

**OPTN/UNOS OPO COMMITTEE REPORT
SUMMARY**

I. Organ Availability Issues

Action Items for Board Consideration:

- The Board Is Asked to Approve the Proposed Reporting Definition for Imminent Neurological Death (Item 1, Page 2).

Other Significant Items:

- Update on the DCD Protocol Development Work Group (Item 2, Page 7).

II. Patient Access Issues

Action Items for Board Consideration:

- None

Other Significant Items:

- None

III. Other Issues

Action Items for Board Consideration:

- The Board is Asked to Approve the Proposed Modifications to Policy 3.2.4 (Match System Access) (Item 3, Page 9)

Other Significant Items:

- None

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**REPORT OF THE OPTN/UNOS ORGAN PROCUREMENT ORGANIZATION
(OPO) COMMITTEE TO THE BOARD OF DIRECTORS**

**Richmond, Virginia
September 20, 2006**

**Charles Alexander, RN, MSN, Chair
Jeffrey Orłowski, MS, CPTC, Vice Chair**

The following report represents the OPO Committee's deliberations and recommendations regarding proposals and updates to be considered by the Board of Directors, September 20, 2006 meeting.

I. Organ Availability Issues

1. Imminent Neurological Death Definition, Imminent and Eligible Death Data Collection Project. The current OPTN contract requires that, "...patient-level data shall be collected from all OPOs and maintained on all eligible deaths and imminent deaths..." This requirement calls for (1) a definition of imminent death to be developed and approved, and (2) that a data collection system be developed to allow for the collection of patient-level data from all OPOs.

Last year, the Committee completed a pilot project collecting patient level data on all eligible deaths from 11 participating OPOs (one from each region, of varying sizes, data capabilities, and eligible potential.) The objectives of the pilot project were to analyze possible predictive factors for conversion and to evaluate the feasibility of completing added data collection. The SRTR noted that the data from the pilot study suggested that age, race/ethnicity, and cause of death were significant predictors of conversion. In follow-up calls held by UNOS staff with the 11 participating OPOs, the OPOs noted that the data collection (for eligible, patient level data) seemed possible and feasible with current OPO resources and some modifications to the collected data elements.

Jeff Orłowski serves as the Chair of the group working on the current imminent and eligible death data collection project and, at the April 2006 meeting, Mr. Orłowski reported to the full Committee on the current direction and work of the project. Mr. Orłowski noted that the intent of the project is to help increase knowledge about donor potential, identify the prevalence of cases in which clinical brain death parameters are met but brain death is not declared, to improve the standardization and validity of reported donor data, and to collect data that may also possibly help to develop future reporting definitions for DCD potential and DCD eligible. The work group for this project met via teleconference on February 15, 2006 and March 27, 2006 to discuss possible paths forward and resources for developing a reporting definition for imminent death and a data collection system for patient level data for all eligible and imminent deaths.

After discussion and review of the materials, the consensus of the Committee was to use the AOPO death record review definition as the foundation for the development of an OPTN imminent death definition. The Committee noted that the imminent death definition should reflect the “next ring out” of donor potential from eligible deaths, e.g. - potential donors referred by hospitals to OPOs based on identified clinical triggers (GCS, absence of 3 or more brain stem reflexes, laboratory evidence, etc.) The AOPO death record definition is well established and well known within the OPO community; some OPOs currently use this definition as the basis for their own internal database tracking of donor potential and missed donor potential identified in death record reviews. At the April 2006 meeting, Virginia McBride, HRSA noted that while the OPTN reporting definition for eligible deaths serves as a metric of OPO and DSA performance evaluation, the future OPTN reporting definition for imminent deaths would be used solely for the purpose of identifying potential areas for improvement.

In preparation for presentation to the Data and Information Committee, AOPO Procurement Directors Council and Medical Directors Meetings at the June 20-23, 2006 AOPO annual conference, the work group met via teleconference on June 7, 2006, to finalize a draft of the imminent death definition and an overview of the project. The Committee noted that feedback and support from the OPO community in the development of a new standardized reporting definition is critical to the success of the project. The presentation given at the June 2006 AOPO meetings is attached here as **Exhibit A**.

Representing the Committee, Jeffrey Orłowski, Charles Alexander, and Deborah Savaria presented the draft definition and overview of the project at the Medical Directors, Procurement Directors, and Data and Information Committee meetings, respectively. The work group reconvened on August 22, 2006 to discuss the feedback from the AOPO meetings. Based on the feedback received (e.g.- the AOPO Medical Directors recommendation to include GCS < 5 in the definition), the work group revised the original draft definition. The original draft definition and the updated proposed definition are listed below. The revisions in the updated draft are noted in *italic* text.

Imminent Death Definition (original draft):

Patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy. Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death.

Imminent *Neurological* Death Definition (updated draft):

Patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes or a *GCS* < 5 but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy, *and who eventually progresses to cardiac death (during the referred hospitalization.)* Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death.

The proposed reporting definition of imminent death and the OPTN reporting definition of eligible death would be mutually exclusive; an imminent death by proposed definition would not be reportable as an eligible death and an eligible death by definition would not be reportable as an imminent death. For consistency of data reporting, the exclusion criteria noted in the proposed imminent definition would be the same as the exclusions to the OPTN reporting definition for eligible death **[Exhibit B.]** Reporting for imminent deaths would also follow the same guidelines of reporting an imminent death “independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice.” This consistency with the OPTN eligible death definition is significant in that it continues the consistency in data reporting noted with CMS adopting the OPTN eligible death definition as its definition for eligible death. Numbers regarding eligible deaths serve as the denominator of two of the CMS OPO performance measures.

