available HIV, HBV, and HCV results during the pre-transplant verifications. If transplanting intestines, then CMV results must also be verified. Transplant hospitals must either verify that all expected results have been received or report that results are pending. The OPTN computer system, organ tracking system, or source documents must be used for this part of the verification. The verification must include that the donor positive infectious disease testing results are acceptable to the recipient according to OPTN Policy. This can be done through a simple attestation by the transplant surgeon.

Living donor recovery hospitals must add verification of available HIV, HBV, and HCV results during the pre-recovery verifications. Source documents must be used for this part of the verification. The verification must include that the donor positive infectious disease testing results are acceptable to recipient according to OPTN Policy. This can be done through a simple attestation by the recovery surgeon.

The resource impact to transplant hospitals, including living donor recovery hospitals will be staff time for protocol revision, form modifications, staff communications, and training in new procedures. IT programming might be involved for some transplant hospitals.

OPOs

OPOs must add verification of available HIV, HBV, and HCV results during the pre-recovery verification. If recovering intestines, then CMV results must also be verified. Source documents must be used for this verification. OPOs must document any required infectious disease testing results that are pending at the time of verification.

The resource impact to OPOs will be staff time for protocol revision, form modifications, staff communications, and training in new procedures. IT programming might be involved for some OPOs.

Will this proposal require members to submit additional data?

No, this proposal will not require members to submit additional data to the OPTN Contractor.

How will members be evaluated for compliance with this proposal?

Members will be expected to comply with requirements in the proposed language. In addition to the monitoring outlined below, all elements required by policy may be subject to OPTN review, and members are required to provide documentation as requested.

The new monitoring elements below will be added to the existing monitoring of each of the policies listed.

Policy 2.15.B: Pre-Recovery Verification

At OPOs, site surveyors will review the OPO's internal policies, procedures, and/or protocols and interview staff to verify that they have and follow a written protocol that includes:

- Verification of available donor test results for:
 - HIV, hepatitis B, and hepatitis C
 - Cytomegalovirus (CMV), if recovering intestine from the donor
- Documenting any required infectious disease test results for the donor that are pending at the time of verification

Site surveyors will also review a sample of deceased donor records for the following documentation:

- A verification for each organ containing:

- Available donor test results for HIV, hepatitis B, and hepatitis C
- Available donor test results for cytomegalovirus (CMV) for the intestine recovery
- Documentation of any required infectious disease test results that are pending at the time of verification

Policy 5.8: Pre-Transplant Verification

At transplant hospitals, site surveyors will review the hospital's internal policies, procedures, and/or protocols and interview staff to verify that they have and follow a written protocol that includes:

- Pre-transplant verification prior to organ receipt that includes:
 - Verification of expected donor's available test results for:
 - HIV, hepatitis B, and hepatitis C
 - Cytomegalovirus (CMV), if transplanting intestine
 - That all expected donor test results for HIV, hepatitis B, and hepatitis C have been received or that results are still pending at the time of verification
 - If intestines are being transplanted, that all expected donor test results for CMV have been received or are still pending at the time of verification
 - If the expected donor has positive infectious disease test results, that these results are acceptable to the recipient according to *Policy 15.3 Informed Consent of Transmissible Disease Risk*
- Pre-transplant verification upon organ receipt that includes:
 - Verification of available donor test results for:
 - HIV, hepatitis B, and hepatitis C
 - Cytomegalovirus (CMV), if transplanting intestine
 - That all donor test results for HIV, hepatitis B, and hepatitis C have been received or are still pending at the time of verification
 - If intestines are being transplanted, that all donor test results for CMV have been received or are still pending at the time of verification
 - If the donor has positive infectious disease test results, that these results are acceptable to the recipient according to *Policy 15.3 Informed Consent of Transmissible Disease Risk*

Policy 5.8.B: Pre-Transplant Verification Upon Organ Receipt

At transplant hospitals, site surveyors will review a sample of medical records, and any material incorporated into the medical record by reference, for documentation that:

- The following infectious disease information was verified between organ arrival and anastomosis:
 - Donor test results for HIV, hepatitis B, and hepatitis C
 - Donor test results for cytomegalovirus (CMV), if transplanting intestine
 - That all required donor test results for HIV, hepatitis B, and hepatitis C have been received or are still pending at the time of verification
 - If intestines are being transplanted, that all donor test results for CMV have been received or are still pending at the time of verification
 - If the donor has positive infectious disease test results, that these results are acceptable to the recipient according to *Policy 15.3 Informed Consent of Transmissible Disease Risk*
- If a pre-transplant verification of donor infectious disease information was not conducted between organ arrival and anastomosis, that:

