

Clinical Policy

Subject: Organ Donation after Cardiopulmonary Death – Adults and Children

Policy #: CPOL-O00-S2278

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Applies to all listed below:

Limited to those specified:

Blodgett Hospital

Butterworth Hospital

Outpatient Non-Surgical Centers

Outpatient Surgical Centers

Helen DeVos Children's Hospital

Resident and Specialty Practices

Aero Med

Occupational Services

Urgent Care Centers

Department/Service/Other (specify):

Purpose: To outline the process, standards, and criteria for organ donation following cardiopulmonary death (DCD). This policy was implemented to enhance access to cadaveric donation options at Spectrum Health Hospitals (SHH), identify donation as a significant component of end-of-life care, improve patient care satisfaction, and recognize the societal value of organ and tissue donation.

Responsibility: Registered Nurse (RN), Respiratory Therapist, Physician/Mid-level provider

Policy Content:

- I. It is the policy of SHH and Gift of Life Michigan (GOLM) to provide an ethically acceptable, medically effective, and legally compliant procedure for DCD.
- II. It is the policy of SHH and GOLM, in accordance with Medicare Conditions of Participation that all patient deaths, and all imminent patient deaths, shall be referred to the Gift of Life Michigan (GOLM) for evaluation as potential cadaveric organ or tissue donors.
- III. It is the policy of SHH and GOLM that all staff and physicians in the emergency department, intensive care and perioperative units receive thorough, on-going education and training on this policy. GOLM and SHH will provide education and training to all involved personnel on this policy.

Background:

Patients have the right to forego life-sustaining treatment. Furthermore, patients have the right to elect organ donation in the event of death. SHH believe that it is ethically appropriate to consider organ donation following cardiopulmonary death. DCD is defined as organ recovery from patients who are pronounced dead on the basis of irreversible cessation of circulatory and pulmonary functions.

Criteria for Candidates for DCD:

Appropriate candidates for DCD shall be limited to those patients who meet all the following criteria (not necessarily in the following order):

- I. The patient has a non-recoverable illness or injury that has caused neurological devastation and/or other system failure resulting in ventilator dependency.
- II. The patient has not met criteria for declaration of brain death as set forth in the Clinical

Policy: Confirmation of Death by Brain Criteria for Adults or the Clinical Policy: Confirmation of Death by Brain Criteria for Infants and Children, as applicable;

- III. A decision is made with the family and physician, to withdraw life sustaining therapy in accordance with Clinical Policy. *Withdrawing, Withholding, Foregoing of Life-Sustaining Treatment*. Health care team members should not introduce or discuss organ donation with the family during, or immediately following any end-of-life care discussion, except at the family's request to discuss available options. The physician and immediate family will discuss withdraw of support with appropriate support staff.

Procedure:

After all the above criteria are met, the following steps will be taken: **(May also see Appendix A for detailed order of events)**

- I. Contact Gift of Life (1-800-482-4881):
 - Prior to a physician initiating a discussion of withdrawal support with family, GOLM will be contacted for pre-evaluation of medical suitability in accordance with Uniform Anatomical Gift Law.
 - Notification of potential candidate to GOLM can be by the nurse or a delegate he/she designates.
- II. Evaluate Eligibility:
 - If a patient is potentially a DCD candidate, the GOLM staff will be present on site to confer with the bedside care providers and the primary intensivist regarding the timing of physician and family care discussions.
 - The GOLM staff will consult with the physician intensivist and conduct additional screening to assist in coordinating appropriately timed discussions with the patient's family regarding the option of organ, tissue and eye donation.
- III. Confirm Authorization for Organ Donation:

With the family's decision to withdraw support, the GOLM staff, along with a representative of the SHH health care team, will present donation options to the family (see Clinical Policy: *Withdrawing, Withholding, Foregoing of Life-Sustaining Treatment*).

- A. First Person Consent
 - If the patient has previously completed first person consent via the statewide donation registry, GOLM will inform the family and explain the implications.
- B. Designated Patient Advocate:
 - If a patient has a designated patient advocate who is authorized to make such a gift pursuant to the Michigan Patient Advocate Statue, GOLM will inform family of options.
- C. Priority of Persons Authorized to Make Anatomical Gift
 - 1. If the patient has not designated a patient advocate, then according to the Uniform Anatomical Gift Law, the order of priority by which persons are authorized to consent is as follows:
 - a. The spouse of the patient.
 - b. Adult children of the patient.
 - c. Parents of the patient.

