At-a-Glance

Proposal to Require Re-Execution of the Match Run when a Deceased Donor's Infectious Disease Results Impact Potential Recipients based upon Screening Preferences

- **Affected/Proposed Policies:** 2.9 (Required Deceased Donor Infectious Disease Testing); 5.3.B (Infectious Disease Screening Criteria); 5.4.C (Liver Offers); 5.5 (Re-Execution of the Match Run Due to New Donor Information); 5.5.B (Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results); 5.5.C (Requirements for Positive HIV Infectious Disease Results)

- **Ad Hoc Disease Transmission Advisory Committee (DTAC)**

  The purpose of Policy 2.9 (Required Deceased Donor Infectious Disease Testing) is to determine whether deceased organ donors have evidence of infection with a number of potentially transmissible pathogens. For some of these specific pathogens, organ transplant candidates may choose not to receive offers from positive donors. In this case, these candidates do not appear on a match run. Current policy does not require the host OPO to re-execute the match run if new results become available after execution of the initial match run. This updated donor information could screen certain candidates from receiving organ offers. Review of OPTN data indicates that a large number of organ allocations take place using match runs executed prior to receipt of all test results. This presents a potential patient safety concern, as organs could unintentionally be allocated to a candidate who is not willing to accept offers from organs who are positive for a specific infectious disease. This could result in unintended donor-derived disease transmission. Better defining in policy the processes that should be followed when new results are learned after the initial match run will reduce the opportunity for error and enhance patient safety.

- **Affected Groups**

  Directors of Organ Procurement
  Lab Directors/Supervisors
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  Transplant Administrators
  Transplant Physicians/Surgeons
  Organ Candidates

- **Number of Potential Candidates Affected**

  In 2012-2013, approximately 21% of match runs had pending Hepatitis B Core antibody or Hepatitis C results at the time of organ acceptance. All potential transplant candidates considering deceased donor organ offers will benefit from these patient safety enhancements meant to reduce opportunity for human error in communicating this information and unintended donor-derived disease transmission.

- **Compliance with OPTN Strategic Goals and Final Rule**

  This proposal supports the OPTN's Strategic Goal of promoting transplant patient safety.

- **Specific Requests for Comment**
  1. Current policy does not include time requirements for the completion of deceased donor infectious disease testing. The testing results are critical to matching donor organs and recipients effectively. Please share your thoughts on a reasonable point in time in the organ allocation and recovery process where results might be required for sharing with the recipient transplant hospitals. The Committee's goal is to enhance patient safety without imposing requirements on OPOs and transplant hospitals that could lead to loss of organs.

  2. Kidneys from deceased donors are classified according to the Kidney Donor Profile Index (KDPI). A deceased kidney donor's Hepatitis C (HCV) status is a component of the KDPI. How much will delayed entry of HCV results impact kidney match run order for those candidates willing to accept an HCV positive donor kidney? (Please see page 7 for more information.)

  3. Hepatitis B core antibody (HBV cAb) positive is used to screen potential candidates from a match run. HBV nucleic acid test (NAT) results will also soon be added to screening criteria upon completion of related programming to the UNet^{SM} system. HBV surface antigen (HBV sAg) is also equivalent in identifying potential risk to recipients. Donor acceptance criteria does not currently include HBV sAg. A donor's result is recorded in the DonorNet^{SM}, but this information does not impact appearance on the match run. Do you believe that screening criteria should be broadened to include HBV sAg?

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Affected/Proposed Policies:

2.9 (Required Deceased Donor Infectious Disease Testing); 5.3.B (Infectious Disease Screening Criteria); 5.4.C (Liver Offers); 5.5 (Re-Execution of the Match Run Due to New Donor Information); 5.5.B (Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results); 5.5.C (Requirements for Positive HIV Infectious Disease Results)

Ad Hoc Disease Transmission Advisory Committee (DTAC)

Public comment response period: January 27 – March 27, 2015

Summary and Goals of the Proposal:

The purpose of Policy 2.9 (Required Deceased Donor Infectious Disease Testing) is to determine whether deceased organ donors have evidence of infection with a number of potentially transmissible pathogens. For some of these specific pathogens, organ transplant candidates may choose not to receive offers from positive donors. In this case, these candidates do not appear on a match run. Current policy does not require the host OPO to re-execute the match run if new results become available after execution of the initial match run. This updated donor information could screen certain candidates from receiving organ offers. Review of OPTN data indicates that a large number of organ allocations take place using match runs executed prior to receipt of all test results. This presents a potential patient safety concern, as organs could unintentionally be allocated to a candidate who is not willing to accept offers from organs who are positive for a specific infectious disease. This could result in unintended donor-derived disease transmission. Better defining in policy the processes that should be followed when new results are learned after the initial match run will reduce the opportunity for error and enhance patient safety.

