

Attachment III to Appendix B of the OPTN Bylaws DCD Model Elements

Sponsored by the Organ Procurement
Organization (OPO) and Organ Availability
Committees (OAC)

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Distributed for Public Comment March 2011

Proposal Overview

- The proposed changes to the Donation after Cardiac Death (DCD) Model Elements will update and clarify language regarding DCD.
- The changes update the bylaws so they will be current with accepted practice.

***No additional data collection is required.

***This change will require programming in the Help Documentation in UNetsm and the glossaries found on the OPTN and UNOS Web sites.

Background

- The OPO and OAC Committees, as part of their annual goals, were tasked to review DCD policy to ensure consistency with current practice.
- Policies were reviewed and found to be acceptable, however, the Committees agreed that the DCD Model Elements needed to be revised, updated and clarified.
- The Committees sought assistance from the UNOS Bylaws expert.
- A crosswalk of changes can be found in Exhibit B.

Collaborative Approach

(The Committees sought input from the following groups)

Committees

- Pediatric Transplantation
- Thoracic Organ Transplant
- Liver and Intestine Organ Transplantation
- Kidney Transplantation
- Transplant Administrators

Organizations

- American Society of Transplantation (AST)
- American Society of Transplant Surgeons (ASTS)
- Association of Organ Procurement Organizations (AOPO)
- North American Transplant Coordinators Organization (NATCO)

Public Comment

- Regions;
 - Approved by 11 regions.
 - 1 region approved everything except it did not approve the terminology change from cardiac to circulatory - because of the difficulty that might be experienced in hospitals and with donor families.

**Public Comment Response Tally
DCD Model Elements**

Type	Response Total	Approve	In Favor as Amended	Opposed	No Comment
Individual	17	8 (47%)	0	2 (12%)	7
Region	11	10 (91%)	0	1 (9%)	0
Committee	6	4 (66%)	2 (33%)	0	11

Bylaws Proposed Changes

- *Since the bylaw was rewritten, only the substantive changes will be summarized here. Please refer to the full language for the bylaws change and to the crosswalk in Exhibit A.*
 1. The terms “**Model Elements**” were changed to “**Requirements**” as they are indeed required.
 2. The terms “Donation after **Cardiac** Death” were changed to “Donation after **Circulatory** Death” to accurately reflect the definition of death determined by cardio-pulmonary criteria.

Proposed Changes Cont'd

3. Two sections were added that mirror CMS requirements:
 - OPOs must have a written agreement with hospitals participating in DCD and
 - OPOs and transplant centers shall establish protocols that define the roles and responsibilities of the OPO and transplant center.
4. “Candidate Evaluation” — neurological injury and irreversible disease was clarified to include end-stage musculoskeletal or pulmonary disease.

Proposed Changes Cont'd

5. Consent/Authorization — added the term “authorization” as it is the current accepted terminology .
 - Clarified examples of procedures and medications that could be used for donor management (i.e. eliminated “heparin” and in its place included “anticoagulant” to be more general and to allow drugs developed in the future to be included).
6. Withdrawal of Life Sustaining ~~Measures/Patient Management~~ Medical Treatment/Support.

Proposed Changes Cont'd

7. The original Model Elements recommended a “timeout” prior to initiation of withdrawal of life sustaining measures; it is now required to ensure appropriate staff are present.
8. Clarified who can be present during withdrawal of life sustaining medical treatment.
 - No members of the Transplant Center surgical team may be present for the withdrawal of life-sustaining medical treatment or ventilated support.

Proposed Changes Cont'd

9. Pronouncement of Death

- Pronouncement of death can only be made after a sufficient time period has passed, as defined by hospital policy .
- Circulatory death is defined as an irreversible, permanent cessation of circulatory and respiratory functions.

10. ~~Financial Consideration~~ was removed as it is law and does not need to be restated here.

