



GIFT^{of} LIFE
DONOR PROGRAM
THE REGION'S ORGAN & TISSUE TRANSPLANT NETWORK

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Pennsylvania House of Representatives
House Majority Policy Committee Hearing - Organ Donation
April 9, 2015

Good morning Chairman Benninghoff and members of the Committee.

My name is Richard Hasz and I am the Vice President of Clinical Services at Gift of Life Donor Program Program. Thank you for providing me with the opportunity to speak with you today about the organ donation process. Gift of Life Donor Program has been coordinating organ donation and transplantation in the eastern half of Pennsylvania for 40 years. That experience has allowed Gift of Life to develop clinical processes that represent best practices not only across the United States, but internationally as well.

I. The Organ Donation Process

The following is an outline of the organ donation process in the Gift of Life service area. While the process in other service areas may vary slightly, much of what is described below is dictated by state and federal law.

1. Hospital Referral

Initial referral

Organ donation is limited to cases where a patient has been admitted into a hospital and is being treated in an ICU. Only after the hospital medical staff determines that a patient is at or near death according to established hospital clinical policies, the hospital initiates a referral phone call to their federally-designated organ procurement organization ("OPO").¹ Every PA hospital patient death is required to be referred to an OPO according to federal regulations. This information is also subject to extensive confidentiality requirements applicable to both the hospitals and the OPOs. Donor and recipient information is required to be maintained as confidential among the medical professionals involved in the process.

Approximately 30,000 PA hospital deaths are referred each year to Gift of Life Donor Program with only an estimated 650 being potentially medically suitable to become an organ donor. There are currently over 8,500 people awaiting transplant in PA and on average more than 8 of them will die each week.

¹ 42 C.F.R. § 482.45; 20 PA. CONS. STAT. § 8617(a).



A Donate Life Organization

The non-profit organization serving patients, families and hospitals in the eastern half of Pennsylvania, southern New Jersey and Delaware.

Phone screening

Hospital staff provides information to the OPO so a preliminary determination can be made by as to whether there is a potential for organ or tissue donation.

On-site evaluation

Where there is a potential for organ donation (patient has a non-survivable brain injury and is supported by a ventilator in the ICU) an OPO Transplant Coordinator is dispatched to the hospital. The Transplant Coordinator collaborates with the hospital care team to initiate an assessment of the patient for preliminary medical suitability for organ donation. The assessment includes chart review and physician-ordered blood tests to aid in identification of suitability and donation opportunities.²

Hospital staff support of patient

Hospital staff continues to support the patient and family and notifies the family of the patient's grave prognosis, including the cessation of brain function.

2. Brain Death

Declaration of death

Physicians, medical ethicists, and state law are unanimous in their acceptance of brain death as death. It has been an accepted medical principle since the 1960s and has been a part of state law across the country since the early 1980s. Attached to this testimony as Appendix A is a recent article published in the New England Journal of Medicine addressing brain death and written by some of the most respected biomedical ethicists in the world.

Passed in 1981, Pennsylvania's Uniform Determination of Death Act is based on the Uniform Law Commission's model act. It provides that a person is brain dead where they have sustained an "irreversible cessation of all functions of the entire brain, including the brain stem" determined "in accordance with accepted medical standards."³ Hospitals develop their internal brain death protocols in accordance with this statute and established medical criteria.

A brain death evaluation is initiated by hospital medical staff, not by an OPO. This typically requires two exams between 6 and 12 hours apart, performed by two separate physicians. **The physicians responsible for brain death testing are not involved in organ donation or recovery in any way.**⁴ If the patient is pronounced brain dead, the family is notified by the hospital that death has occurred.

² 42 C.F.R. § 486.344; 20 PA. CONS. STAT. § 8617(d).

³ 35 P.S. § 10203.

⁴ 20 PA. CONS. STAT. § 8616(b).

OPO contact with Coroner or Medical Examiner

Typically, after the first brain death exam is performed, the OPO contacts the Medical Examiner or Coroner (“ME/C”) regarding the potential death and preliminary determination of a donation opportunity. The OPO contacts the ME/Coroner regarding every potential organ donor, regardless of the circumstances surrounding death in order ensure that the ME/C has full opportunity to be involved in every case.