Background and Significance of the Proposal:

Prior to the implementation of electronic organ offers using DonorNet[SM] in 2007, organ placement often began prior to receipt of final donor serologies. Match runs were frequently executed prior to the receipt of final laboratory results. As donor management could be successfully extended with better outcomes, and the efficiency of receiving laboratory results improved, it became more feasible to allocate organs electronically after receipt of final serology results. As a result of these changes, many OPOs moved to generating match runs after receipt of these final serologies, and starting the allocation process much later than what was done previously due to the availability of electronic organ offers through DonorNet[SM]. This has become such a common occurrence that many transplant programs now question offers they receive that do not include final donor serology results.

Reasons for generating match runs prior to receipt of final donor serologies include a "crashing donor" who may be hemodynamically unstable and require expedited recovery before donation is no longer viable. In this instance, a surgeon may need to move quickly to get on site while donation is still an option. Sometimes, a donor family may impose time constraints that require expediting recovery as well. In such cases, the DTAC expected that only rarely would organs to be accepted for transplant be removed from the donor before final serologies are received by the OPO. However, there are limited occurrences where kidneys may be recovered and packaged from a crashing donor prior to receipt of these important laboratory results.

Executing a match run prior to receipt of final serology results allows time for tissue typing and serology results (as some OPOs must send out samples a great distance, and this takes time), allowing time for a surgeon at the top of match run time to travel to a center to inspect and recover

organs, and time to start preliminary crossmatching for hearts and lungs early (which can add approximately six hours to a donor case).

Currently, candidates may choose not to appear on match runs for donors who are positive for specific infectious diseases, as outlined in Table 1, below. This means that they will not receive offers from positive donors. Programming to include nucleic acid test (NAT) screening results was approved at the November 2014 Board meeting, but has not yet been implemented. All other screening criteria are currently operational, though it should be noted that this is currently a manual process for vascular composite allograft (VCA) match runs. If results for these tests are noted as pending or not done, these candidates will still appear on the match run. If a match run is not re-executed to reflect results that are found to be positive later in the evaluation process, candidates may still receive organ offers.

Human T-Lymphotrophic Virus (HTLV) screening is no longer required for deceased donors; however, the screening option is still in place for candidates who choose not to receive offers for the small number of donors who are tested and found to be positive. The Ad Hoc Disease Transmission Advisory (DTAC) discussed removing the HTLV screening option, and agreed it is no longer practical for inclusion when most donors are not tested for this virus. This screening option will be removed as the new NAT options are added for candidates, and is noted below with strikethrough over the text. The Committee also discussed adding a new screening option for Hepatitis B surface antigen (HBV sAg) which is equivalent to HBV in identifying potential risk to recipients. This modification to screening criteria, however, is not part of this proposal, but may be pursued at a later date

Table 1: Donor Infectious Disease Screening Options

If the donor tests positive for…	**Then candidates may choose not to receive offers on the following match runs:**
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis B Nucleic Acid Test (NAT)*	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C Nucleic Acid Test (NAT)*	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
~~**Human T-Lymphotrophic Virus (HTLV)**~~	~~Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas~~

***approved by the Board in November 2014, but not yet implemented**

The Chairs of the DTAC, Organ Procurement Organization (OPO), and Operations & Safety Committees received a letter from a surgeon at a transplant hospital that had recently received offers for HCV positive livers allocated from a match run executed prior to receipt of final serologies. This particular center does not accept HCV or HBV core positive donors. If an updated match run had been executed, these potential recipients would not have received offers. While the positive serologies were recognized by transplant hospital staff considering the offer and no harm came to any candidates awaiting transplant, this is an example of a patient safety concern that could lead to donor-derived disease transmission. The Board of Directors assigned these committees to review this concern and develop a path forward that promotes patient safety late in 2012. While working to avoid withdrawing organ offers, such changes in donor information are

critical to communicate and education will be needed for both OPOs and transplant hospitals going forward to allow for allocating organs from appropriately updated match runs to candidates appearing on the match run. A suggestion was made for such acceptances to be considered as provisional pending information needed that may require a match to be re-executed.

A joint subcommittee was formed with representatives from each of these committees. Members agreed with concerns outlined in the letter, and some noted that they had also received organ offers without final serologies. The group discussed why a match run would not be re-executed upon receipt of final serologies or other pertinent changes to donor information that would potentially screen candidates off of the list. Joint subcommittee members suggested that re-running the match run would be practical, not particularly time consuming, and in the best interest of patient safety. It was suggested that accepted organ offers made from the preliminary match run might have to be withdrawn due to changes, requiring organs to be re-offered. This could set up pushback or frustration from a transplant program that may not want to give up the organ, but perhaps transplant it into another recipient on its waiting list based upon the positive serology result. An OPO representative noted that the re-executed match run could turn out very different as far as candidate inclusion and sequence based upon such updated information.

