

**OPTN/UNOS Organ Procurement Organization Committee
Report to the Board of Directors
November 12-13, 2014
St. Louis, Missouri**

**Sean F. Van Slyck, MPA, HSA, CPTC, Chair
Jennifer K. Prinz, RN, BSN, MPH, CPTC, Vice Chair**

Contents

Action Items	2
1. Imminent and Eligible Death Data Definitions	2
Committee Projects	2
2. Deceased Donor Registration Completion	2
3. HIV Organ Policy Equity Act	3
4. Limit Paper Documentation.....	3
Committee Projects Pending Implementation.....	4
5. Change Consent to Authorization	4
6. Donation After Circulatory Death.....	4
Implemented Committee Projects	5
Review of Public Comment Proposals.....	5
7. Proposal to Establish a Quality Assurance and Performance Improvement Requirement for Transplant Hospitals and OPOs.....	5
8. VCA Committee - Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs).....	5
9. Improving the OPTN Policy Development Process	6
10. Histocompatibility Committee - Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II).....	6
11. Clarification of Multi-Organ Policies.....	6
12. Policy Rewrite Parking Lot "Quick Fixes"	6
13. Proposal to Clarify Definition of Organ Transplant and Transplant Date.....	6
14. Serum Lipase.....	6
15. Other Committee Work.....	8
Meeting Summaries.....	8

**OPTN/UNOS OPO Committee
Report to the Board of Directors
November 12-13, 2014
St. Louis, Missouri**

**Sean F. Van Slyck, MPA, HSA, CPTC, Chair
Jennifer K. Prinz, RN, BSN, MPH, CPTC, Vice Chair**

This report reflects the work of the OPTN/UNOS OPO Committee during the May 2014 to October 2014 period.

Action Items

1. Imminent and Eligible Death Data Definitions

Public Comment: [September 21 – December 14, 2012](#)

Board Approval: [June, 2013](#)

Board Approval: [November, 2013](#) (Delayed implementation)

The proposed changes clarify the data collection definitions for determining whether a death can be classified as “imminent” or “eligible.” OPOs must classify a death as one of the following: Imminent Neurologic Death (“imminent”), Eligible Death (“eligible”), or neither “eligible” nor “imminent” (“neither”). The OPOs then report the “imminent” and “eligible” deaths to the OPTN. Because OPOs interpret reporting definitions differently and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

This proposal was developed over several years in an effort to improve the inconsistent reporting of imminent and eligible deaths by OPOs. This proposal was originally approved by the Board of Directors in 2013 and the effective date was set for January 1, 2015. The delayed effective date was intended to provide time for CMS (Centers for Medicare and Medicaid Services) to accept the new OPTN definitions. During the September 23, 2014 meeting, HRSA staff noted that while there is not time to make a CMS regulation change, there is a possibility that CMS could make internal administrative changes to allow for the use of the new definitions. The Committee agreed that if CMS does not act before the November 12-13, 2014 Board of Directors meeting, the Committee will request that the effective date be delayed.

****RESOLVED, that the effective date for changes to Policy 7.1.6 (Eligible Death Definition) and Policy 7.1.7 (Imminent Neurological Death), as set forth in Exhibit A, be changed from January 1, 2015 to January 1, 2016.**

Committee Projects

2. Deceased Donor Registration Completion

Public Comment: [September 29 – December 5, 2014](#)

Board Consideration: [June 2015](#)

The deceased donor registration (DDR) completion subcommittee has been working over the past year to address the information that OPOs are required to submit on patients who are referred to the OPO as a potential donor and non-donors. The DDR was never intended to be used for authorized but not recovered, or referral only donors.