- All required donor test results for HIV, hepatitis B, and hepatitis C (and CMV if intestines are being transplanted) were available at the time of the pre-transplant verification prior to organ receipt
- Verification of the donor infectious disease information was completed and documented as part of the pre-transplant verification prior to organ receipt

Policy 14.7: Living Donor Pre-Recovery Verification

At living donor recovery hospitals, site surveyors will review the hospital's internal policies, procedures, and/or protocols and interview staff to verify that they have and follow a written protocol that includes:

- Verification of:
 - All required donor test results for HIV, hepatitis B, and hepatitis C
- Timing of verification:
 - Before induction of general anesthesia
 - On the day of the organ recovery
- If the donor has positive infectious disease test results, that these results are acceptable to the intended recipient according to *Policy 15.3 Informed Consent of Transmissible Disease Risk*

Site surveyors will also review a sample of living donor medical records, and any material incorporated into the medical record by reference, for documentation that:

- The following were verified:
 - All required donor test results for HIV, hepatitis B, and hepatitis C
 - If the donor has positive infectious disease test results, that these results are acceptable to the intended recipient according to *Policy 15.3 Informed Consent of Transmissible Disease Risk*
- The verification took place:
 - Before the induction of general anesthesia
 - On the same date as the organ recovery

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

OSC will request patient safety event data reported to the OPTN related to infectious disease verification one year after the proposed changes are implemented.

The committee will review these data to assess:

- Infectious disease verification issues that result in an inability to transplant;
- Transplant discards as a result of an inability to verify infectious disease;
- Delays in allocation due to infectious disease verification related issues;
- Near miss and actual disease transmission due to an inability to verify infectious disease.

Additionally, the committee will request the number of HOPE Act transplants performed as well as the data related to HCV positive organs transplanted into HCV negative recipients to monitor potential infectious disease verification events. These data might provide an indication for the denominator of how many potential adverse events were avoided.

Data will be reviewed yearly and as needed by the Committee to assess potential policy modifications related to infectious disease verification.

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20**Table 2-3: Additional Pre-Recovery Verification Requirements When the Intended Recipient is Known Prior to Organ Recovery**

The host OPO must verify <i>all</i> of the following information:	Using at least <i>one</i> of these sources:	By the following individuals:
Intended recipient unique identifier	<ul style="list-style-type: none"> • OPTN computer system 	Two qualified health care professionals
Intended recipient blood type	<ul style="list-style-type: none"> • OPTN computer system 	Two qualified health care professionals
Donor and intended recipient are blood type compatible (or intended incompatible)	<ul style="list-style-type: none"> • OPTN computer system 	Two qualified health care professionals

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The host OPO must document that the verifications were completed according to the OPO's protocol and the above requirements.

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5.8 Pre-Transplant Verification

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Transplant hospitals must develop and comply with a written protocol to perform pre-transplant verifications as required below.

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5.8.A Pre-Transplant Verification Prior to Organ Receipt

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If the recipient surgery will begin prior to organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification that meets *all* of the following requirements:

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~~1. Two licensed health care professionals must participate in the verification~~

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~~2. 1. The intended recipient must be present in the operating room~~

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~~3. 2. The verification must occur *either*:~~

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a. Prior to induction of general anesthesia

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b. Prior to incision if the patient has been receiving continuous sedation prior to arrival in the operating room

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~~4. 3. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification prior to organ receipt to verify all of the following information in *Table 5-2* below. Assistance using an OPTN-approved electronic method is permitted. Transplant hospitals may use the OPTN organ tracking system for assistance in completing these verifications.~~

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Table 5-2: Pre-Transplant Verification Prior to Organ Receipt Requirements