Joint subcommittee members from all three groups were supportive of requiring that a match run be re-executed if new information that would remove a potential recipient from a match run is determined. It was noted that HBV core positive deceased donors may be considered as an exception. Some centers may be willing to accept HBV core positive donors, even if this is new information and they had not previously noted a candidate as willing to accept such a positive serology donor. This was seen as an occasion where a transplant program may be willing to move forward regardless based upon donor quality. In this scenario, a potential policy violation would occur if the match was re-executed, due to transplanting a candidate not on the match run.

The joint subcommittee agreed that policy should be developed to require that a match run be re-executed when pertinent new donor information that will affect allocation becomes available. There was, however, some disagreement on how to handle situations where organs had been allocated using the original match run but the provisional recipient did not appear on the updated match run. There were concerns that a patient with higher medical priority might be bypassed to accommodate a provisional acceptance. Additionally, Policy 5.4.C (Liver Offers) currently limits the opportunity for match runs to be re-executed as a safeguard to prevent potential manipulation of listing criteria to advantage a specific candidate.

The joint subcommittee considered several potential solutions to address this patient safety concern:

(1) Require complete serology results prior to allowing execution of a match run

While this solution would ultimately provide the best patient safety protections, joint subcommittee members were not supportive of removing the opportunity to generate a match run prior to receiving final donor testing results. The joint subcommittee agreed this is warranted in some limited scenarios, such as “crashing” donors who are unstable or donor family time constraints. Requiring this could ultimately lead to loss of donors and a potential increase in discarded organs. Ideally, a match run should be generated once all critical information has been received in order to promote patient safety during organ allocation. However, the joint subcommittee recognized instances where expedited placement may be necessary and a match run would be generated prior to receipt of serology results.

(2) Require any match run to be re-executed when new infectious disease testing results are received, re-starting allocation from the top of the new match run regardless of whether an offer has been accepted pending serologies

The group agreed that it is important for the Host OPO to inform all recipient centers that they are re-generating a match run due to new donor information, with the understanding that a provisional acceptance is not binding in this situation. The joint subcommittee agreed that if this information is learned during allocation and before an organ is accepted that re-execution of the match run should be required.

The joint subcommittee, however, could not unanimously support rescinding pending or preliminary offers as a rule. Surgeons in the group noted circumstances where recovery teams may already be en route to the donor hospital or candidates listed as unwilling to accept a positive organ may be at a point where the seriousness of their condition may impact their risk tolerance for accepting an organ positive for one of these infectious diseases. Once an offer is accepted, a number of factors are mobilized: potential recipients are notified, hospital staff is mobilized, and organ recovery teams may be in flight to a donor hospital. Though such an offer is not binding, a joint subcommittee member noted that rescinding an offer will feel like a violation of trust, with candidates perceiving that something was not done appropriately or that there is no good explanation. The group was hesitant to put forth a proposal that would discount the provisional acceptance in these circumstances, and preferred to allow for medical judgment and informed consent decisions to be made in these instances, as noted below. The need for documentation related to these decisions based upon new donor information was highlighted.

One exception was highlighted after completion of the joint subcommittee. Recent legislation has removed the prohibition of organ donation involving those known to be positive for Human Immunodeficiency Virus (HIV). Recent changes to federal law will allow HIV-positive candidates participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery of organs from individuals known to be infected with HIV to receive kidneys or livers from these donors.

(3) Honor the pending/provisional acceptance, with the OPO providing the potential recipient's transplant hospital with new infectious disease information before re-executing the match run

Ultimately, the joint subcommittee, and later the full DTAC, believed that it is appropriate to require that a match run be re-executed in the interest of protecting potential transplant recipients. If a positive serology result for one of the tests used to screen potential candidates from a match run is learned after a match run is executed, and could screen a potential recipient on or off a match run based upon donor acceptance criteria, a new match run must be executed for the donor *unless* the *first* candidate for whom an organ has been accepted pending final information is still willing to accept it despite the new infectious disease result. In this case, the Committee believed that the current informed consent requirements in Policy 15.3.A (Deceased Donors with Additional Risk Identified Pre-Transplant) will appropriately address concerns regarding notification and documentation.

If this intended recipient is no longer willing to accept the organ, the new donor information must be entered into DonorNet[SM] and a new match run be executed to reflect this new result and potential recipients willing to receive positive organ offers. Allocation would then take place using the new, updated match run.

When considering implementation of these proposed requirements, the community is asked to think about the potential impact of re-executing the match run on the new kidney allocation system. Kidneys from deceased donors are classified according to the Kidney Donor Profile Index (KDPI). The KDPI is a score ranging from zero to 100 percent that is associated with how long a

kidney is likely to function when compared to other kidneys. For example, a KDPI score of 20 percent means that a kidney is likely to function longer than 80 percent of other available kidneys. A deceased kidney donor's HCV status is a component of this score, as outlined in Policy 8.5.B (Deceased Donor Classifications). The Committee welcomes Kidney Transplantation Committee and general kidney transplant community input on whether proposed changes regarding re-executing the match run may have any potentially negative impact on donors with match runs executed without HCV results that are later found to be positive. Based upon the small component size, the DTAC does not suspect any concerning impact, but welcomes input here from the kidney transplant community.