Hospital and OPO collaborate on resources

The hospital care team and OPO collaborate to identify resources to be made available to the family including social work and pastoral care. The hospital and OPO collaborate on a plan to approach the family regarding donation in a manner sensitive to their circumstances. As part of the plan, the OPO checks advance health care directives and state driver’s license registry for information regarding donor designation to share with the family.⁵ If there is no family or next-of-kin on sight at the hospital, the OPO conducts an extensive search to locate the decedent’s family. Depending on the decedent’s condition, this search may range from several hours to several days and includes the use of location services, law enforcement, PennDOT and hospital records in order to locate family members.

3. The Donor Option

Family approach and initiation of donation discussion

As required by federal and state law, the OPO Transplant Coordinator, with the support of hospital staff, approach the family regarding the donation option in a manner encouraging discretion and sensitivity to the family’s circumstances.⁶ The coordinators are extensively trained before participating in these family interactions and most already have a background in critical care nursing. Their training is designed to ensure that the coordinator is an advocate for the donor and donor family, that they are experienced in understanding grief, and that they understand how to support families in the acute phases of loss. Overall, coordinators undergo 3 months of training comprised of didactic and clinical instruction under the guidance of clinical preceptors. They coordinate cases independently while being supervised by experienced coordinators and leadership staff for an additional 3 months before they are considered fully-trained. All coordinators at Gift of Life are expected to become Certified Procurement Transplant Coordinators after their first 12 months of service. Moreover, they must participate in 7 annual trainings, skills workshops, and continuing education programs.

If the decedent authorized donation before their death, information about the donation process is provided to the family. In the absence of a decision by the decedent regarding donation, authorization is requested from the next-of-kin according to statutory hierarchy.⁷ While the family is notified of the donation option, the decedent’s body is maintained on a ventilator.

⁵ 20 PA. CONS. STAT. § 8619(b).

⁶ 42 C.F.R. § 486.342; 20 PA. CONS. STAT. § 8617(d).

⁷ 42 C.F.R. § 486.342(a); 20 PA. CONS. STAT. § 8617(b).

The information reviewed with the family includes: (1) the organs and/or tissues that may be recovered; (2) the most likely uses for the donated organs or tissues; (3) a description of the screening and recovery processes; (4) information about the organizations that will recover, process, and distribute donated tissue; (5) information regarding access to and release of the donor's medical records; (6) an explanation of the impact the donation process will have on burial arrangements and the appearance of the donor's body; and (7) contact information for individual(s) with questions or concerns.⁸

Comprehensive medical/social history

If the decedent or their next-of-kin authorized donation, comprehensive medical and social history questionnaire similar to that used in blood donation is completed with the family or another appropriate historian. Diagnostic and other testing is performed to determine organ function, suitability for transplant, and to assist in allocation.

OPO and ME/C Collaboration

The OPO updates the ME/C regarding the declaration of death. The OPO then reviews with the ME/C the comprehensive report including known clinical information, organ function, injuries sustained, physical assessment, radiologic imaging, chest x-rays, CT scans, contact information of any investigating agencies and other information in the hospital chart or collected from the family.

Until the ME/C makes a decision regarding jurisdiction, or if the ME/C assumes jurisdiction, the OPO inquires as to additional information relevant to their inquiry and requests permission to proceed with organ recovery. Certain ME/Cs (or their designee, such as a Deputy Coroner) travel on-site to the hospital at this point to initiate their review. The ME/C frequently request additional testing be performed at the hospital including toxicology, skeletal series and CT scans. Pictures, blood, bodily fluids, and tissue specimens are also frequently requested. Proper collection and documentation of these tests, specimens and pictures has proven to be sufficient for the ME/C to successfully conduct their investigations of potential homicides (including child abuse cases).

When permission to move forward with organ donation is granted, the ME/C and OPO coordinate timing of recovery, testing and imaging to be performed and samples to be collected.