In addition, in order to evaluate the data burden and estimate the possible missed potential that could be identified through the reporting of imminent deaths, the Committee work group agreed to develop and implement a data collection PDSA. This initial PDSA is intended to give a general idea of the range of reportable imminent deaths per DSA using the draft proposed definition; this informal survey is intended to help guide the second phase of the project.

- *Plan:* Each member of the OPO Committee work group affiliated with an OPO (9 OPOs are represented on the work group) will submit a completed data survey by July 15, 2006.
- *Do:* For the months of January and February of 2006, complete the survey with the following data (by month)
 - Total number of recovered organ donors who are CMS eligible (no DCD or over 70 donors)
 - Total number of CMS eligible deaths including those referred and those identified on Death Record Review (DRR)

- Total number of deaths meeting the proposed definition of Imminent Death, including those referred and those identified on DRR
- *Study*: Review data for general estimate and current feasibility of additional data collection using the proposed imminent death definition.
- *Act*: Evaluate results and plan next step

Data received to date suggests that the potential estimate of donor potential identified through imminent death reporting appears to be approximately 15-20 %; this percentage would be substantial if it applies nationally.

At its August 16, 2006, meeting, the POC reviewed the original draft of the imminent death definition and an overview presented by Mr. Orlewski, and noted its support that the definition is based on common guidelines approved by the American Neurological Association (ANA.) The POC also noted that the imminent death definition appears to be a natural evolution from the updated eligible death definition.

The Committee, therefore, offers the following resolution for consideration by the Board of Directors:

****RESOLVED, that the following imminent death definition be approved for adoption as the UNetsm definition for reporting of imminent deaths, effective pending distribution of appropriate notice and programming on UNetsm.**

Imminent Neurological Death Definition: Patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes or a GCS < 5 but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy, and who eventually progresses to cardiac death (during the referred hospitalization.) Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death.

Brain Stem Reflexes:

- Pupillary reaction
- Response to iced caloric
- Gag Reflex
- Cough Reflex
- Corneal Reflex
- Doll's eyes reflex
- Response to painful stimuli
- Spontaneous breathing

2. Update on the Joint DCD Protocol Development Work Group. At the June 2006 Board meeting, in support of the HHS Program Goal to increase the number of DCD donors and in support of efforts in the donation and transplantation community, the Board unanimously approved the following two proposals:

OPO Committee proposal:

RESOLVED, that the Bylaws shall be amended and submitted for public comment, to include the following criterion for both OPOs and Transplant Centers:

Donation after Cardiac Death (DCD) Protocols. OPOs/Transplant Hospitals must develop by January 1, 2007 [and once developed must comply with*], protocols to facilitate the recovery of organs from DCD donors.

*Following consideration of this proposal by the MPSC, it was noted that the Bylaws could be strengthened by including express provisions regarding compliance with DCD protocols. Suggested language is included in brackets.

The above proposal is currently out for public comment and is scheduled to be reviewed by the Board at its December 2006 meeting.

Membership & Professional Standards Committee (MPSC) proposal:

RESOLVED, that a working group be created under the auspices of the OPO Committee to develop the important elements that must be addressed in protocols for DCD procurements and addressed by OPTN Members in developing such protocols.

Following the June 2006 Board meeting and the charge of the Board approved MPSC proposal, the Committee formed the DCD Protocol Development Work Group. Charles Alexander, Committee Chair, is serving as the Chair of this work group; the work group has both OPO and MPSC Committee representation. In the membership of this group, the Committee has worked to include both surgeon and physician (including pediatric and critical care) representation, and representation from high performing OPOs and OPOs with the current highest number of DCD donors. The Committee is currently working to add hospital administration representation.

The charge of the work group is to develop an outline of the important elements that must be addressed in a DCD recovery protocol. It is the intent of the work group to identify and list the overview of elements that must be addressed in OPTN member DCD protocols; it is not the intent to be prescriptive in how members meet the recommendations.

The work group held its initial meetings via teleconference on August 17 and 18, 2006. The work group discussed its charge and also agreed that its role should extend to offering resources and references to OPOs and transplant hospitals that may be working to determine how to address the model protocol elements in their specific

DSA. The group noted that the final outline document from the work group should be intended to both assist OPOs and transplant hospitals in taking steps to put policies and protocols in place, and also to reinforce the importance of utilizing and complying with the protocols once implemented. The work group also noted the importance of keeping the outline of protocol elements “high level”, i.e., to identify general areas and elements to be addressed, but to also allow for the individual circumstances of individual DSAs and organizations. The group further noted the importance of maintaining a tone or statement of strong support for the practice of DCD. The group suggested drafting a mission statement to be included as an introduction to its final document.

Maggie Allee, Chair of the Ethics Committee, noted that, at the September 2006 meeting, the Ethics Committee is submitting an ethics document to the Board for its approval. The group noted that this document may be an important addition to the resources and references to accompany the final protocol element document. The group further noted that having UNOS as the sponsoring organization of the document may be helpful; some members of the group noted that transplant hospitals may perceive UNOS as a neutral third party, and this perception may allow DCD resources and recommendations to be better received.

The work group noted that a great deal of work has already been done in the donation and transplant community around DCD recovery and protocol development. The work group agreed that its charge may be most effectively met by reviewing and then clarifying and making accessible existing resources and recommendations. The work group identified the following four categories to serve as the structure of the final document outlining DCD recovery protocol elements to be addressed:

- Ethics
- Clinical Protocols and Practice
- Conflict of Interest
- Financial Aspects

Work group members volunteered to work in small groups to address the components of each of these four categories. The work group is scheduled to reconvene the week of August 28, 2006, to discuss drafts of specific category components/elements. The group is scheduled to report an update to the Board at the September 2006 meeting, and submit a final document to the Board for its consideration in December 2006.