As part of this proposal, the Committee also considered recently implemented requirements in Policy 2.9 (Required Deceased Donor Infectious Disease Testing). This policy requires the host OPO to report instances when HBV, HCV, or HIV testing is not completed as required in policy to the Improving Patient Safety portal. The DTAC intended this language to trigger immediate notification to the OPTN when an OPO was not testing donors according to policy. Since its implementation on September 1, 2014, several OPOs may have mistaken this as a pathway to report using an alternate testing types rather than a potential policy violation. The Committee feels strongly that the required tests outlined in this policy are necessary information for considering organ offers. Screening tests were selected based upon the patient safety enhancing qualities. These tests are approved by the FDA for donor screening. To eliminate any perception of this being an alternate to testing donors as required, the Committee proposes striking this language from policy.

Finally, Policy 2.9 is currently silent on the timeframe in which these donor test results must be available. While from a patient safety perspective, it is clear that this information would be a critical component in the evaluation of a donor, the recent addition of nucleic acid testing (NAT) requirements to policy have complicated this. While having all test results back prior to organ transplant is optimal, the Public Health Service specifically notes in its 2013 *PHS Guideline for Reducing Human Immunodeficiency Virus, Hepatitis B Virus, and Hepatitis C Virus Transmission Through Organ Transplantation*[1] that when it is not feasible to have NAT results prior to transplant, the results are still useful in guiding recipient treatment.

The intent of such a requirement would not be to impede OPOs, but to clarify expectations and enhance patient safety. Due to the operational nature of such a policy requirement, the DTAC will seek feedback from the UNOS Organ Center as well as the OPO and Operations & Safety Committees. This may be a future policy consideration for these groups, and specific feedback on this topic is requested from the transplant community on the At-A-Glance page that proceeds this proposal.

[1] The full 2013 PHS Guideline may be reviewed at:
http://www.publichealthreports.org/issueopen.cfm?articleID=2975.

Supporting Evidence:

The Committee requested data to better understand how often match runs are executed without the relevant infectious disease results. All donor matches executed from January 2012 through December 2013 were reviewed.

As noted in Figure 1, below, the data indicates that it is relatively common for OPOs to execute match runs with ambiguous results for screening tests (e.g. a result of not done or pending, anything other than negative or positive). This practice is becoming less common over the last few years, but there is still great variation in practice across OPOs. Figure 2 reflects the reduction in this OPO practice since 2009; however, 18-19% of all matches in 2013 were generated using a match run with pending HBV core or HCV serology test results. The trends were the same when limiting the analysis to only those match runs with a documented acceptance. It should be noted that the dramatic change in HTLV reporting is due to the 2009 policy modification that made this test optional for deceased donors.

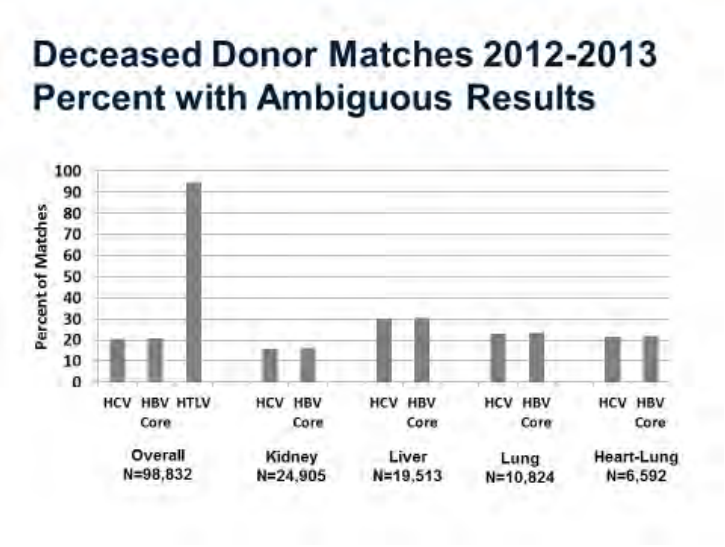

Figure 1. Percent of Deceased Donor Matches 2012-2013 with Ambiguous Results for Screening Tests

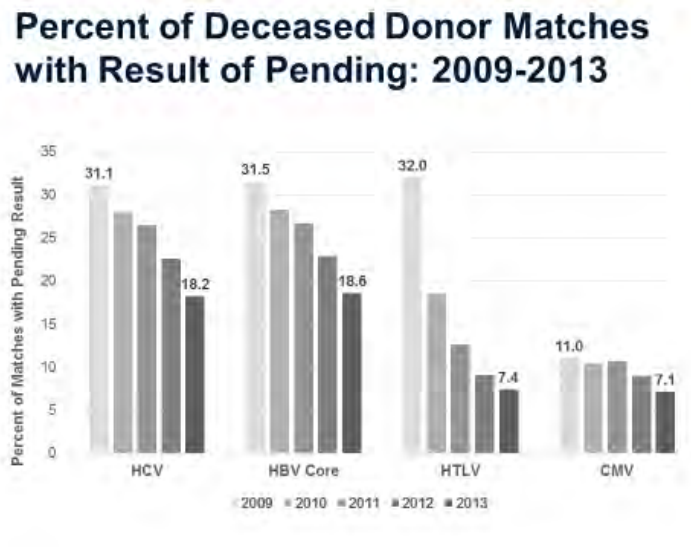

Figure 2: Annual Percent of Deceased Donor Matches with Result of Pending: 2009-2013