The transplant hospital must verify all of the following information:	Using at least one of these sources:	<u>By the following individuals:</u>
Expected donor ID	<ul style="list-style-type: none"> • OPTN computer system • <u>OPTN organ tracking system</u> • Recipient medical record 	<u>Two licensed health care professionals</u>
Expected organ (and laterality if applicable)	<ul style="list-style-type: none"> • OPTN computer system • <u>OPTN organ tracking system</u> • Recipient medical record 	<u>Two licensed health care professionals</u>
Expected donor blood type and subtype (if used for allocation)	<ul style="list-style-type: none"> • Donor blood type and subtype source documents • OPTN computer system 	<u>Two licensed health care professionals</u>
<u>Donor infectious disease testing results available at the time of verification for HIV, hepatitis B, and hepatitis C</u>	<ul style="list-style-type: none"> • <u>Donor infectious disease testing source documents</u> • <u>OPTN computer system</u> • <u>OPTN organ tracking system</u> 	<u>Two licensed health care professionals</u>
<u>If transplanting intestines, donor infectious disease testing results available at time of verification for cytomegalovirus (CMV)</u>	<ul style="list-style-type: none"> • <u>Donor infectious disease testing source documents</u> • <u>OPTN computer system</u> • <u>OPTN organ tracking system</u> 	<u>Two licensed health care professionals</u>
<u>Receipt of all expected donor infectious disease testing results for HIV, hepatitis B, hepatitis C, and CMV (intestines only) or report that results are pending</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>OPTN organ tracking system</u> 	<u>Two licensed health care professionals</u>
Recipient unique identifier	<ul style="list-style-type: none"> • Recipient identification band 	<u>Two licensed health care professionals</u>
Recipient blood type	<ul style="list-style-type: none"> • Recipient blood type and subtype source documents • Recipient medical record 	<u>Two licensed health care professionals</u>
<u>Expected donor's positive infectious disease testing results are acceptable to recipient according to <i>Policy 15.3: Informed Consent of Transmissible Disease Risk</i></u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>Attestation following verification of donor infectious disease testing results</u> 	<u>Two licensed health care professionals</u>

The transplant hospital must verify all of the following information:	Using at least one of these sources:	<u>By the following individuals:</u>
Expected donor and recipient are blood type compatible (or intended incompatible)	<ul style="list-style-type: none"> • OPTN computer system • <u>OPTN organ tracking system</u> • Recipient medical record • Attestation following verification of donor and recipient blood types 	<u>Two licensed health care professionals</u>

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If a pre-transplant verification was conducted prior to organ receipt, the transplant hospital must document that the verification was completed according to the hospital’s protocol and the above requirements.

5.8.B Pre-Transplant Verification Upon Organ Receipt

At the time of organ receipt in the operating room, the transplant hospital must conduct a pre-transplant verification with all the following requirements:

- ~~1. The transplant surgeon and another licensed health care professional must participate in the verification~~
2. 1. The intended recipient must be present in the operating room
3. 2. The verification must occur after the organ arrives in the operating room, but prior to anastomosis of the first organ
4. 3. Transplant hospitals must use at least one of the acceptable sources during the pre-transplant verification upon organ receipt to verify all of the following information in *Table 5-3* below. ~~Assistance using an OPTN-approved electronic method is permitted~~ Transplant hospitals may use the OPTN organ tracking system for assistance in completing these verifications.

Table 5-3: Pre-Transplant Verification Upon Organ Receipt Requirements

The transplant hospital must verify all of the following information:	Using at least one of these sources:	<u>By both of the following individuals:</u>
Donor ID	<ul style="list-style-type: none"> • External and internal organ package labels • Documentation with organ 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>
Organ (and laterality if applicable)	<ul style="list-style-type: none"> • Organ received 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>
Donor blood type and subtype (if used for allocation)	<ul style="list-style-type: none"> • Donor blood type and subtype source documents 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>

The transplant hospital must verify all of the following information:	Using at least one of these sources:	By both of the following individuals:
<u>Donor infectious disease testing results for HIV, HBV, and HCV</u>	<ul style="list-style-type: none"> • <u>Donor infectious disease testing source documents</u> • <u>Documentation in the recipient medical record of test results for deceased donor organs communicated from the OPO</u> • <u>OPTN computer system</u> • <u>OPTN organ tracking system</u> 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>
<u>If transplanting intestines, donor infectious disease testing results for CMV</u>	<ul style="list-style-type: none"> • <u>Donor infectious disease testing source documents</u> • <u>Documentation in the recipient medical record of test results for deceased donor organs communicated from the OPO</u> • <u>OPTN computer system</u> • <u>OPTN organ tracking system</u> 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>
<u>Receipt of all required donor infectious disease testing results for HIV, HBV, HCV, and CMV (intestines only) or report that results are pending</u>	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>OPTN organ tracking system</u> 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>
Recipient unique identifier	<ul style="list-style-type: none"> • Recipient identification band 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>
Recipient blood type	<ul style="list-style-type: none"> • Recipient blood type source documents • Recipient medical record 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>
Donor and recipient are blood type compatible (or intended incompatible)	<ul style="list-style-type: none"> • <u>OPTN computer system</u> • <u>OPTN organ tracking system</u> • Recipient medical record • Attestation following verification of donor and recipient blood types 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>
<u>Donor positive infectious disease testing results are acceptable to recipient according to <i>Policy 15.3: Informed Consent of Transmissible Disease Risk</i></u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>Attestation following verification of donor infectious disease testing results</u> 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>
Correct donor organ has been identified for the correct recipient	<ul style="list-style-type: none"> • Recipient medical record • <u>OPTN computer system</u> • <u>OPTN organ tracking system</u> 	<ul style="list-style-type: none"> • <u>Transplant surgeon</u> • <u>Licensed health care professional</u>