- d. Adult siblings of the patient.
- e. Adult grandchildren of the patient.
- f. Grandparents of the patient.
- g. An adult who exhibited special care and concern for the patient.
- h. The persons who were acting as the guardians of the patient at the time of death.
- i. The persons assigned by the state of Michigan to authorize medical care for the patient at the time of death, including public ward custodians, correctional or mental health facility personnel, or foster parents.
- j. Any other person that has the authority to dispose of the patient's body, including unidentified bodies, under section 3206 of the estates and protected individuals code, 1998 PA 386, MCL 700.3206.

- 2. If the person(s) in the listing with authorized prioritization voices opposition to the patient donating organs pursuant to this policy the healthcare team shall not proceed with the donation, unless the patient is First Person Consent.
- 3. If there is more than 1 member of a class listed in subsections 1 b, c, d, e, f, g, or h entitled to make an anatomical gift, an anatomical gift may be made by a member of the class unless that member or GOLM knows of an objection by another member of the class. If an objection is known, the gift may be made only by a majority of the members of the class who are reasonably available.

D. Obtain Consent:

Consent forms approved by the Hospital's Organ and Tissue Donation Committee (currently the GOLM "Consent for Anatomical Gift Donation" consent form *and* GOLM "Donation after Cardiac Death Anatomical Gift Donation Addendum") will be completed and signed by the individual authorized to make the donation on behalf of the patient.

E. Revocation/Withdrawal of Consent:

- 1. An anatomical gift by a person authorized under Section III. C may be amended or revoked orally or in a record by any member of a prior class who is reasonably available. If more than 1 member of the prior class is reasonably available, the gift may be amended or revoked as follows:
 - o Amended only if a majority of the reasonably available members agree to the amending of the gift;
 - o Revoked only if a majority of the reasonably available members agree to the revoking of the gift or if they are equally divided as to whether to revoke the gift.
- 2. A revocation is effective only if, before an incision has been made to remove a part from the donor's body, or before invasive procedures have begun to prepare the recipient, a member of the organ procurement team knows of the revocation.

IV. Involve Family in Decisions Regarding Donation:

- Families will be fully informed regarding donation options and organ recovery procedures.
- The family can be provided with the opportunity to be present during withdrawal of ventilator support and remain with their loved one until the time of death.
- Families should be informed about the administration of pre-treatment medications that have been approved by the attending physician.

V. Conflict with Advance Directives or Hospice Enrollment; Resolution Process

If the patient has made a declaration, an advance health care directive, or is enrolled in a hospice program, and the terms of the declaration, directive or enrollment and the express or implied terms of a potential anatomical gift are in conflict with the administration of measures necessary to ensure the medical suitability of a body part for transplantation or therapy, the attending physician, the prospective donor (or the person authorized by law to make health care decisions on behalf of the donor), and the hospice medical director shall confer to resolve the conflict as expeditiously as possible.

Before resolution of the conflict, measures necessary to ensure the medical suitability of the body part are permissible if they are not contraindicated by appropriate end-of-life care as determined by the stated wishes of the prospective donor, by a written advance health care directive, or, if appropriate, by the hospice medical director.

VI. Coordinate Patient Management:

- A team huddle is to be conducted to include physician, nursing, respiratory therapist, care management and pastoral care if appropriate, and GOLM staff regarding withdrawal of support and organ donation timelines.
- To facilitate vital organ recovery, the patient must be maintained on a ventilator and hemodynamically supported for organ perfusion until the withdrawal of ventilator support.
- The GOLM staff will work in conjunction with the medical staff to request medical consultations and laboratory studies to determine the suitability of the organs for transplantation.
- If the case falls under the jurisdiction of the medical examiner, it will be the responsibility of the GOLM staff to contact the appropriate person(s) to arrange for the release of organ/tissue prior to ventilator withdrawal.
- Standard care and patient comfort measures will be administered prior to the withdrawal of ventilator support pursuant to the professional judgment of the attending physician or his/her physician designee.
- Pretreatment medications for organ donation will be administered at a time, route, dose, and method approved by the physician intensivist or his/her physician designee.

VII. Responsibilities for Patient Management; Withdrawal of Support; and Recovery of Organs

- When it has been determined that the patient is a suitable donor, the physician intensivist or his/her physician designee will remain responsible for patient management until the pronouncement of death (Appendix B).
- The critical care team will be responsible to carry out all physician orders prior to declaration of death.
- The GOLM and the transplant team will be responsible for all orders subsequent to the declaration of death.