While it is uncommon for allocation to take place with a pending result and for the final reported donor result to be positive, this does occur. There is notable variation among OPOs in whether match runs are executed with ambiguous infectious disease testing results. This may be partly the result of local and regional availabilty of STAT results for these required tests. Some OPOs will not execute a match run until all results are available. Others execute a match run while awaiting results from tests that require donor samples to be transported to contract laboratories when tests are not available locally. This may require driving samples to another location or even flying samples to another state for testing. An example of this variation in OPO practice is shown below, in Figure 3. Each bar represents a single OPO, and displays the percentage of total liver match runs generated where the HCV result was not positive or negative. During the two year period, the percentage of such liver matches at each of the 58 OPOs ranged from 0 to 92%. At ten OPOs more than 50% of liver matches had ambiguous HCV results. The median value across all OPOs, reflected by the light gray bar, was 21.1%. Similar results were seen for HBV and HCV for all organs types.

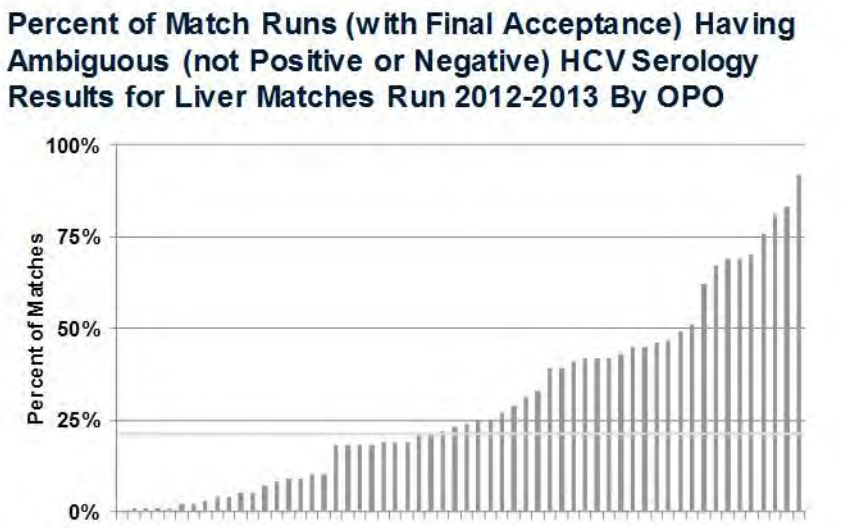

Figure 3: Liver Matches with Final Acceptance 2012-2013, OPO Variation in Percent with Ambiguous (Not Positive or Negative) HCV Results

Figure 4 demonstrates a different pattern for CMV results, with more than half of OPOs allocating intestines with complete CMV results at the time the match was run.

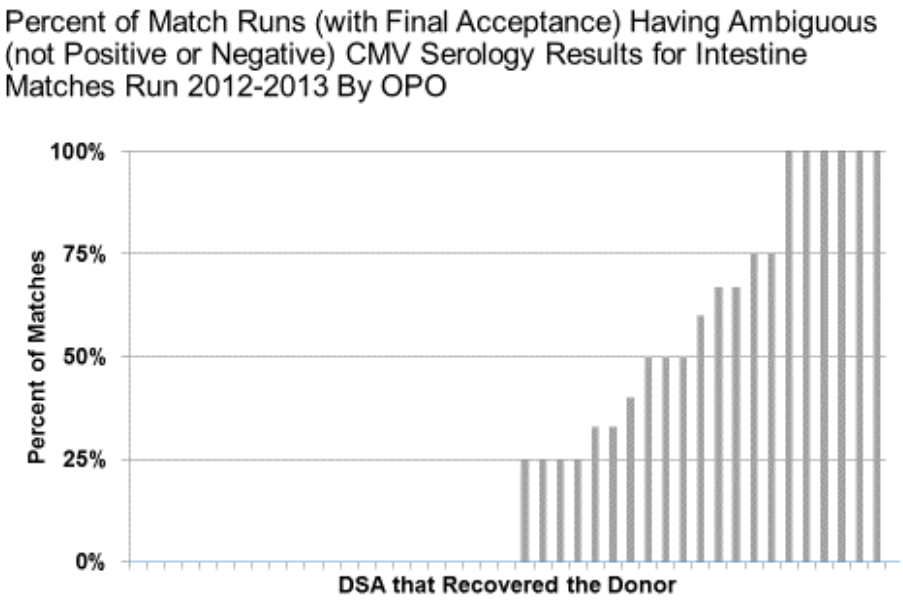

Figure 4: Intestine Matches with Final Acceptance 2012-2013, Percent of Match Runs with Final Acceptance Having Ambiguous CMV Serology Results, by OPO/Donor Service Area