Prior to 2001, information on non-donors was collected on the Cadaver Donor Referral Form. When this form was eliminated, only the DDR remained. The subcommittee discussed the purpose of collecting data on authorized but not recovered donors or those for whom authorization was not obtained. Because OPOs do not have relevant information available on non-donors there is no need to collect it. Additionally, basic demographic information is collected on non-donors through the Death Notification Registration form. The subcommittee provided the following recommendations to the OPO Committee:

- OPOs should only be required to complete the deceased donor registration (DDR) form on actual donors, defined as having at least one organ recovered for the purpose of transplantation.
- Make the following change to the deceased donor definition: An individual from whom at least one organ is recovered for the purpose of transplantation after declaration of death.
- Make the following label change to the deceased donor feedback form: Change “Referral Only” to “No organs were recovered for the purpose of transplantation.”

During a conference call on September 5, 2014, the Committee reviewed the final policy language and unanimously supported the proposal moving forward to public comment on September 29, 2014.

3. HIV Organ Policy Equity Act

Public Comment: [September 29 – December 5, 2014](#)

Public Comment: *January 2015*

Board Consideration: *June 2015*

The HIV Organ Policy Equity Act (HOPE Act) was enacted on November 21, 2013. The initial deadline for deliverables is November 21, 2015. The Secretary of HHS must develop and publish research criteria, and revise the OPTN Final Rule, while the OPTN must revise policies in accordance with the criteria developed by the Secretary. A joint work group was formed with representation from the OPO Committee, Operations and Safety Committee, Ad Hoc Disease Transmission Advisory Committee (DTAC), SRTR, and HRSA. The work group met on several occasions to review policies and discuss potential operational issues. The work group developed an initial proposal to remove the prohibition on the recovery and transplant of HIV organs if participating in the research study. The initial proposal also prohibits the storage of HIV positive extra vessels.

The work group met by conference call on August 27, 2014 and approved the policy language. The OPO Committee reviewed the final policy language and unanimously supported the language moving forward to public comment on September 29, 2014.

The work group and Committee are continuing work on the project and will produce an updated public comment proposal before the Board considers the policy proposal.

4. Limit Paper Documentation

Public Comment: *August, 2015 (Estimated)*

Board Consideration: *December, 2015 (Estimated)*

The OPO Committee formed a subcommittee to address the paper documentation that is packaged and shipped with each organ. OPTN Policy 16.5.A requires that complete donor documentation be sent in the container with each transported organ. This often

takes a coordinator a considerable amount of time to make copies of the large volume of documents that need to accompany each organ. These requirements originated prior to the availability of electronic medical records and functionality to upload information into DonorNet®.

The subcommittee held its initial conference call on August 25, 2014. The initial recommendation from the subcommittee was to require the ABO verification and infectious disease testing documentation to be included with the organs. Additional information such as the complete donor record, anatomy information and authorization forms can be uploaded into DonorNet®. The subcommittee also recommended the development of a guidance document to address when to upload the information as well as document management strategies to allow transplant centers to easily locate the documents. This includes creating separate documents instead of one large PDF file that contains numerous documents. The subcommittee also discussed the development of standard naming conventions for these individual documents. Finally, the subcommittee agreed to draft recommendations to forward to the Transplant Coordinators Committee and Transplant Administrators Committee for feedback.

The subcommittee provided an update to the OPO Committee during its September 23, 2014, meeting.

Committee Projects Pending Implementation

5. Change Consent to Authorization

Public Comment: [September 16, 2011 – January 12, 2012](#)

Board Approval: [June 2012](#)

Projected Implementation: TBD

Currently, UNOS policy uses the term “consent” to describe the act of making an anatomical gift. However, the public associates “consent” with the medico-legal concept of “informed consent” through which physicians must give patients all the information they need to understand the risks, benefits, and costs of a particular medical treatment. In the context of organ/tissue/eye donation after death, this blending of terms leads to misunderstandings about the act of donation and the application of anatomical gift law versus informed consent which could hinder our national goal of increasing organ, tissue, and eye donation and transplantation. The OPO community has responded to this circumstance by changing the donation terminology from “consent” to “authorization.” This change focuses attention on the altruistic act of donation and reinforces the fact that donation after death does not involve medical treatment. This policy change was effective on September 1, 2012. Programming work is needed to update the terminology in UNetsm.