II. Patient Access Issues

- None

III. Other

3. Proposed Modifications to OPTN/UNOS Policy 3.2.4 (Match System Access).

The Committee is proposing changes to the current documentation requirements for donor ABO data verification. These proposed changes would standardize and clarify the verification process across all OPOs; reduce the risk of discrepancy between UNetsm system logs and separate OPO documentation; and support the efficiency and safety of the verification and documentation process.

Background

Policy 3.2.4 requires that, “each OPO shall establish and implement procedure for providing on-line verification of donor ABO data by an individual other than the person initially entering the donor’s ABO data in UNetsm.” The UNetsm system is currently designed to require this separate verification as part of the donor listing process. The system tracks the user initially entering the donor ABO data and then requires a different user to verify the ABO data before a match may be run. UNetsm system programming prevents the initial user from verifying the ABO data that he/she has already entered. This verification process currently takes place at the OPO level; two distinct password entries from two different members of the OPO verifying the donor ABO data are required in order to run a match.

Policy 3.2.4 further requires that, “the OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.” Once entered, there is currently no UNetsm user-level option to view or print the donor ABO data verification information; only system administrators can access and create reports of the user activity logs regarding ABO verification. OPOs can submit a data request to UNOS to receive a report of the OPO’s ABO verification logs, however, this report cannot currently be generated in real time. Each OPO currently maintains this additional verification documentation in a non-standardized format and location (separate log, donor chart, etc.) for OPTN/UNOS audit purposes; no guideline or format for this additional documentation is outlined in policy 3.2.4. This requirement was included in policy prior to implementation of the UNetsm system requirement for double on-line verification of the entered donor ABO data. The original intent of this policy was to insure that OPOs maintain documentation that the lab hardcopy of donor ABO results was reviewed and verified prior to recovery; this intent and practice is maintained in Policy 3.2.4 with the current language, “the OPO shall be responsible for two separate determinations (e.g., 1) two samples sent to two labs, or 2) one sample sent to two labs, or 3) two samples from

separate draws sent to the same lab) of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data in UNetsm (see policy text below.)”

At its April 5, 2006 meeting, the OPO Committee discussed options for ABO verification documentation process improvement. The Committee noted that safety is the most significant factor in verifying donor ABO data. Since the UNetsm system is now programmed to require and document two separate verifications of donor ABO data before matches may be run, the Committee agreed that the additional documentation on the individual OPO level does not seem to add significantly to the safety of the placement and allocation process, and may create the risk of discrepancy and error through duplication of information. Providing users with access to the names of those who entered the ABO as well as the names of those who provided the second party verification would allow for a nationally standardized verification and documentation process for all OPOs. This information could be made available for viewing or printing by displaying the names on the donor record in UNetsm. As the ABO verification documentation is now captured in the UNetsm system and, with the proposed policy modifications, would be displayed at the user level, there would not be a need for additional auditing. In addition, patient safety would be addressed in the UNetsm documented double verification of donor ABO data and the ability of the OPO to easily access the information regarding the users who verified the ABO data. This proposal maintains and supports the original safety intent of the current policy, and offers a potential system improvement to the current ABO verification documentation process. The proposed recommendations reflect current practice and updated UNetsm capabilities.

Policy Proposal

During its April 5, 2006 meeting, the Committee discussed its objective in considering this policy modification. The aim is to standardize the verification process across all OPOs, reduce the risk of discrepancy between UNetsm system logs and separate OPO documentation, and support the efficiency and safety of the verification and documentation process.

The OPO Committee unanimously approved recommending the following modifications to Policy 3.2.4 (Match System Access) for public comment:

- 3.2.4 Match System Access. OPOs are required to use the Match System (UNetsm) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9 and 3.8.5) and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. The OPO shall be responsible for two separate determinations (e.g., 1) two samples sent to two labs, or 2) one sample sent to two labs, or 3) two samples from separate draws sent to the same lab) of the donor's ABO type prior to incision and for ensuring the accuracy of the donor's ABO data in UNetsm. Each OPO shall establish

and implement procedure for providing on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNetsm. ~~The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.~~ Organs shall be allocated only to candidates who appear on a match run. In the event that an organ has not been placed after the organ has been offered for all potential recipients on the initial match run, the Host OPO may give transplant programs the opportunity to update their transplant candidates' data, and the Host OPO may re-run the match system. In any event, the organ shall be allocated only to a candidate who appears on a match run. For all deceased donor organs, the organ must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If an organ is accepted for a candidate who ultimately is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the organ is being distributed, then the organ shall be released back to the Host OPO or to the Organ Center for allocation to other transplant candidates in accordance with the organ-specific allocation policies. The Host OPO may delegate this responsibility to the Local OPO. Further allocation at the local OPO level must be done according to the match run. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for the specific candidate. If an organ is declined for a candidate, a notation of the reason for the decision refusing the organ for that candidate must be made on the appropriate form and promptly submitted.

Public Comment Response:

As of 7/18/2006, 63 responses have been submitted to UNOS regarding this policy proposal. Of these, 48 (76.19%) supported the proposal, 1 (1.59%) opposed the proposal, and 14 (22.22%) had no opinion. Of the 49 who responded with an opinion, 48 (97.96%) supported the proposal and 1 (2.04%) opposed the proposal.

Proposed Modifications Based on Public Comment, Committee or Regional Review:

The Operations Committee reviewed the proposal and noted several comments for consideration by the Committee. Representatives from the OPO and Operations Committees met via teleconference on July 18, 2006 to discuss the Operations Committee comments regarding the OPO Committee proposed modifications to OPTN/UNOS Policy 3.2.4 (Match System Access.)