Transplants did occur during the period where positive donor organs were allocated on a match run with ambiguous or incorrect test results. It is unclear when transplant hospital was made aware of the positive donor result prior to transplant. Table 2 looks specifically at cases where the

donor was indicated to be Hepatitis B Core antibody positive on the deceased donor registration (DDR) form, which is completed within 35 days of organ recovery. Of the 1,300 match runs in this two year period where the donor was noted as positive, 65 match runs indicated that results were pending (3 heart-lung, 2 heart, 8 kidney, 47 liver, 5 lung). In 9 cases, the match run with organ acceptance still indicated pending results, but a subsequent match run was re-executed to reflect the positive results. In one instance, the results were indicated as not done for all liver matches executed for the donor. On four match runs (1 heart-lung, 1 kidney, 1 kidney-pancreas, and 1 liver), the donor was indicated as negative for HBV Core antibody on all match runs.

Table 2: Match HBV Core Antibody Results for Matches Run 2012-2013 with Documented Acceptance and Donor HBV Core Antibody Positive on DDR

		Match Run Organ Type														Total	
		Heart-Lung		Heart		Kidney		Kidney-Pancreas		Liver		Lung		Pancreas			
		N	%	N	%	N	%	N	%	N	%	N	%	N	%	N	%
Donor HBV Core on Match with Acceptor	**Donor HBV Core on Last Match Run***																
Positive	**Positive**	39	90.7	24	92.3	545	98.0	7	77.8	520	90.6	84	93.3	2	100.0	1,221	93.9
Negative	**Negative**	1	2.3	0	0	1	0.2	1	11.1	1	0.2	0	0	0	0	4	0.3
Not Done	**Not Done**	0	0	0	0	0	0	0	0	1	0.2	0	0	0	0	1	0.1
Pending	**Positive**	0	0	0	0	2	0.4	1	11.1	5	0.9	1	1.1	0	0	9	0.7
	Pending	3	7.0	2	7.7	8	1.4	0	0	47	8.2	5	5.6	0	0	65	5.0
Total		43	100.0	26	100.0	556	100.0	9	100.0	574	100.0	90	100.0	2	100.0	1,300	100.0

***If no additional matches were run, or the results were the same, the two columns will have identical results**

As demonstrated above, a significant number of organs are currently allocated using match runs without serology results. The Committee recognizes that time of receipt of test results also plays a role in executing the match run, and seeks feedback from the OPO community on appropriate expectations in this area that will, at the same time, not eliminate a pathway for urgent allocation in extreme circumstances. The Committee is keenly aware that putting stringent requirements into place here could have an undesirable effect on the transplant system, causing a potential increase in loss of organ donors or discard of usable organs.

Expected Impact on Living Donors or Living Donation:

Not applicable; these changes only apply to deceased donors.

Expected Impact on Specific Patient Populations:

In 2012-2013, approximately 21% of match runs had pending Hepatitis B Core antibody or Hepatitis C results at the time of organ acceptance. This proposal is expected to enhance patient safety for all recipients of deceased donor organs by creating new requirements for re-executing the match run when necessary to match donors and potential recipients appropriately based upon desired screening criteria. This would reduce opportunity for human error in verbally communicating this information and unintended donor-derived disease transmission for all potential transplant candidates considering deceased donor organ offers.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

This proposal seeks to promote transplant patient safety. It is anticipated that by modifying and creating new policies to clarify expectations regarding re-execution of match runs for organ allocation, OPOs and transplant centers will have a straightforward and consistent interpretation of these requirements.

The DTAC's proposal will address two of the OPTN Strategic Plan Goals:

- Goal 1: Increase the number of transplants: Maximize the number of transplants through careful screening of deceased and living donors and clear requirements for communicating these results.
- Goal 4: Promote transplant patient safety: Reduce opportunities for unintended donor-derived disease transmissions

The Committee's goals for these policy modifications meet provisions of the Final Rule as outlined in §121.6(a)[2].

Plan for Evaluating the Proposal:

This proposal is designed to reduce opportunities for unintended donor-derived disease transmissions. The evaluation of this proposal will assess whether the number of instances where a donor is positive for HCV, HBV, or CMV (intestine only) and was not indicated to be positive on the match run with documented acceptance has decreased between the pre-policy and post-policy periods. Due to the small number of such instances, this analysis will be first initiated one year after implementation, and will be monitored by the committee annually for three years.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

If public comment on this proposal is favorable, this proposal will be submitted to the OPTN Board of Directors in June 2015 and, if approved, new policy requirements will be implemented upon completion of programming in UNet[SM] to:

- Create a pop up message in DonorNet[SM] to remind OPOs of policy requirements related to re-executing the match run when the OPO learns new infectious disease results that will impact candidate appearance on match run.
- Add functionality that will prevent the host OPO from sending electronic notifications on matches where serology was first noted as "negative", "unknown", "indeterminate" or "pending" and then changed to "positive."