6. Donation After Circulatory Death

Public Comment: [March 11 – June 10, 2011](#)

Public Comment: [March 16 – June 25, 2012](#)

Board Approval: [November 2013](#)

Projected Implementation: TBD

The proposed changes to the Donation after Circulatory Death (DCD) Model Elements will clarify and update language for the donation and transplantation community. These

Model Elements identify specific requirements that OPOs and transplant centers must include in their DCD policies. This proposal only requires a labeling update in DonorNet®.

Implemented Committee Projects

None

Review of Public Comment Proposals

The Committee reviewed 7 of the 18 proposals released for public comment from September 29, 2014 – December 5, 2014.

7. Proposal to Establish a Quality Assurance and Performance Improvement Requirement for Transplant Hospitals and OPOs

There was a question raised about what triggers the MPSC's review of a transplant center or OPO's QAPI plan. MPSC staff noted that CMS performs a more detailed review of QAPI plans so the MPSC would only review a plan if an OPO or transplant center was being reviewed by the MPSC due to compliance or performance issues.

8. VCA Committee - Implement the OPTN's Oversight of Vascularized Composite Allografts (VCAs)

An OPO Committee member noted that one of the criteria listed under the definition of VCA addresses the use of devices. The member's OPO has plans to use a mechanical device to support VCA grafts and the recommendation was made to change "not combined with another article such as a device" to "not permanently combined with another article such as a device." The VCA Committee liaison noted that the intent was for any devices being permanently implanted at the time of transplant but agreed that the policy language should be clarified. It was also noted by UNOS staff that due to the evolving field of VCA transplants, if OPOs or transplant center are using technology to assist with VCA transplants they should notify the OPTN so there is an awareness and education about the technology. Additionally, this will assist when making the determination about what technology is monitored by the OPTN and by the FDA.

An OPO Committee member noted that currently a significant number of brain dead patients who get ruled out as organ donors could potentially qualify as a VCA donor. Moving forward, VCA alone donors could potentially have an impact on the OPOs observed versus expected data. It was noted by SRTR staff that VCA data is not currently being collected for that purpose.

There was a question raised about whether OPOs and transplant centers that are currently involved in VCA transplants will be required to submit a letter of intent to the OPTN. UNOS staff noted that a letter of intent will be required from all transplant centers wanting to perform VCA transplants and that letter will include the information about the OPOs they will be working with on VCA transplants.

The OPO Committee recommended that there be a central location for all the information about VCAs and that it includes specific information for OPOs. UNOS staff noted that once the guidance documents and other information is approved by the Board of Directors, they will be posted on the OPTN website. Additionally, the OPO Committee recommends that for patient safety reasons future programming should be done to facilitate VCA transplants.

9. Improving the OPTN Policy Development Process

Upon review, the Committee had no comment regarding this issue

10. Histocompatibility Committee - Proposed Changes to the OPTN Bylaws Governing Histocompatibility Laboratories (Phase II)

An OPO Committee member noted that the proposal was not clear regarding the requirements within the PhD pathway for laboratory director. The proposal states within the PhD pathway that there be “at least two years full-time, post-doctoral experience or four years pre-doctoral experience in immunology, histocompatibility, or immunogenetics and two years post-doctoral training in directing or supervising clinical histocompatibility testing for solid organ transplantation.” It was not clear if the time period needed to be consecutive or concurrent events. The Histocompatibility Committee liaison agreed to bring the question back to the Histocompatibility Committee for clarification.

There was also a question raised about the reporting of HLA discrepant typing and the identification of labs that show a trend of discrepant typing. It was noted by UNOS staff that the computer system will flag discrepancies within Tiedi and through the donor and recipient histocompatibility forms. The Histocompatibility Committee has taken the additional step of reviewing the match runs to identify errors. Histocompatibility labs are provided with a report of all discrepancies that the system has identified so they can be resolved. The new policy requires that the discrepancies be resolved within 30 days.

