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Policy: Organ and Tissue Donation

POLICY:
In accordance with New Jersey’s Uniform Anatomical Gift Act as amended and Federal Medicare regulations, all acute care hospitals are required to develop policies and procedures to ensure the routine referral of all deaths and pending deaths to their regional organ procurement organization (OPO) for the determination of medical suitability for organ and tissue donation. The New Jersey Organ and Tissue Sharing Network (The Sharing Network) is the federally designated, state certified organ procurement organization for this hospital.

This policy assures that all potential organ and tissue donors are identified and families are provided the option of donation in compliance with the law. This policy provides a mechanism for all acute care hospitals to document each referral in accordance with federal and state regulations and guidelines promulgated by the Health Care Financing Administration, the New Jersey Department of Health and Senior Services and the Joint Commission for Accreditation of Healthcare Organizations.

Adherence to this policy also provides a permanent record for the purpose of quality assurance and quality improvement

DEFINITIONS:
1. Organ Donation – Refers to solid vascular organs: kidneys, heart, liver, pancreas, lungs and small bowel. Death must be determined by neurological criteria for organs to be donated except on limited occasions when organs may be donated after cardiac death.

2. Tissue Donation – Refers to cartilage, bone, tendons, ligaments, and soft tissue i.e., skin, fascia, dura, heart valves and saphenous veins. Tissue donation requires donor death to be determined by either brain or cardiopulmonary criteria.
3. Eye donation – Refers to corneas and/or whole eyes. Eye donation requires donor death to be determined by either brain or cardiopulmonary criteria.

4. Brain Death – Irreversible cessation of all functions of the entire brain, including the brain stem. The criteria and procedures whereby death can be determined and certified in accordance with neurological criteria as set forth in the policy – Brain Death – Declaration of Death on the Basis of Neurological Criteria.

5. Imminent death” is defined as the first indication of brain death, when there is absence of 2 or more brain stem reflexes with minimal or absence of respiration, and/or Glasgow coma scale of 5 or less

CONTENT:

I. Making the Referral
The hospital shall notify The Sharing Network of each hospital patient whose death is imminent or who has died. In the case of imminent death the referral must be made within one (1) hour of patient meeting clinical triggers of GCS ≤ 5 or loss of ≥ two cranial nerve reflexes, and prior to any discussion about organ and/or tissue donation with the patient’s family. The referral should be made prior to discussion of DNR, prior to withdrawal of the ventilator and while the organs are still viable. In the event of cardiac death, the referral should be made as soon as possible, but no later than two hours after declaration of death. The phone number to make referrals is 1-800 541-0075
a. Patient’s name and identifier number
b. Patient’s age
c. Cause of death or anticipated cause of death
d. Past medical history
e. Other pertinent medical information requested by the OPO.

II. Medical Suitability for Organ Donation
a. The Sharing Network has sole responsibility to determine medical suitability for donation
b. The Sharing Network will collaborate with hospital staff in securing information or tests necessary to determine suitability
c. The Sharing Network is responsible to notify and coordinate with the Medical Examiner for the recovery of the donor.
d. A note must be placed in the patient’s medical record regarding the potential donor’s medical suitability as determined by the Sharing Network. If the patient is determined to be an unsuitable candidate for donation, an explanatory notation shall be made part of the patient’s medical record.

III. Declaring Brain Death
a. A definition of brain death can be found in the “Brain Death Criteria” policy. Brain death must be determined according to the steps outlined in that policy.
b. The transplant or recovery surgeon may not be involved in the pronouncement of brain death.
c. Legal declaration occurs when a licensed physician places a time note in the patient’s record.

d. Appropriate medical care must be maintained until such time as it is determined whether the decedent is an organ donor or not.

IV. Obtaining Consent

a. Consent must be in either written, witnessed facsimile or tape recorded telephonic message form

b. The Sharing Network will provide all appropriate consent forms

c. If the patient has a validly executed donor card, will, other document of gift, driver’s license or identification card evidencing an anatomical gift. The Sharing Network representative or the Designated Requestor, if any, shall attempt to notify an appropriate person as described below of his/her gift. If there is no document of gift available to The Sharing Network representative or Designated Requestor, he/she shall ask persons in the following order of priority:

1. Spouse or domestic partner
2. Adult Child
3. Parent
4. Adult Sibling
5. Legal Guardian
6. A person authorized or under obligation to dispose of the body pursuant to N.J.S.A 26: 6-58.1 (b) (6) shall include but not be limited to a hospital administrator, a designated healthcare representative, a holder of a durable medical power of attorney or a person named in the decedent’s will.

d. The consent process is completed when the person in the highest category available consents or declines to donate and there is no known contrary indication from anyone in the same or higher category.

e. A notation shall be made in a deceased person’s medical record indicating whether or not consent for organ and tissue donation was granted. The notation shall include the following information:
1. Whether consent was granted or refused.
2. The name of the person granting or refusing consent
3. That person’s relationship to the decedent
4. Documentation of telephone contact with the Sharing Network