69 Pre-transplant verification of donor infectious disease testing results does not need to be
 70 completed if all the following are true:

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- 72 1. Verification of donor infectious disease testing results was completed according to Policy
 73 5.8.A: Pre-Transplant Verification Prior to Organ Receipt
- 74 2. All required infectious disease testing results for HIV, HBV, HCV, and CMV (intestines only)
 75 were completed, available and verified

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77 The transplant hospital must document that the pre-transplant verification upon organ receipt was
 78 completed according to the hospital’s protocol and the above requirements.

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80 **14.7 Living Donor Pre-Recovery Verification**

81 Recovery hospitals must develop and comply with a written protocol to perform pre-recovery
 82 verifications as required below.

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84 The recovery hospital must conduct a pre-recovery verification that meets all of the following
 85 requirements:

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1. ~~The recovery surgeon and another licensed health care professional must participate in the verification.~~
2. 1. The verification must occur prior to the induction of general anesthesia on the day of the living donor recovery.
3. 2. Recovery hospitals must use at least one of the acceptable sources during the pre-recovery verification to verify all of the following information in Table 14-12 below. Assistance using an OPTN approved electronic method is permitted. Recovery hospitals may use the OPTN organ tracking system for assistance in completing these verifications.

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88 **Table 14-12: Pre-Recovery Verification Requirements**

The recovery hospital must verify all of the following information:	Using at least one of these sources:	By both of the following individuals:
Donor ID	<ul style="list-style-type: none"> • Donor identification band 	<ul style="list-style-type: none"> • <u>Recovery surgeon</u> • <u>Licensed health care professional</u>
Organ type and laterality (if applicable)	<ul style="list-style-type: none"> • OPTN computer system 	<ul style="list-style-type: none"> • <u>Recovery surgeon</u> • <u>Licensed health care professional</u>
Donor blood type and subtype (if used for ensuring transplant compatibility or allocation)	<ul style="list-style-type: none"> • Donor blood type and subtype source documents 	<ul style="list-style-type: none"> • <u>Recovery surgeon</u> • <u>Licensed health care professional</u>
<u>All required donor infectious disease testing results for HIV, hepatitis B, and hepatitis C</u>	<ul style="list-style-type: none"> • <u>Donor infectious disease testing source documents</u> 	<ul style="list-style-type: none"> • <u>Recovery surgeon</u> • <u>Licensed health care professional</u>

The recovery hospital must verify <i>all</i> of the following information:	Using at least <i>one</i> of these sources:	<u>By both of the following individuals:</u>
Intended recipient unique identifier	<ul style="list-style-type: none"> • Recipient medical record • OPTN computer system 	<ul style="list-style-type: none"> • <u>Recovery surgeon</u> • <u>Licensed health care professional</u>
Intended recipient blood type	<ul style="list-style-type: none"> • Recipient medical record • OPTN computer system 	<ul style="list-style-type: none"> • <u>Recovery surgeon</u> • <u>Licensed health care professional</u>
Donor and intended recipient are blood type compatible (or intended incompatible).	<ul style="list-style-type: none"> • OPTN computer system • Recipient medical record • Attestation following verification of donor and recipient blood types 	<ul style="list-style-type: none"> • <u>Recovery surgeon</u> • <u>Licensed health care professional</u>
<u>Donor positive infectious disease testing results are acceptable to intended recipient according to Policy 15.3: Informed Consent of Transmissible Disease Risk</u>	<ul style="list-style-type: none"> • <u>Recipient medical record</u> • <u>Attestation following verification of donor infectious disease testing results</u> 	<ul style="list-style-type: none"> • <u>Recovery surgeon</u> • <u>Licensed health care professional</u>
Correct donor organ has been identified for the correct intended recipient	<ul style="list-style-type: none"> • Donor medical record • OPTN computer system 	<ul style="list-style-type: none"> • <u>Recovery surgeon</u> • <u>Licensed health care professional</u>

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90 The recovery hospital must document that the verification was completed according to the hospital's
 91 protocol and the above requirements.

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93 **14.11 Living Donor Pre-Transplant Verification**

94 Transplant hospitals must perform pre-transplant verifications ~~as required by~~ according to Policy 5.8: Pre-
 95 Transplant Verification.

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