11. Clarification of Multi-Organ Policies

Upon review, the Committee had no comment regarding this issue.

12. Policy Rewrite Parking Lot “Quick Fixes”

The Committee agreed to review the policy language to ensure that none of the proposed changes from “should” to “must” will create problems for OPOs. One committee member noted that the only change that might cause issues is the requirement to include the ABO on all the blood tubes. It could be a challenge for some blood banks to receive a red top tube with the ABO although that might be specific to living donors. The OPO Committee will review the policy language and provide feedback via email.

13. Proposal to Clarify Definition of Organ Transplant and Transplant Date

Upon review, the Committee had no comment regarding this issue

14. Serum Lipase

The OPO Committee has reviewed this proposal during three committee meetings. The proposal makes serum lipase a required field in DonorNet® in order to make electronic pancreas offers. The OPO Committee has previously noted that serum lipase testing is not always locally available and if the test results are delayed, the ability to allocate the pancreas becomes difficult under the proposed policy change. The OPO Committee also previously noted that not all donor hospitals have the ability to perform serum lipase testing. Below is an overview of the previous comments from the OPO Committee:

The Committee discussed several other concerns:

- Is there scientific data to show how deceased donor serum lipase relates to pancreas graft survival? One member of the Committee volunteered to send recent literature on this topic to the Pancreas Committee.

OPTN/UNOS Organ Procurement Organization Committee

- One of the purposes of the proposal is to promote a more efficient allocation system. However, Committee members argued that requiring serum lipase before making organ offers will make organ allocation less efficient.
- Because of the timing issues, it might be difficult for OPOs to comply with these new requirements.
- Does the data show that requiring serum lipase will lead to more pancreas transplants? If serum lipase is not available are the pancreata still being transplanted?
- Is it known why 1% of serum lipase results were not reported? Was it due to lab results being received later or unable to obtain at all?

Recommendations from the OPO Committee:

- Make serum lipase a desired test when available. One option is to require the tests be sent but organ offers can be made before test results are received.
- Support the creation of a new field in DonorNet® where OPOs will report the upper limit of normal (i.e. maximum normal value or highest reference value) of the laboratory's normal serum lipase reference range.
- Wait for information from the pancreas utilization subcommittee to determine impact on pancreas utilization.
- Make the Pancreas Committee aware that requiring serum lipase results before making pancreas offers will create logistical challenges for the OPOs.

Since the last discussion held during the April 24, 2014 OPO Committee meeting, the Pancreas Committee chair has reached out to several OPO Committee members. There were discussions about allowing for a “best practices” solution such as a letter from the lab director explaining the lab cannot provide the serum lipase value in time for the electronic pancreas offer. The OPO would then upload this letter to the donor record as a means to justify the non-compliance. It was noted that this would not be a policy compliance exemption.

The Pancreas Committee and OPO Committee leadership also had discussions via teleconference in an effort to find a solution that works for both parties. There was a suggestion made by the OPO Committee chair to monitor serum lipase similar to what was previously done for gamma-glutamyl transpeptidase (GGT) for liver donors, make serum lipase a “preferred field” (similar to some of the thoracic fields), or have some sort of guarantee that the OPO will not be in non-compliance if it cannot adhere to the serum lipase requirement. It was noted that DEQ does not monitor “preferred fields” so in order to make serum lipase a “preferred” field it would have to be written into policy. There are some thoracic fields that are required upon request. Other suggestions included sending blood with HLA materials to the lab for serum lipase testing, using handheld chemical testing devices, or contracting with local labs when the main labs cannot provide timely results. The Committee noted that HLA labs do not perform serum lipase testing and the purchase and maintenance of handheld chemical testing devices would be expensive.