At its May 11, 2006 meeting, the Operations Committee reviewed the proposal and noted concerns regarding preserving the intent of the policy as originally developed in 2004 by the ABO Joint Subcommittee. The original intent of this requirement was for OPOs to implement and utilize a procedure of two-person verification and

comparison of the two ABO source documents. The Operations Committee acknowledged that the current sentence placement in Policy 3.2.4 regarding the requirement for OPOs to maintain documentation of separate verification could lead to confusion. Currently the sentence regarding this requirement follows the requirement for on-line verification in UNetsm; the placement of the sentence has previously led to both OPOs and UNOS auditors interpreting the policy as requiring separate OPO documentation of the on-line UNetsm verification process. The Operations Committee noted that policy modifications approved in 2004 separated this requirement from the requirement of “two separate determinations...of the donor’s ABO type prior to incision.”

On the July 18, 2006 conference call, the original intent of the policy, for documentation of two-person verification and comparison of the two ABO source documents, was reviewed and discussed. The members of the OPO and Operations Committees participating on the call agreed that the process of two individuals reviewing the source documents of the donor’s ABO testing and verifying correctness was a valuable part of patient safety that should not be eliminated. It was agreed by both Committee Chairs that the policy language recommended by the Operations Committee clarified the intent of the policy and also addressed the OPO Committee’s concerns regarding what documentation is required of the OPO, what documentation promotes patient safety (two-person verification of two ABO source documents) and what documentation may be confusing and may contribute to discrepancy in reporting (additional log of UNetsm verification, user data is already captured in the UNetsm system.) The Committee Chair agreed to accept the Operations Committee recommendations for modifications to Policy 3.2.4 (see below.)

In addition, it was noted on the call that Policy 3.2.4 may now be inconsistent with the recently released CMS Conditions for Coverage for Organ Procurement Organizations (OPOs), excerpted below, see underlined text under section *c(3)*, *Testing*:

§ 486.344 Condition: Donor evaluation and management and organ placement and recovery.

The OPO must have written protocols for donor evaluation and management and organ placement and recovery that meet current standards of practice and are designed to maximize organ quality and optimize the number of donors and the number of organs recovered and transplanted per donor.

(a) Donor protocol management.

(1) The medical director is responsible for ensuring that donor evaluation and management protocols are implemented correctly and appropriately to ensure that every potential donor is thoroughly assessed for medical suitability for organ donation and clinically managed to optimize organ viability and function.

(2) The OPO must implement a system that ensures the medical director or other qualified physician is available to assist in the medical management of a donor when the surgeon on call is unavailable.

(b) *Evaluation.* The OPO must do the following:

- (1) Verify that death has been pronounced according to applicable local, state, and federal laws pertaining to organ donation.
- (2) Determine whether there are conditions that may contraindicate donation.
- (3) If possible, obtain the potential donor's medical and social history.
- (4) Review the potential donor's medical chart and perform a physical examination of the donor.
- (5) Obtain the donor's vital signs and perform all pertinent tests.

(c) *Testing.* The OPO must do the following:

- (1) Arrange for screening and testing of the donor for infectious disease according to current standards of practice, including testing for the human immunodeficiency virus.
- (2) Ensure that screening and testing of the donor (including point-of-care testing and blood typing) are conducted by a laboratory that is certified in the appropriate specialty or subspecialty of service in accordance with part 493 of this chapter.
- (3) *Ensure that the donor's blood is typed using two separate blood samples.*
- (4) Document the donor's record with all test results, including blood type, before organ recovery.

The OPO and Operations Committee Chairs and members on the call agreed that it may be beneficial for both patient safety and consistency with CMS guidelines to strike the language in Policy 3.2.4 that currently allows for "one sample sent to two labs" as an option for completing two separate ABO determinations.

The Policy Oversight Committee (POC) reviewed this revised proposal at its August 16, 2006 meeting and recommended that the modifications to Policy 3.2.4 (Match System Access) proposed by the OPO Committee should be considered by the Board during its September 2006 meeting [**Exhibit C**].

The Committee, therefore, offers the following resolution for consideration by the Board of Directors:

****RESOLVED, that the following modifications to Policy 3.2.4 be approved, effective pending distribution of appropriate notice and programming on UNetsm.**

3.2.4 Match System Access. OPOs are required to use the Match System (UNetSM) for the allocation of all deceased donor organs. The Host OPO must enter required information about the donor (Policies 3.5.7, 3.6.9, 3.7.9 and 3.8.5) and execute the Match System to determine organ allocation priorities. Such information must be entered into the Match System for all deceased donors. The OPO shall be responsible for two separate determinations (~~e.g., 1) two samples sent to two labs, or 2) one sample sent to two labs, or 3) two samples from separate draws sent to the same lab~~) of the donor's ABO type prior to incision and for ensuring the

accuracy of the donor's ABO data in UNetSM. The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit. Each OPO shall establish and implement a procedure utilizing the ABO source documents for ~~providing~~ on-line verification of donor ABO data by an individual other than the person initially entering the donor's ABO data in UNetSM. ~~The OPO shall maintain documentation that such separate verification has taken place and make such documentation available for audit.~~
[The remainder of Policy 3.2.4, is unchanged.]

In addition, committee members on the call agreed that it may be helpful to develop a guidance document outlining the intent of the policy to help clarify for both OPOs and UNOS Department of Evaluation and Quality auditors that the intent of the policy is to have two separate processes for verification of ABO determinations: (1) two-person verification and comparison of the two ABO source documents, and (2) two-person verification of ABO data entry to the UNetsm system to initiate a match run.