V. Approaching the Family

a. Only individuals employed by The Sharing Network or hospital staff (Designated Requestor) trained by The Sharing Network may approach families for organ donation.

b. The approach to the family must be a collaborative effort with The Sharing Network. The approach may include pastoral, nurses, physicians who are not trained as long as it is a collaborative effort with The Network and/or a hospital appointed Designated Requestor.
VI. Tissue Donation
a. All expired patients will be considered by The Sharing Network for tissue donation.
b. The referral of tissue donors will follow the same process as found in Section I of this policy.
c. While medical suitability and consent for donation are being determined, the body must be placed in the morgue with saline soaked gauze applied to the eyes.
d. Should the deceased be suitable for eye donation, The Sharing Network will place the referral with the Eye Bank selected by the hospital.
e. As soon after death as possible, secure two (2) red top tubes of blood.
f. Consent for tissue donation will proceed as described in Section II of this policy.
g. The recovery of tissue will be accomplished in the operating room by surgical recovery specialists trained by The Sharing Network.

VII. Non Heart Beating Donation (donation after Cardiac Death)

a. Please see policy for removal of life support (Withholding/Withdrawing Life Sustaining Medical Treatment).
b. Patients who do not fulfill brain death criteria but whose condition is terminal may be considered for donation after cardiac death has been established under the following conditions:
   1. Suitability for donation as determined by The Sharing Network
   2. The family or patient, via an advanced directive, have decided to withdraw life support.
   3. Consent is obtained for a Do Not Resuscitate order and donation.
   4. A physician will be present when life support is withdrawn to pronounce the death.
c. When conditions in Section VII are satisfied, the family, Jersey City Medical center (JCMC) staff and The Sharing Network will agree to time and place for the respirator to be terminated (OR preferred; acute care setting acceptable)
d. Specific Procedures will be established with the OR staff, ICU staff and The Network prior to discontinuing life support to coordinate the time and a place/

VIII. Reimbursement
a. The Sharing Network agrees to reimburse JCMC for all charges incurred from the time that death has been declared and which are directly related to organ and tissue procurement such as room and board, laboratory test, drugs, operating room cost and intensive care unit charges. Physicians’ fees shall also be covered by The Sharing Network provided that they are incurred after the declaration of death and that the service provided was
related specifically to donor evaluation, maintenance and/or surgical recovery of the organs. JCMC agrees to provide The Sharing Network with an itemized statement of all services and tests for which reimbursement is sought.

b. The Sharing Network will notify in writing the billing office of all donors.

IX. Quality Improvement
a. Medical record reviews will be conducted by The Sharing Network to ensure early referral of all potential organ donors. A periodic review of all death charts will be conducted by The Sharing Network to ensure the timely notification of all hospital deaths. Charts will be reviewed for documentation of the referrals to The Sharing Network.

b. All brain death declarations/cardiac deaths and organ/tissue donor requests should be reviewed with The Sharing Network for adherence to this policy.

c. The Sharing Network will provide to the hospital a quarterly report. The report will include all patients referred to The Network with outcomes.

X. Clinical Triggers for Notification to the New Jersey Sharing Network:
1. Glasgow Coma Scale of 5 or less or loss of 2 or more cranial nerve reflexes
2. Prior to the removal of life support
3. Prior to discussions of a DO NOT RESUSCITATE (DNR) status
4. First order of “Palliative Care” or “Palliative Care Only”

ADDENDUM TO
ORGAN AND TISSUE DONATION
ADMINISTRATIVE POLICY AND PROCEDURE

I. POLICY

To provide an ethically justifiable and auditable policy that respects the rights of patients to have life support removed and to donate organs: This institution believes that it is ethically appropriate to allow patients (or their surrogates) who have exercised their right to have life support removed to consider organ donation (e.g., kidney donation even though such donation will necessitate declaration of death based on cardio-respiratory criteria, not brain death.

II. DEFINITION
Cardiopulmonary criteria for death is the irreversible cessation of cardiopulmonary function “recognized by persistent cessation of functions during an appropriate period of observation.”

Clinical definitions of cardiac arrest such as the absence of a palpable pulse in a large artery (i.e., the carotid, femoral or brachial artery) do not suffice for this application. The absence of a clinically palpable pulse does not necessarily mean cessation of mechanical activity of the heart.
The diagnosis of death by traditional cardiopulmonary criteria requires confirmation of correct EKG lead placement and confirmation of absent pulse via a femoral artery catheter. The pulse pressure must be zero or by definition the heart is beating. In addition to pulselessness the patient must be apneic and unresponsive to verbal stimuli. Give the above, any one of the following electrocardiographic criteria will be sufficient for certification of death:

- five minutes of ventricular fibrillation
- five minutes of electrical asystole (i.e., agonal baseline drift only).
- five minutes of electromechanically dissociation

III. PURPOSE

The purpose of this policy is to assist patients, families, healthcare representatives, physicians and healthcare professionals to appropriately implement the right of each patient to choose both to have life support withdrawn and to donate organs by establishing principles and procedures to be followed in these cases.