VIII. Initiate Recovery Procedure:

- After suitability has been determined and consent obtained, GOLM will assemble a transplant team to recover organs for transplant.
- When the transplant team is present in the hospital, the patient will be transferred to the operating room while being mechanically ventilated and monitored.
- The SHH perioperative staff will prepare and drape the body in a sterile fashion. When the body is prepared and all necessary equipment and preservation solutions are in place, the transplant team will leave the operating room.
- Extubation may then proceed.
- The attending physician or his/her physician designee will make an accurate and timely determination of death based on accepted standards of care. If the patient expires, a pronouncement of death will occur in accordance with Section IIX.
- If patient does not expire within the designated time frame of 60 minutes, the patient will be transported back to their critical care room with Palliative Care Measures/Do Not Resuscitate status in place (as referenced in Withdrawal of Care policy).

- IX. Pronouncement of Death:
 - The attending physician/designee will pronounce death and record the date and time of death in the medical record and, if applicable, complete the death certificate. The physician certifying death may not be involved as part of a transplant or procurement team.
 - The patient will be pronounced dead by cardiopulmonary criteria determined by the attending physician or his/her physician designee, in accordance with hospital protocol, and the Michigan Determination of Death Act.

- X. Proceed With Organ Procurement:
 - Surgical recovery of organs will not take place until after a 5-minute period of cessation of circulatory and respiratory functions per the recommendation of the Institute of Medicine.
 - After pronouncement of death, the family and the critical care team leave the OR and the organ transplant team shall proceed with organ procurement and transplant.

- XI. Financial Responsibility:
 - GOLM will be responsible for all costs related to the donor evaluation and recovery of organs and tissues for transplantation. Costs associated with the donation will not be charged to the patient or the patient's family.

- XII. Conflict with Staff Personal Convictions or Beliefs:
 - Any staff member who perceives that the DCD procedure is in conflict with his or her personal cultural, ethical or religious beliefs/values should act pursuant to the Human Resources Policy: Staff Rights Related to Patient Care.

Spectrum Health reserves the right to alter, amend, modify, or eliminate this policy/procedure at any time without prior notice and in compliance with Administrative Policy: Developing or Revising Policy and Procedure Manual Content.

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References: Michigan Patient Advocate Statute, MCL 700.5506 to 5512.
Michigan Uniform Anatomical Gift Law, **UAGL: MCL 333.1014 (3)**
Michigan Determination of Death Act MCL, 333.1031 to 1034.
Medicare Conditions of Participation for Hospitals, 42 CFR 482.45.
Medicare Conditions of Participation for OPOs, 42 CFR 486.301-486.325.
JCAHO Standard RI.2.
Agreement between Gift of Life Michigan and Midwest Eye Banks, and
Spectrum Health Hospitals.
1997 IOM Report, and 1999 IOM Study, on Non-Heart Beating Organ
Transplantation.
[Clinical Policy: Confirmation of Death by Brain Criteria for Infants and Children](#) (CPOL-D00-S1083)
[Clinical Policy: Confirmation of Death by Brain Criteria for Adults](#) (CPOL-D00-S0008)
[Clinical Policy: Withdrawing, Withholding, Foregoing of Life-Sustaining Treatment](#) (CPOL-W00-S0026)
Resuscitation Status (MSPOL-MS4.29)
Human Resources Policy: Staff Rights Related to Patient Care

Key Words: Organ Donation, Cardiopulmonary Death, Cardiac Death, Non-Heart Beating, Gift of Life

Appendix A

Outline Summary of Order of Events for Organ Donation after Cardiopulmonary Death (DCD)

After the family has decided to withdraw life support pursuant to the applicable policy (Reference: Withdrawing, Withholding, Foregoing Life-Sustaining Treatment policy), the following steps are to be followed:

1. Gift of Life (GOLM) will be contacted for pre-evaluation of the case.
2. At that time, the GOLM staff will respond and complete an evaluation for potential donor candidacy.
3. The GOLM staff shall not have any contact with the family and/or GOL until the family's decisions are made (see #5 below.) *NOTE: GOLM may be notified prior to this step if so required by applicable Medicare Conditions of Participation or other applicable law or regulation.*
4. *The clinical team providers and GOLM clinical coordinator may communicate/develop a plan of care management if patient is a potential candidate at this time.*
5. The family will be informed of end of life options in a discussion led by the physician intensivist or attending physician and GOLM staff.
 - a. Wait for brain death to occur
 - b. Proceed with DCD
 - c. Withdrawal of life without organ donation
6. The health care team will assemble and proceed with the Team huddle. Detailed discussion will occur with the physician intensivist, and /or attending physician, GOLM staff, nursing and ancillary staff regarding procedures involved in each option available to families.
7. The attending physician and GOLM staff will limit the number of medical providers and/or support staff that provide information or have contact with the family.
8. In conjunction with GOLM staff, the physician may perform a respiratory challenge based on best medical evidence to determine likelihood of progression to cardiopulmonary death within 60 minutes. Family will be informed of the procedure by the physician, give consent and be given the opportunity to be in attendance. See Appendix B.
6. If the family decides to wait for brain death, the health care team will continue in current patient management with provision to re-evaluate for conversion to DCD.
7. If the family chooses DCD, the process will then continue with detailed consent pursuant to the policy. Discussion among the physician intensivist, attending physician, GOL coordinator, next of kin (NOK), and family members will occur. This is based on confirmation that the specific family member/NOK has the authority to consent for the patient (consistent with established donor policy and procedure and Michigan's Uniform Anatomical Gift Law). Discussion and consent would clearly and specifically include:
 - a. Palliative care per hospital policy
 - b. Removal of endotracheal and tracheostomy tube, not to be replaced
 - c. Cessation of all cardiac activity or nonperfusing electrical activity with no attempt to restart the heart
 - d. If asystole not achieved in 60 minutes DCD will be aborted but DNR status and comfort care measures will be continued.

8. When consent is obtained for DCD, the team will proceed with recovery procedure steps as outlined in the policy under *Recovery Procedures below*.
9. Family will be offered the opportunity to spend private time with the patient in the critical care unit, depending upon the physiologic status of the patient.
10. If the family elects to accompany patient in the operative phase, they may be escorted via the medical social worker and /or chaplain to the private waiting room in the OR suite or to the perioperative suite if previous arrangements have been put in to place.

See Recovery Procedure Steps

<i>Recovery Procedure Steps</i>	Responsibility
A. Coordinate surgery: Arrange transplant team(s) arrival and coordinate patient arrival to OR to coincide with the team's arrival	<i>GOLM</i>
B. Communicate with Medical Examiner if indicated	Intensivist and/or GOLM
C. Transport to OR: 1. When all arrangements are completed, accompany patient during transport to OR (see D. below). Family may accompany patient to OR if they so desire. <i>Family presence in the OR (the number of family members entering the OR + room preparation)</i> , will be coordinated by the following: GOLM/MSW, pastoral care, critical care nurse, and peri-operative coordinator. This process will be dictated by OR policy and guidelines. 2. Patient transport team: Intensivist physician/or designee, critical care nurse, support personnel, family (if desired) and respiratory therapist.	Intensivist/or designee MSW/chaplain Nursing GOLM Patient transport team
D. Monitors & Equipment: 1. Critical care monitors will remain on the patient and will be utilized in the OR until the declaration of death. 2. The patient's ventilator will be transported to the OR by a respiratory therapy team member. 3. Anticipatory medication to be brought and signed out from Critical Care by nursing, e.g. sedation and anticoagulant medications.	Respiratory therapist Critical Care Nurse
E. Patient monitoring in the OR: 1. Patient placed on OR table with specific draping instruction via	Peri operative nurse Critical Care Nurse