If approved, “*Cardiac*” will be changed to “*Circulatory*” in the following Bylaws, Policies and Form

Appendix B of the OPTN Bylaws - Criteria for OPO, Transplant Hospital, and Histocompatibility Laboratory Membership (Section I – OPO and Section II – Transplant Hospitals)

2.7 & 2.8	Removal of Non-Renal Organs
3.5.3.3	Sharing
3.5.5	Payback Requirements
3.5.11.5.1	Pediatric Kidney Transplant Candidates
6.4.2	Developmental Protocols in International Exchange
6.4.3	Ad Hoc Organ Exchange
Form #0915-0184	OMB approved Membership Application Form for Transplant Hospitals and OPOs

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Policy 5.0 – Standardized Packaging, Labeling and Transporting of Organs, Vessels and Tissue Typing Materials

Sponsored by the Organ Procurement
Organization (OPO) Committee

Lori Brigham MBA, Chair

Rich Pietroski MS, CPTC, Vice-chair

Distributed for Public Comment March 2011

Current Policy Requirements for Vessel Labeling when Stored

- Current policy requires that a label be placed on the vessel rigid container when vessels are **stored**, but does not require the labeling of the vessel rigid container when they are **transported**.
- Vessels must be stored in a triple sterile barrier, one of which can be the rigid container with the UNOS distributed label affixed to the outermost barrier.

***No additional data collection is required.

***This change will not require programming in Unetsm.

Overview of Proposed Change

The proposed policy language:

1. Originally, the Committee recommended that the requirement to place a label on the rigid container for vessel storage be eliminated. Following PC, this was changed due to feedback.
2. Makes the policy requirements for labeling vessel storage and transport consistent.
3. Clarifies that vessels be stored in a triple sterile barrier labeled with the UNOS distributed label.
4. Changes the words “CDC Guidelines” to the “Public Health Service Guidelines.”

Rationale for Change

- There should be consistency in labeling between vessel storage and vessel transport.
- Following public comment, the committee recommends that the label be required on the rigid container when **stored or transported**.
- The proposed language change also clarifies that vessels must be stored in a triple sterile barrier (one of which is the rigid container). This is required to maintain the specimen's sterility.

Rationale Cont'd

- Requiring the UNOS distributed label to be affixed to the outmost barrier and maintained there during storage enhances patient safety by maintaining the sterility of the specimen and including the required information about the donor on the label.
- The Committee recommends that a label for the rigid container be produced electronically and provided for members to print.

Public Comment Response Tally Vessel Labeling

Type	Response Total	Approve	In Favor as Amended	Opposed	No Comment
Individual	17	8 (47%)	0	2 (12%)	7 (41%)
Region	11	11 (100%)	0	0	0
Committee	13	4 (30%)	0	2 (15%)	7 (53%)

5.4.3 Vessels

Proposed Policy Change

Both the vessels container and outer sterile barrier must be labeled with the standardized vessel labels distributed by the OPTN contractor. The information must contain the: recovery date, ABO, all ~~serology~~ infectious disease testing results, container contents, and the UNOS Donor ID.

5.4.3 Cont'd

- If the donor is in a “high risk” group as defined by the Centers for Disease Control and Prevention (CDC), US Public Health Service (PHS) guidance, the label must indicate that the vessels are from a donor who meets the CDC PHS criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state “for use in organ transplantation only.” If packaged separately from the organ, the vessels must be protected by a triple sterile barrier, one of which must be a rigid container and the standardized vessel label s must be affixed to the outermost barrier and container.

Policy 5.10.2 Proposed Changes

- The vessels must be stored in a rigid, sterile sealed container and must be protected by a triple sterile barrier, one of which must be the rigid container labeled with the recovery date, ABO, serology infectious disease results. container contents, and the UNOS Donor ID for tracking. The standardized vessel label distributed by the OPTN contractor must be ~~attached~~ affixed to the outer most sterile barrier bag and information on the label must include ~~all of the above information and all serology testing results~~ the: recovery date, ABO, all serology infectious disease results, container contents, and the UNOS Donor ID.

5.10.2 Cont'd

- If the donor is in a “high risk”¹ group as defined by the Centers for Disease Control and Prevention (CDC) US Public Health Service (PHS) guidance¹, the label must indicate that the vessels are from a donor who meets the CDC(PHS) criteria for high risk. The appropriate packaging of vessels should be completed in the donor operating room. The label should clearly state for use in organ transplantation only. If removed from the triple sterile barrier, the transplant center must re-label the vessels prior to storage.

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