The host OPO will still be able to send electronic notifications on matches where the result is noted as "pending." Additionally, if the OPO entered a "positive" result in error and then updated the result to negative, the system will allow the user to send electronic notifications from this original match.

[2] To view the full text of the Final Rule, please visit the following link: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&tpl=/ecfrbrowse/Title42/42cfr121_main_02.tpl

OPOs will need to:

- Familiarize themselves with new policy requirements
- Educate allocation staff regarding requirements to re-execute the match run when new infectious disease results are learned that are included in infectious disease screening criteria
- Update internal policies and procedure to address changes made to OPTN policy, including updating any internal documents or processes accordingly
- Educate all staff impacted by these changes (e.g. medical directors, laboratory directors, allocation coordinators, data entry coordinators, etc.)

Transplant hospitals will need to:

- Familiarize themselves with new policy requirements
- Educate transplant coordinator staff regarding new requirements to re-evaluate a provisionally accepted organ offer when new infectious disease results are learned that could impact match run appearance due to infectious disease screening criteria
- Review informed consent policies in Policy 15.3.A (Deceased Donors with Additional Risk Identified Pre-Transplant) with transplant team staff involved in having these discussions with transplant candidates or their agents
- Update internal policies and procedure to address changes made to OPTN policy, including updating any internal documents or processes accordingly
- Educate all staff impacted by these changes (e.g. transplant surgeons, transplant physicians, transplant coordinators, etc.)

Communication and Education Plan:

This proposal may require an instructional program for members and will be monitored for specific educational needs throughout the public comment process. Communication and educational activities will provide information to members to include:

- Policy notice
- System notice
- Presentation at Regional Meetings
- Formal training, if required (e-learning, webinars, etc.)

Compliance Monitoring:

OPTN Contractor staff will continue reviewing all deceased donor match runs that result in a transplanted organ to ensure that allocation was carried out according to OPTN requirements and investigating potential policy violations.

Based on the proposed language, OPTN Contractor staff would begin verifying that a host OPO re-executes a match run according to OPTN requirements when the OPO receives new positive infectious disease test results for a deceased donor after a match run has been executed.

The following new monitoring would also be added to the current routine monitoring of members:

Policy 5.5.B *Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results*

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 transplant program has obtained informed consent before transplant from a potential transplant recipient or the potential recipient's agent to accept an organ from a deceased

donor when the program is informed by the host OPO that the donor has new positive test results for:

- Cytomegalovirus (CMV) (Intestine candidates only)
- Hepatitis B core antibody (HBcAb)
- Hepatitis B Nucleic Acid Test (NAT)
- Hepatitis C Antibody
- Hepatitis C Nucleic Acid Test (NAT)

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

2.9 Required Deceased Donor Infectious Disease Testing

The host OPO is responsible for ensuring that *all* of the following infectious disease testing below is completed in CLIA-certified laboratories, or in laboratories meeting equivalent requirements as determined by the Centers for Medicare and Medicaid Services (CMS):

1. Blood and urine cultures

2. Infectious disease testing for all potential deceased organ donors using FDA licensed, approved or cleared tests, as listed below:

    a. HIV antibody (anti-HIV) donor screening test *or* HIV antigen/antibody (Ag/Ab) combination test
    b. Hepatitis B surface antigen (HBsAg) donor screening test
    c. Hepatitis B core antibody (anti-HBc) donor screening test
    d. Hepatitis C antibody donor screening test (anti-HCV)
    e. Hepatitis C ribonucleic acid (RNA) by donor screening or diagnostic NAT
    f. Cytomegalovirus (CMV) antibody (anti-CMV) donor screening *or* diagnostic test
    g. Epstein-Barr Virus (EBV) antibody (anti-EBV) donor screening *or* diagnostic test
    h. Syphilis donor screening *or* diagnostic test

3. If the donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to *the U.S. Public Health Services (PHS) Guideline*. HIV RNA by donor screening or diagnostic NAT or HIV antigen/antibody (Ag/Ab) combination is *also* required unless *either of the following* is true:
    - The donor has already been tested for HIV using the HIV Ag/Ab combination test according to section 2.a above.
    - The donor's only increased risk factor is having received hemodialysis within the past 12 months.