<p>GOLM staff and transplant team.</p> <ul style="list-style-type: none"> • Prior to extubation, the OR nurse will request assistance from the critical care nurse in the placement of posterior leads to prevent lead interference with the surgical field. A posterior lead pack can also be obtained from OR and placed on the patient while still in the critical care unit. • GOLM will instruct staff on all steps of the process • GOLM will inform and secure family for OR suite attendance for extubation. 	
<p>F. End of Life Procedure:</p> <ol style="list-style-type: none"> 1. Extubate patient in OR 2. Monitor time of asystole/non-perfusing electrical activity (60 minutes timeframe) 3. Provide comfort care measures in accordance with <i>Policy: Withdrawing, Withholding, Foregoing Life-Sustaining Treatment</i> 4. The attending physician or his/her designee will remain responsible for patient management until a pronouncement of death is made. 5. The critical care nurse will remain responsible for administering medications per order of the attending physician and will be responsible for all nursing documentation in the OR up to patient termination. To include medicine/fluid administration, mechanical ventilator settings, vital signs, extubation, respiration cessation, time of death, family interventions, end of life care management. 6. At the time of asystole/non-perfusing electrical activity the family will be escorted out of the OR suite and a 5 minute clock will begin per (Institute of Medicine recommendation). 8. Immediately relinquish patient management to the transplant team. 9. Fill out Administrative Report of Death (ARD), physician death summary note and death certificate, if applicable, and other documentation as necessary. 	<p>Intensivist/designee Critical Care Nurse</p>
<p>G: Organ Recovery:</p> <ol style="list-style-type: none"> 1. The critical care intensivist/designee and the patient care team will leave at this time and the transplant team(s) enters the OR. 2. Rapid organ recovery will commence. 3. When the organ recovery surgical procedure is completed, the body will be transported to morgue by OR staff in the usual manner. 	<p>Intensivist /designee Patient transplant team Intensivist/designee GOLM</p> <p>Transplant team Perioperative staff</p>
<p>H. If greater than 60 Minutes, abort the DCD process but do not re-intubate. The patient will be transported to their previous unit/bed, this will be based on bed placement protocols with DNR orders written for the receiving unit/staff. (<i>Reference: Withdrawal /Withholding Life Sustaining Treatment Policy</i>).</p> <ol style="list-style-type: none"> 1. The patient will be accompanied by the critical care nurse and the MSW or the Chaplain. An exchange report will be communicated to the receiving nursing staff as needed. GOLM will then inform 	<p>Intensivist/designee, Critical care nurse, MSW, or pastoral care GOLM</p>

family.	
I. All information is to remain confidential pursuant to Spectrum Health policies (<i>Reference: Disclosures of Protected Health Information for Organ, Eye or Tissue Donation</i>)	All Spectrum Health and Medical staff Public Relations

Appendix B

RESPIRATORY CHALLENGE TEST FOR DCD
INTENDED FOR USE IN ADULT PATIENTS in 4-
HC/5HC/Blodgett ACC & Burn Center ONLY

The Respiratory Challenge for DCD evaluation will only be done when specifically requested by the organ transplant center receiving the organs. The Respiratory Challenge for DCD evaluation will not occur until after the decision has been made by patient's Next of Kin, or appropriate legal guardian decision maker, to withdraw life support. The attending physician must write an order for the Respiratory Challenge for DCD evaluation to occur and will remain at the patients bedside until the challenge has been completed. The physician will document the clinical responses to the procedure.

The Respiratory Challenge for DCD evaluation procedure will be conducted by a respiratory therapist. The respiratory therapist will:

- i. Verify that an order for a Respiratory Challenge for DCD evaluation has been written and obtain any necessary equipment.
- ii. Confirm that the attending physician will remain at the patient's bedside during the entire Respiratory Challenge procedure.
- iii. Record all patient vital signs including oxygen saturation, systolic blood pressure, heart rate, respiratory rate, and ventilator settings before beginning the procedure.
- iv. Position head of patient's bed flat, if tolerated by patient, for the Respiratory Challenge.
- v. Place the patient on PSV 0 and PEEP 0 and FiO2 21% for up to 10 minutes and monitor the patient's vital signs.
- vi. The patient is NOT to receive any supplemental Oxygen or ventilator support during this procedure.
- vii. If at any time during the 10 minute procedure the patient's oxygen saturation drops below 85% or systolic blood pressure is less than 90mmHg, the evaluation will immediately be stopped and the patient will be placed back on full ventilator support.
- viii. At the end of the 10-minute evaluation with the head of the patients bed still flat, the respiratory therapist will perform a NIF maneuver, record exhaled tidal volume, record vital signs and place the patient back on their previous ventilator settings.
- ix. Assess presence of cuff leak by slowly removing air from the pilot balloon while auscultating the trachea. Once a leak is detected re-inflate the cuff to MOV. Prior to assessing for a cuff leak sub glottal suctioning must be preformed.
- x. Return head of bed to previous position upon completion of Respiratory Challenge.
- xi. Document patients tolerance to the procedure

Following the Respiratory Challenge for DCD evaluation the respiratory therapist will complete a full ventilator check and patient assessment including a note that indicates patient tolerance of the evaluation as well as the attending physician that ordered and observed the procedure.