The OPO Committee has the following recommendations:

- The Committee remains in support of the new fields in DonorNet® to report the upper limit of normal (i.e. maximum normal value or highest reference value) of the laboratory's normal serum lipase reference range.
- The Committee does not support the requirement to report serum lipase prior to electronic pancreas offers because OPOs will be unable to comply with the new policy 100% of the time.

OPTN/UNOS Organ Procurement Organization Committee

- While the option to obtain letters from the labs is an option, it could be burdensome for some OPOs.
- The OPO Committee did agree that OPOs should be able to justify the reasons why they were unable to get serum lipase results completed in time for the electronic pancreas offers in order to justify the policy violation. It was recommended that the Pancreas Committee work with the OPTN contractor to address the potential compliance issues.
- The OPO Committee remains concerned that this requirement could impact pancreas allocation although OPOs are committed to placing as many organs as possible.
- The OPO Committee also recommends that the Pancreas Committee collect data to determine how many labs do not perform serum lipase testing and how many OPOs decline to test for serum lipase even though they had the capability to perform the test.
- The OPO Committee is concerned that requiring this field might result in a less efficient allocation process and could result in fewer pancreas grafts being available for transplantation.

Other Committee Work

None

Meeting Summaries

The Committee held meetings on the following dates:

- July 29, 2014
- September 5, 2014
- September 23, 2014

Meetings summaries for this Committee are available on the OPTN website at: <http://optn.transplant.hrsa.gov/converge/members/committeesDetail.asp?ID=18>.

Title: Imminent and Eligible Death Data Definitions – Change Effective Date

Name of the Sponsoring Committee: Organ Procurement Organization Committee

Summary and Goals of the Proposal: This proposal, approved by the Board of Directors in June 2013, clarifies the data collection definitions for determining whether or not a death can be classified as “imminent” or “eligible.” The approved language eliminates multi-system organ failure (MSOF) as an exclusionary criterion for classifying a death as “eligible” and adds a list of organ-specific exclusionary criteria to give OPOs more guidance. The Committee also changed the definition of “imminent” to restrict it to those deaths that would most likely be classified as “eligible” had brain death been legally declared.

Background and Significance of the Proposal:

The new definitions were approved by the Board of Directors in June 2013. Center for Medicare and Medicaid Services (CMS) regulations contain the current OPTN definition of eligible donors and the plan is to keep the CMS and OPTN definitions aligned. The initial OPO Committee resolution stated that the new definitions would become effective pending approval by CMS; however, the Board of Directors set the effective date at December 1, 2013. Since there was no formal response from CMS as of the September 10, 2013 OPO Committee meeting, the Committee unanimously agreed to request the effective date be delayed until January 1, 2015. The hope was that the additional time would allow for collaboration with CMS to adopt the OPTN definitions and allow time for member education and computer programming.

During the September 23, 2014 meeting, the OPO Committee discussed the effective date since there has been no decision reached by CMS. HRSA staff noted that CMS could make administrative changes to allow for the adoption of the OPTN definitions without making a regulation change. The Committee discussed the options and agreed that if this administrative change can be made by CMS the effective date should remain January 1, 2015. Since no decision was reached by the end of October 2014, the Committee will request that the effective date be delayed until January 1, 2016.

Other Considerations: N/A

Additional Data Collection: N/A

Expected Implementation Plan: This proposal will require programming in UNetSM. There will be a minor change in UNetSM to the Online Help Documentation; however, no changes will be required to any of the data fields.

Communication and Education Plan:

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice	OPOs	Electronic – Included in the monthly e-newsletter sent on the 3 rd Monday of each month	30 days after the Board of Directors approves the change.
UNet sm based instructional model	OPOs	Electronically	Within 60 days of implementation

Policy Proposal:

****RESOLVED, that the effective date for changes to the definitions of Eligible Death and Imminent Neurological Death in Policy 1.2, which were approved by the Board of Directors on June 24, 2013, be changed from January 1, 2015 to January 1, 2016.**

Eligible death

For reporting purposes of DSA performance assessments, an eligible death for deceased organ donation is defined as the death of a patient who meets *all* the following characteristics:

- Is 75 years old or less
- Is legally declared dead by neurologic criteria according to the current standards of accepted medical practice and state or local law
- Has body weight of 5 kg or greater
- Has a body mass index (BMI) of 50 kg/m² or less
- Has at least one kidney, liver, heart or lung that is deemed to meet the eligible data definition as defined below:
 - The kidney would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
 - Greater than 70 years old
 - Age 50-69 years with history of type 1 diabetes for more than 20 years
 - Polycystic kidney disease
 - Glomerulosclerosis greater than or equal to 20% by kidney biopsy
 - Terminal serum creatinine greater than 4.0 mg/dL
 - Chronic renal failure
 - No urine output for 24 hours or longer
 - The liver would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
 - Cirrhosis
 - Terminal total bilirubin greater than or equal to 4 mg/dL
 - Portal hypertension
 - Macrosteatosis greater than or equal to 50%
 - Fibrosis greater than or equal to stage II
 - Fulminant hepatic failure
 - Terminal AST/ALT greater than 700 U/L

- The heart would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
 - 60 years old or older
 - 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1 diabetes
 - History of coronary artery bypass graft (CABG)
 - History of coronary stent/intervention
 - Current or past medical history of myocardial infarction (MI)
 - Severe vessel diagnosis as supported by cardiac catheterization
 - Acute myocarditis or endocarditis, or both
 - Heart failure due to cardiomyopathy
 - Internal defibrillator or pacemaker
 - Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
 - Serial echo results showing severe global hypokinesis
 - Myxoma
 - Congenital defects (surgically corrected or not)
- The lung would initially meet the eligible data definition unless the donor meets *any* of the following criteria:
 - Age 65 years or older
 - Diagnosed with COPD
 - Terminal PaO₂/FiO₂ less than 250 mmHg
 - Asthma (with daily prescription)
 - Asthma is the cause of death
 - Pulmonary fibrosis
 - Previous lobectomy
 - Multiple blebs documented on computed axial tomography (CAT) scan
 - Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
 - Bilateral severe pulmonary contusions as per CT

If a deceased patient meets the above criteria they would be classified as an eligible death unless the donor meets *any* of the following criteria:

- The donor has no suitable organ for transplant (as defined above)
- The donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplant
- The donor exhibits *any* of the following:
 - Active infections (with a specific diagnosis)
 - Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
 - Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex, varicella zoster, or cytomegalovirus viremia or pneumonia, acute epstein barr virus (mononucleosis), West Nile virus infection, SARS
 - Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active candidemia or invasive yeast infection
 - Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or malaria (*plasmodium sp.*)
 - Prion: Creutzfeldt-Jacob disease
 - General [Exclusions to the Definition of Eligible]: aplastic anemia, agranulocytosis
 - Current malignant neoplasms, except non-melanoma skin cancers such as basal cell and squamous cell cancer and primary CNS tumors without evident metastatic disease
 - Previous malignant neoplasms with current evident metastatic disease
 - A history of melanoma
 - Hematologic malignancies: leukemia, Hodgkin's disease, lymphoma, multiple myeloma

- Active fungal or parasitic meningitis or encephalitis
- No discernible cause of death

Imminent neurological death

Imminent Neurological Death is defined as the death of a patient who meets *both* of the following criteria:

- Meets the eligible death definition with the exception that the patient has not been declared legally dead by neurologic criteria according to current standards of accepted medical practice and state or local law.
- Has a severe neurological injury requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has no observed spontaneous breathing and is lacking at least *two* of the additional brain stem reflexes that follow:
 - Pupillary reaction
 - Response to iced caloric
 - Gag Reflex
 - Cough Reflex
 - Corneal Reflex
 - Doll's eyes reflex
 - Response to painful stimuli

A patient who is unable to be assessed neurologically due to administration of sedation or hypothermia protocol does not meet the definition of an imminent neurological death.