    ~~If a deceased donor is identified as being at increased risk for HIV, HBV, and HCV transmission according to *the U.S. Public Health Services (PHS) Guideline*, testing must also include HIV ribonucleic acid (RNA) by donor screening or diagnostic NAT or HIV antigen/antibody (Ag/Ab) combination test. This does not apply to donors whose only increased risk factor is receiving hemodialysis within the preceding 12 months, as they are at risk only for HCV according to the *U.S. Public Health Services (PHS) Guideline*.~~

~~Additionally, if, for any reason, HIV, HBV, or HCV testing is not performed as described above in #2, the host OPO must:~~

~~1. Document in the donor record which test was used to assess the potential donor~~
~~2. Provide this information to the receiving transplant hospital before transplant~~

~~3. Report the reason for using another test to the OPTN Improving Patient Safety portal as soon as possible, but no later than 24 hours after organ recovery.~~

5.3.B Infectious Disease Screening Criteria

A transplant hospital may specify whether a candidate is willing to accept an organ from a donor known to have certain infectious diseases, according to *Table 5-1* below:

Table 5-1: Donor Infectious Disease Screening Options

If the donor tests positive for	Then candidates may choose not to receive offers on the following match runs:
Cytomegalovirus (CMV)	Intestine
Hepatitis B core antibody (HBcAb)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis B Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C (HCV) Antibody	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Hepatitis C Nucleic Acid Test (NAT)	Heart, Intestine, Kidney, Liver, Lung, Pancreas, Heart-Lung, Kidney-Pancreas
Human Immunodeficiency Virus (HIV); Organs from HIV positive donors may only be recovered and transplanted according to the requirements in the OPTN Final Rule.	Kidney, Liver; Use of HIV positive donor organs is only permissible for kidney and liver transplantation at this time.

5.3.~~B~~C Informed Consent for Kidneys Based on KDPI Greater than 85%

Prior to receiving an offer for a kidney with a Kidney Donor Profile Index (KDPI) score greater than 85%, transplant programs must obtain written, informed consent from each kidney candidate willing to receive offers for kidneys in this category.

Subsequent headings affected by the renumbering of this policy will also be changed as necessary.

5.4.C Liver Offers

The host OPO must make the initial liver offer using only a match run that is less than eight hours old. The host OPO may only re-execute the match run for use in allocation sooner than eight hours if ~~*either*~~ *one of the following* occurs:

- A previously accepted liver is later refused because there is a change in specific medical information related to the deceased liver donor
- The deceased donor liver has not been allocated within two hours of procurement
- New donor information is received that would screen any potential recipient from appearing on the match run due to donor acceptance criteria according to in *Policy 5.5: Re-Execution of the Match Run Due to New Information*

5.5 Re-Execution of the Match Run Due to New Information

5.5.A (*Reserved*)

5.5.B Requirements for Positive Hepatitis B, Hepatitis C, or Cytomegalovirus (CMV) Infectious Disease Results

If a host OPO receives a positive test result for any of the infectious diseases listed in *Table 5-1: Donor Infectious Disease Screening Options* for a deceased donor after executing any match run and the organs have *not* been accepted for a potential transplant recipient, then the OPO must report the updated information to the OPTN Contractor and do *all* of the following for each organ being allocated:

1. Stop allocation on the original match run for this donor
2. Re-execute the match run
3. Allocate organ using the updated match run

If any of the deceased donor's organs have been accepted for a potential transplant recipient:

The host OPO must report the updated information to the OPTN Contractor and do *all* of the following for each organ being allocated:

1. Report this new infectious disease test result to the first transplant hospital on the match run that accepted the organ as soon as possible, but within one hour of receipt of the new test result
2. Re-execute the match run *if* the potential transplant recipient declines the organ after being informed of the positive infectious disease test results
3. Re-allocate the organ using the updated match run

Once notified by the host OPO, the transplant hospital must do *all* of the following:

1. Inform the potential transplant recipient or the potential recipient's agent of the positive infectious disease test result
2. Notify the host OPO whether the organ will be accepted or declined, but within an hour of receipt of the new test result
3. Meet the requirements of *Policy 15.3.A: Deceased Donors with Additional Risk Identified Pre-Transplant if* the potential transplant recipient proceeds with transplant of the organ after receipt of the new positive infectious disease test results

5.5.C Requirements for Positive HIV Infectious Disease Results

Organs from HIV positive donors may only be recovered and transplanted according to the requirements in the OPTN Final Rule. Use of HIV positive donor organs is only permissible for kidney and liver transplant of HIV-positive candidates.

If a donor is found to be positive for HIV after any match run has been executed, the host OPO must report the updated information to the OPTN Contractor and do *all* of the following for each organ being allocated:

1. Stop allocation on the original match run for this donor
2. Re-execute the kidney and liver match runs in order to include *only* HIV-positive candidates participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery of organs from individuals known to be infected with HIV
3. Withdraw any pending offers to candidates who are not HIV positive *and* participating in an institutional review board approved research protocol that meets the requirements in the OPTN Final Rule regarding the recovery of organs from individuals known to be infected with HIV

4. Allocate *only* kidneys and livers from HIV positive donors.

5.~~5~~6 Receiving and Accepting Organ Offers

Subsequent headings affected by the renumbering of this policy will also be changed as necessary.