The original OPO Committee proposal also outlined the addition of user level data fields to UNetsm to allow the OPO to see who verified the ABO data entry. The new fields would also include a date and time stamp for ABO data entry and verification. On the July 18, 2006, call, the OPO Committee members noted that, with the clarification of intent and policy language, these user level data fields may no longer be necessary. User data is currently recorded in UNetsm and is accessible with administrator access. After discussion with UNOS Department of Evaluation and Quality and Organ Center staff, UNOS staff is recommending that these data fields still be added in UNetsm as an enhancement to the current system, i.e.- the fields will be added at a lower scheduled priority and as other scheduled work to this section of UNetsm is being updated.

**Teleconference, Imminent/Eligible Death Data Collection Project
August 22, 2006**

Work Group Members Attending:

Jeffrey Orłowski, MS, CPTC Chair

Charles Alexander, RN, MSN

Deborah Savaria, RN, CPTC

Ellen Sheehy

PJ Geraghty, BS, CPTC

Work Group Members Unable to Attend:

Dan Hayes, MD

Lloyd Jordan, CPA

Ginny McBride, RN

UNOS Staff Attending:

Hilary Kleine, MSW

John Rosendale, MS

Courtney Bland, MCIS

Kristal Wood

SRTR Staff Attending:

Franki LaPorte, MS

**Teleconference, DCD Protocol Development Work Group
August 17 & 18, 2006**

Work Group Members Attending:

Charles Alexander, RN, MSN, Chair
Posy Durning, PA, CPTC
Dina Steinberger, PA-C
Virginia McBride, HRSA
Meg Rogers
Tom Gonwa, MD
Rick Hasz, MFS
Jeff Punch, MD
Michael Thibault, RN, BSN, CPTC

Work Group Members Unable to Attend:

Anthony D'Alessandro, MD
Juan Arenas, MD
Tom Nakagawa, MD
Rob Linderer, RN, BSN
Alan Reed, MD
Randolph Steadman, MD

UNOS Staff Attending:

Sally Aungier
Hilary Kleine, MSW
Courtney Bland, MCIS
Lin McGaw, RN, MEd

**Teleconference, OPO and Operations Committees
July 18, 2006**

OPO Committee Members Attending:

Charles Alexander, RN, MSN, Chair
PJ Geraghty, BS, CPTC

OPO Committee Members Unable to Attend:

Deborah Savaria, RN, CPTC

Operations Committee Members Attending:

Marlon Levy, MD, Chair
Rick Hasz, MFS, Vice Chair

UNOS Staff Attending:

Hilary Kleine, MSW
Chris Williams, RN
Gloria Taylor, RN
Joyce Hager, MPH

OPTN/UNOS OPO Committee, Work Group Summary: Imminent Death Definition Project

OPO Committee Meeting, April 5, 2006
OPO Committee Work Group, June 7, 2006
AOP Meeting, June 21-22, 2006



History

- **AOP** – research, workgroup, and consensus to work on standardizing eligible death definition.
- **Pilot project** – collected data on all non-consenting, eligible deaths
- **Contract** – “...**patient-level** data shall be collected from all OPOs and maintained on **all eligible deaths and imminent deaths...**”
- **Eligibility definition** – Need to collect information on all potential donors that meet brain death criteria, but are never declared.

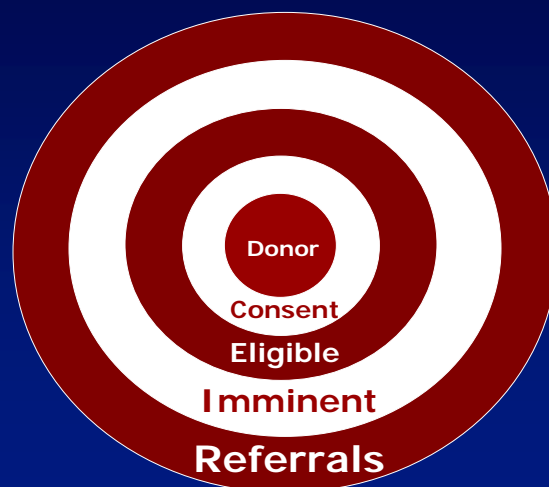


Project Purpose & Overview

- This project may help to:
 - Increase knowledge about donor potential
 - Identify the prevalence of cases in which clinical brain death parameters are met but brain death is not declared
 - Improve the standardization and validity of reported donor data
 - Help to develop future reporting definitions for DCD potential and DCD eligible



Project Purpose & Overview



Proposed Imminent Death Definition, key points

- Based on the AOPO Death Record Review definition—well tested and well known within the OPO Community
- Consistency with the recently approved OPTN eligible death definition (= the CMS eligible death definition), to be implemented August 1, 2006.



Proposed Imminent Death Definition [*Draft*]

- Proposed Definition of Imminent Death: Patient who is 70 years old or younger with severe neurological injury and requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has an absence of at least three brain stem reflexes (see below) but does not yet meet the OPTN definition of an eligible death, specifically that the patient has not yet been legally declared brain dead according to hospital policy. Persons with any condition which would exclude them from being reported as an eligible death would also be excluded from consideration for reporting as an imminent death.



Proposed Imminent Death Definition [*Draft*]

- Brain Stem Reflexes:
 - Pupillary reaction
 - Response to iced caloric
 - Gag Reflex
 - Cough Reflex
 - Corneal Reflex
 - Doll's eyes reflex
 - Response to painful stimuli
 - Spontaneous breathing



Proposed Imminent Death Definition [*Draft*]

- **Note:** The proposed definition of Imminent Death and the OPTN definition of Eligible Death would be mutually exclusive; an Imminent Death by proposed definition would not be reportable as an Eligible Death and an Eligible Death by definition would not be reportable as an Imminent Death.