IV. PRINCIPLES

a. A decision has been reached to withdraw life support consistent with the policy “Withholding/Withdrawing Life Sustaining Medical Treatment”

b. The patient, the patient’s advance directive, or a person legally authorized to make healthcare decisions for the patient as appropriate, has indicated that organ donation is desired. Consideration of organ donation shall occur only after a decision has been made by the patient or surrogate, family and physicians that the patient be assigned the status of “comfort measures only” as indicated in the policy guidelines for “withdrawal of life support”.

c. The patient is ventilator dependent (preferably apneic) but not brain dead.

d. This policy explicitly prohibits any intervention whose primary intention is to shorten the patient’s life.

e. Appropriate candidates for organ donations shall be limited to those patients on life sustaining treatment in whom withdrawal of that therapy is likely to result in death within a few hours (e.g. patients who are ventilator dependent).

f. Utmost attention and caution shall be taken to protect the dignity and rights of donors.

g. Healthcare professionals shall not be required to participate in the procedures described below if such participation is against their personal, ethical or religious beliefs.

V. PROCEDURES

a. The patient must have a DNR order written and the decision for the withdrawal of life-sustaining treatment (e.g., ventilator) must be reached.

b. Discussions with the patient, surrogate or proxy leading to decisions to withdrawal of life-sustaining therapy must be appropriately documented in the medical record.

c. Discussion of organ donation shall be deferred until after the decision to withdraw life support has been reached and documented in the chart. It is then that The Sharing Network is notified of a potential donor after cardiac death.

   (i) Medical suitability of a potential organ donor can only be made by The Sharing Network.
The Sharing Network Coordinator Team shall initiate discussions with the patient, surrogate, or proxy regarding donation and will present the option of donation, if appropriate.

d. If the patient or surrogate does initiate the discussion of potential organ, tissue and cornea donation, the patient’s physician or designee will ensure that The Sharing Network is notified to identify medical suitability prior to cessation of mechanical ventilation.

e. Organ procurement may proceed only if the patient or surrogate agrees to organ procurement upon death of the patient and signs the appropriate consent form. Consent for donation can be withdrawn at any time. No pressure or coercion shall be used to obtain consent. During discussion with the family, the family must also be specifically advised that medications which are not beneficial nor harmful to the patient (i.e., Heparin) may be administered. This information must also be specifically set forth in the consent form.

f. The location for withdrawal of life support shall be the operating room suite. Cannulation of the femoral artery and vein will take place just prior to the removal of the ventilator if prior consent is obtained. The death will be considered a non operating room death.

g. Appropriate support will be provided for the patient, surrogate or family by the healthcare professionals. Pastoral care of the patient, surrogate or family shall be provided in the Intensive Care Unit by clergy as requested.

h. The patient’s attending physician must agree with the proposed procedure and note this in the chart. After the patient is removed from life support and meets the accepted hospital criteria for death, the declaration of death will be made by the attending physician or by another fully licensed physician with admitting privileges at the hospital designated by the attending physician.

i. The physician certifying death must not be involved with in procuring organs or the care of any of the transplant recipients. Completion of the death certificate and death summary in the medical record are the responsibility of the primary service.

j. The surgical staff responsible for organ procurement shall in no way participate in the removal of life support.

k. If narcotics or a sedative are administered, these drugs must be titrated to the patient’s need for provision of comfort. Medications must be justified by their effectiveness in the care of the patient. No medications will be used for regulating the time of death. For details regarding the removal of mechanical ventilatory support, please refer to the guidelines for “Withdrawal of Life Support.”

l. If organ ischemia is prolonged, it may not be possible to utilize organs designated for donation and procurement may not be performed. The decision to cancel organ procurement because of prolonged ischemia rests with the responsible transplantation surgeon.

m. No organ may be procured until death has been certified. To keep warm ischemia time to a minimum, all other appropriate preparations for the procurement operation (such as cleansing of the skin, draping of the field) may take place prior to death. No incision will be made until the patient has been pronounced dead.

n. Immediately after certification of death, organ procurement is to proceed following The Sharing Network protocol.
Cases may be reviewed by the Ethics Committee. The panel may include the hospital’s liaison to The Sharing Network and the physician withdrawing life support. The purpose of this review is to:

- assure that the above principles are adhered to
- assure that the above procedures are complied with
- identify problems and complications, potential or actual, and recommend changes toward their solutions.
- protect the interest of the donor, recipients, the institution and involved healthcare workers.

REFERENCES:

- Uniform Anatomical Gift Act; PL 1969 NJSA 26:6-ET SEQ.
- Conditions of Participation for Organ/Tissue and Eye Procurement 42 CFR 482.45.
- JCAHO Accreditation Manual for Hospitals (Patient Rights, Leadership)
- NJ Department of Health licensing Standards NJAC 8:34G-5.