Proposed Imminent Death Definition [Draft]

- The contraindications to be included are the contraindications outlined in the approved OPTN eligible death reporting definition.
- For consistency of data reporting, these exclusion criteria would be the same for both the eligible and proposed imminent definitions.



Proposed Imminent Death Definition [Draft]

- PDSA, Data Collection:
- *Plan:* Each member of the OPO Committee work group affiliated with an OPO (9 OPOs are represented on the work group) will submit a completed data survey by June 30, 2006–
- *Do:* For the months of January and February of 2006, complete the survey with the following data (by month)
 - Total number of recovered organ donors who are CMS eligible (no DCD or over 70 donors)
 - Total number of CMS eligible deaths including those referred and those identified on Death Record Review (DRR)
 - Total number of deaths meeting the proposed definition of Imminent Death, including those referred and those identified on DRR



Proposed Imminent Death Definition [Draft]

- **Study:** Review data for general estimate and current feasibility of additional data collection using the proposed imminent death definition.
- **Act:** Evaluate results and plan next step
- **Note:** this initial PDSA is intended to give a general idea of the range of reportable imminent deaths per DSA using the draft proposed definition; this survey is intended to help guide the second phase of the project--the OPTN contract requirement (to be implemented by September 2007) calls for the collection of patient-level data on all imminent and eligible deaths.



Input & Feedback, AOPO Meeting

- OPO Committee work group welcomes input and feedback regarding the current draft of the imminent death definition
- Discussion & Questions
- Thank you!



Excerpt from the OPTN OPO Committee Report to the Board of Directors, November 17-18, 2005, and [revised] March 22-23, 2006 meetings.

****RESOLVED, that the following eligible death definition be approved for adoption as the UNetsm definition for reporting of eligible deaths, effective pending distribution of appropriate notice and programming on UNetsm.**

Although it is recognized that this definition does not include all potential donors, for reporting purposes for DSA performance assessment, an eligible death for organ donation is defined as the death of a patient 70 years old or younger who ultimately is legally declared brain dead according to hospital policy independent of family decision regarding donation or availability of next-of-kin, independent of medical examiner or coroner involvement in the case, and independent of local acceptance criteria or transplant center practice, who exhibits none of the following:

Active infections (specific diagnoses) [Exclusions to the Definition of Eligible]

Bacterial:

Tuberculosis

Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis

See "sepsis" below under "General"

Viral:

HIV infection by serologic or molecular detection

Rabies

Reactive Hepatitis B Surface Antigen

Retroviral infections including HTLV I/II

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

Extreme Immaturity (<500 grams or gestational age of <32 weeks)

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

Multi-system organ failure (MSOF) due to overwhelming sepsis or MSOF without sepsis defined as 3 or more systems in simultaneous failure for a period of 24 hours or more without response to treatment or resuscitation

Active Fungal, Parasitic, viral, or Bacterial Meningitis or encephalitis

FURTHER RESOLVED, that to ensure effective implementation and validity of the definition, (1) the OPO Committee conduct a periodic review of the UNetsm eligible death definition to ensure that the definition maintains relevance, and accurately reflects practice and donor potential, and (2) OPTN/UNOS conduct appropriate training for OPO staff regarding the new definition and reporting requirements, e.g-live net meeting training sessions.

Committee vote: 17 yes-0 no-0 abstentions.

The Committee agreed that extensive effort, community input, and community support have been dedicated to this revision. Because this definition is for data reporting purposes only, is not outlined in policy, and has already received extensive input through the OPO community with transplant clinician recommendations and feedback, the Committee requests that this definition be implemented ~~*concurrent with~~ directly without further review in the public comment cycle. Based on the discussion regarding continuous review of practice, the Committee requested data on the placement practice and outcome of transplanted donor organs recovered from a donor with a primary CNS tumour. The Committee also noted in closing discussion that it supports the next step of collecting data on all eligible and imminent deaths to truly measure potential across DSAs. The Committee further noted that, moving forward, case based recommendations from OPOs for UNetsm eligible death definition revisions may be able to be captured in the electronic reporting system for all eligible and imminent deaths.

March 22, 2006, OPTN/UNOS Board of Directors, VOTE: 34 Yes—0 No—0 Abstentions

Implementation Plan

Proposed Modifications to Policy 3.2.4 (Match Access/ABO Verification)

Proposal Summary

The Organ Procurement Organization (OPO) Committee is proposing changes to the current documentation requirements for donor ABO data verification. These proposed changes would clarify the verification process across all OPOs; reduce the risk of discrepancy between UNetSM system logs and separate OPO documentation; and support the efficiency and safety of the verification and documentation process.

Following a conference call with the OPO and Operations Committee Chairs, some policy language changes to the initial proposed modifications were made. Please see attached.

OPTN/UNOS OPO Committee

Author(s) - Hilary Kleine

Date- for review by the POC at its August 18, 2006 meeting.



United Network for Organ Sharing
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Table of Contents

1 Executive Summary--included

The POC is charged with advising the Board of Directors about how effectively OPTN policies further the mission, strategic plan and long term goals of the OPTN and HHS Organ Transplantation performance goals. This will be done via a written recommendation to the Board, which will be accompanied by the Executive Summary. The Executive Summary will allow the POC members an “at-a-glance” review of the status of each proposal with respect to the program goals and strategic plan and the various components that are required for policy review.

Part one of the Executive Summary is essentially a checklist for submission of policies by policy-making Committees for review by the POC. Parts 2 through 5 will be used when the policy is transmitted to the Board. While a full written recommendation to the Board must be provided by the POC, part 6 will contain the highlights of the POC’s recommendation, to include an assessment of the scientific basis for the policy proposal.

2 Resource Analysis Plan—N/A

This plan includes an estimated assessment of UNOS staff, OPTN/UNOS Committee(s), and member transplant hospitals, OPOS and histocompatibility labs resources that will be required to implement, comply with, monitor and maintain the new/revised policy. It projects the number of allocations impacted and describes the potential impact to the members and transplant community.

3 Communication and Education Plan--included

This plan describes the types of actions that will be taken to communicate and educate OPTN members and the public on proposed policy and programming changes. System notices, policy notices, training sessions, and printed resources may be part of this plan.

4 Specification Document(s)—N/A

The functional and technical specification documents contain the detailed programming changes from to be made to UNetSM and any other OPTN applications/websites. The functional specification document is written in plain language for audiences of all reading levels and includes a list of business rules, visual representation of the screen changes, forms, tables and flow diagrams to provide a clear view of how the application will look and function when the changes are implemented. The technical specification document provides a detailed outline of the proposed technical solution, technical requirements, and security and database modifications. Each document is reviewed by a variety of audiences for approval before programming changes are initiated.

5 Monitoring and Evaluation Plan--included

This plan establishes the primary methods by which a policy will be monitored and evaluated. It includes a policy performance plan in relation to specified objectives and timelines.

1 Executive Summary, Policy Oversight Committee (POC)

1.1 I. Background/History

Submitted to POC: 08/16/2006

Initial POC review: [yes/no]

Proposed submission to Board of Directors: September 2006

Proposal distributed for Public Comment? Yes

If yes supply dates:

Date of distribution: May 19, 2006

End date for Public Comment: July 18, 2006

If no, provide narrative explaining reason:

Reason not distributed:

5-Point Checklist for Analytic Modeling

Document	Assessed by Committee?
Statement of the Objectives of the Proposed Policy	Please see attached Public Comment Proposal and summary of recent proposed modifications to the proposal.
Building the Models	N/A, no analytic modeling associated with this proposal
Testing the Models	N/A
Testing the Consequences of the Formulated Proposed Policy Prior to Implementation (Simulation Modeling)	N/A
Evaluation of the Effectiveness of the Policy	

Proposed Modifications to Policy 3.2.4
OPTN/UNOS OPO Committee

II. Impact on Program Goals

Program Goal	Impact
Increase number of deceased donor transplants	This policy clarifies a crucial patient safety and documentation issue. Patient safety and clarity of guidelines for blood type verification support the goals of improving and increasing safety, recovery and transplantation.
Increase number of DCD donors	
Increase number of non-DCD donors	
Increase life years gained	Please see above
Increase organs transplanted/donor - non-DCD	Please see above
Increase organs transplanted/donor - DCD	Please see above

1.2 III. Relationship to the Strategic Plan

Strategic Plan	Comments
Increase number of deceased donor organs transplanted	Please see above comment under Program Goal 1.
Support live donor transplantation	
Decrease regional variation in opportunity for transplants	

Proposed Modifications to Policy 3.2.4
OPTN/UNOS OPO Committee

Increase recipient benefit of transplantation	Please see above comment under Program Goal 1.
Improve the OPTN and SRTR data system	Please see above comment under Program Goal 1.

1.3 IV. Additional Data Collection

Does proposal require additional data collection? No, this proposal reduces redundant data collection/documentation at the OPO level.

Reason for Additional Data Collection	Details
Organ Allocation	
Policy Compliance Monitoring	
Institutional Performance Evaluation	
Ongoing Policy Development	
OPTN Contractual Obligations	
Patient Care	

1.4 V. Current UNOS Resource Utilization Summary

Board of Directors Approved Policy Modifications	
Title	Estimated Resource Use (FTEs)
Other Resource Uses (e.g., UNet SM enhancements, transfer center requests)	
Title	Estimated Resource Use (FTEs)
UNet SM Enhancement	

1.5 VI. POC Recommendations to Board of Directors

Summary of Recommendations:

The POC recommends that the modifications to Policy 3.2.4 (Match System Access) proposed by the OPO Committee should be considered by the Board during its September 2006 meeting.

Summary of Scientific Basis of Proposal:

N/A. However, in eliminating the requirement for OPOs to keep separate logs, the proposed change would clarify the verification process across all OPOs, reduce the risk of discrepancy between UNetSM system logs and separate OPO documentation, and support the efficiency and safety of the verification and documentation process.

Submitted to Board of Directors: 08/16/2006.

2 Communication and Education Plan

I. COMMUNICATION OUTCOMES

What information channels will be used to most effectively communicate this type of policy change?

- Article in UNOS Update Magazine
 - Policy change is of broad interest to multiple audiences.
 - Feature length articles allow you to fully present the context.
- Brochure
 - Terminology/change is complex and difficult to understand.
 - Changes to policy are significantly different from existing process.
 - UNOS staff have received multiple questions about policy change from members (via Help Desk, calls to regional administrators, emails to the Web master, etc.).
- FAQs:
 - UNetSM
 - Public websites: OPTN, UNOS, Transplant Living, etc.
- Listing in product catalog
- News story on UNOS.org
- News story on OPTN.org
- Policy notice
- Presentations at:
 - Regional meetings and forums
 - National organization meetings/conferences
- System notice
- Targeted e-mail from member communications mailbox
 - Useful when announcing availability of free brochures and informational resources
- Video
- Other: summary to AOPO for inclusion in the AOPO Newsletter

II. EDUCATION AND TRAINING OUTCOME CONSIDERATIONS

Brief training goals/objectives

- Internal UNOS Staff, DEQ OPO Auditors and Regional Administrators, understand changes to Policy 3.2.4
- OPO staff understand the impact of changes to Policy 3.2.4 for daily process and documentation

The following groups will need education/training on this change:

- Internal (UNOS) staff
- Members
 - OPO personnel
 - Transplant program/center personnel
 - Histocompatibility labs
- Committees
- Regions
- Public at large
- BOD

The below training utilities and tools are needed to educate internal and/or external users on the policy change:

- Customized hands-on training sessions scheduled for on-site training at UNOS (internal or external)
- Demos at

Proposed Modifications to Policy 3.2.4
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- Committee meetings
- Regional meetings
- National conferences/meetings
- BOD
- Exhibits at national meetings
- Microsoft® Live Meeting® (Integrated interactivity through web-based discussions with a simple automated registration process)
- Online tutorials
- Online and printed Help documentation
- Recorded sessions posted in UNetSM
- System notices
- Targeted e-mails
- Training opportunities at regional forums and meetings

III. COMMUNICATION RESPONSIBILITIES AND OUTCOMES

Deliverable Details					
Deliverable	Audience(s)	Delivery Method(s)	Timeframe	Owner	Sender
<i>Describe the communication deliverable. (number each one for easy reference)</i>	<i>Who is (are) the target audience(s)?</i>	<i>How will the message be delivered (e.g. print, e-mail, web-posting)?</i>	<i>Date to deliver relative to BOD approval / implementation date (e.g. 60 days before implementation)</i>	<i>Primary person responsible for the content & deliverable</i>	<i>Primary person responsible for delivering end product</i>
1 Targeted Email/Policy Notice	OPO Executive Directors and Clinical Directors/Staff	Guidance Document and Policy Notice delivered via email	4 weeks prior to implementation	OPO Committee Liaison	UNOS Communications Staff
2 Summary Notice to AOPO	OPO Executive Directors and Clinical Directors/Staff	Email to AOPO for inclusion in newsletter or update to Executive Director and Clinical Director groups	4 weeks prior to implementation	OPO Committee Liaison	OPO Committee Liaison/UNOS Communications Staff
3 Slides for summary update at Regional Meetings	OPO Staff	Slides, verbal update	Scheduled Regional Meetings	OPO Committee Liaison	OPO Committee Regional Representatives

Proposed Modifications to Policy 3.2.4
OPTN/UNOS OPO Committee

IV. EDUCATION / TRAINING RESPONSIBILITIES AND OUTCOMES

Education / Training Details							
Education / Training Description	Audience(s)	Delivery Method(s)	Timeframe	Owner	Trainer	Dept / Organization	Accompanying Documentation
<i>Describe the deliverable. (number each one for easy reference)</i>	<i>Who is (are) the target audience(s) ?</i>	<i>How will the education / training be delivered?</i>	<i>Estimated training dates/ months</i>	<i>Primary person responsible for creating the content & materials</i>	<i>Primary person responsible for providing the training</i>	<i>List all parties to be trained (including internal staff by Dept)</i>	<i>List any accompanying documentation to be created as a training resource</i>
1 Educate appropriate UNOS staff	DEQ OPO Audit Staff and Regional Administration	Internal Meeting and written guidance document outlining the intent of the policy	5 weeks prior to implementation	OPO Committee Liaison	OPO Committee Liaison	DEQ OPO Audit Staff, Regional Administrators, and Organ Center Managers, UNOS	Guidance Document

3 Proposed Modifications to OPTN/UNOS Policy 3.2.4, Monitoring and Evaluation Plan

Policy Implementation	Policy Goal(s)	Date to Achieve Goal(s)
October 20, 2006 (pending Board approval)	<ul style="list-style-type: none"> clarify the verification and documentation process across all OPOs reduce the risk of discrepancy between UNetsm system logs and separate OPO documentation support the efficiency and safety of the verification and documentation process 	

3.1 Metrics Monitoring

Metrics and Results		
Primary Metrics to Monitor	Date	Monitoring Results
	First date is at implementation	

3.2 Evaluation

Measuring Effectiveness of Policy Goal(s)		
Effectiveness	Date	Action Taken
<i>Is policy meeting or on track to meeting it's goal?</i>	[mm/dd/yyyy]	<i>Synopsis of action(s) taken to inform others and/or provide feedback to committee(s)/BOD on</i>

3.3 Policy Compliance Monitoring

1 Policy purpose

The Organ Procurement Organization (OPO) Committee is proposing changes to the current documentation requirements for donor ABO data verification. These proposed changes would clarify the verification process across all OPOs; reduce the risk of discrepancy between UNetsm system logs and separate OPO documentation; and support the efficiency and safety of the verification and documentation process.

2 What is expected of members

OPOs are expected to have a documented procedure in place for the double verification of the donor's ABO in UNetsm and a documented procedure for double verification and comparison of a donor's two ABO source documents. This written procedure and the two source documents (for every donor) should be available for review during site surveys. The separate documentation of verification in UNetsm will no longer be required; that information is captured electronically in the UNetsm system.

3 Monitoring efforts

Currently DEQ conducts site reviews at OPOs every 3 years. Approximately 20 site visits are performed per year. The current requirement for the OPO to retain documentation of the double verification of the donor's ABO in UNetsm is one of the more frequently cited policy violations. The current site survey process involves reviewing the OPOs procedure and its documentation of the double verification of the donor's ABO in UNetsm. This is done for each donor chart in the on site review sample.

By removing the requirement for OPOs to retain documentation of the double verification process, this would *reduce* the number of hours spent preparing for and reviewing this requirement on site. Site surveyors would continue to review the OPO's policy and procedure while on site.