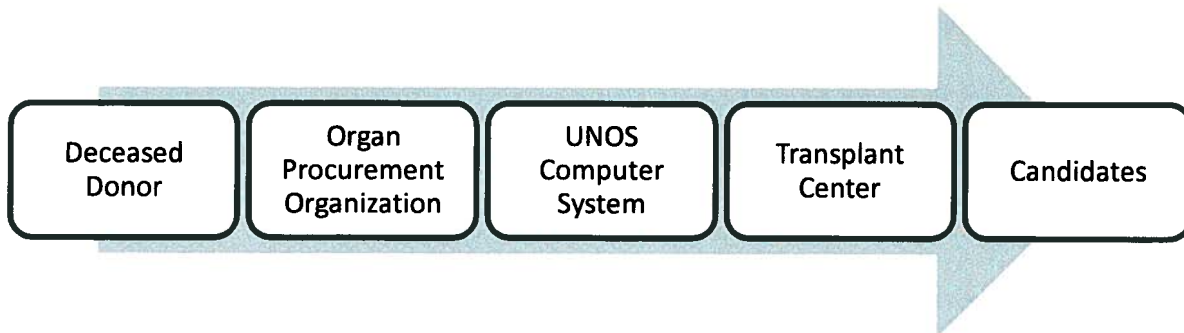
Diagnostic and compatibility testing

Standard tests are performed to determine organ function, suitability for transplant, and to assist in allocation.

Organ donor and recipient matching

The OPO enters donor information and compatibility testing results into the national system and potential matches are identified. Organs are allocated based on those results.

⁸ 42 C.F.R. § 486.342(a).



4. Organ Recovery

Recovery procedure

The organ recovery procedure is scheduled to accommodate the interests of the donor family, ME/C, the donor hospital and transplant surgeons. Typically, the recovery takes place in the donor hospital operating room. If the ME/C has elected to participate in the recovery, they (or a designee) would be present for the procedure and could examine the organs in situ and post-recovery. If evidence relevant to the forensic investigation were identified with a particular organ, the ME/C would document the evidence and permit transplant to proceed, or withhold that organ as evidence. If the ME/C (or designee) does not attend the recovery, and during the recovery any additional findings are noted, the OPO communicates them to the ME/C prior to the recovery of the particular organ.

Surgical report

During the recovery procedure, information regarding the recovered organs is recorded by the transplanting surgeon and photographs of the organs are taken, all of which are made part of the donor record and shared with the ME/C.

OPO collaboration with ME/C post-recovery

Following the organ recovery procedure, the OPO notifies the ME/C that all requested testing, samples and other information is being transported together with the body to the location designated by the ME/C.

Additional information is available to the ME/C regarding the donation outcome and any post-transplant organ function to inform their forensic investigation. Transplant Surgeons will also be available to testify regarding the condition the organ and any other injuries noted while recovering the organ.

All of the above information is incorporated into the OPO donor record, which also includes certain checklists to ensure that all required information has been collected.

5. Family Support Services

Initial post-donation support

Supporting donor families after donation has long been an important part of the donation process for Gift of Life. The Family Support Services department (FSS) was created in 1990 and was one of the first of its kind among OPOs. Currently, the department has several counselors dedicated to supporting the needs of organ and tissue donor families.

If a family chooses to authorize donation or if the deceased had the donor designation, we ask the family if they would like a donor recognition kit. If so, this package is sent within 72 hours so that the materials may be shared at the donor's funeral. The kit includes the following:

- A personalized certificate honoring the donor for their support of donation inserted in a custom made leatherette holder embossed with the Gift of Life Donor Medal
- *The Next Place* by Warren Hanson, which is a non-religious message about hope and compassion after the death of a loved one
- Donate Life/Done Vida green bracelets and a basket for display
- Donate Life lapel pins for the immediate family
- Additional Donate Life brochures and materials highlighting adding donor designation to a driver's license

Within 7 days of the donation, the Transplant Coordinator who spoke with the family sends a letter describing the gifts that were made and a general description of the transplant recipients (using de-identified information only). This letter also contains information about the services available through FSS.

Periodic follow-up

A few weeks after donation, an FSS counselor calls the legal next-of-kin to find out how they are coping and to see if they need Gift of Life to research community resources or counseling. After several attempts, if the family cannot be reached, FSS sends a letter to let them know we are hoping to contact them. Gift of Life also offers to family members eight free counseling sessions in our office in Philadelphia. The counselors in FSS follow up with the family members six months after the initial call, and hand-written notes are sent during the anniversary month.

FSS also coordinates annual Donor Family Remembrance Ceremonies. Gift of Life hosts five separate Donor Remembrance Ceremonies in Philadelphia, Harrisburg, the Scranton area, New Jersey and Delaware. Over 2,000 local organ and tissue donor families are invited to these ceremonies, which are designed to honor the donor and recognize the gifts they have given to help others. During the ceremony, every donor's name is called and their family members are invited to come to the front of the room and receive a donor medal, a flower, and a hand-knit wrap as a remembrance of their loved one.

Correspondence between donor families and recipients

Gift of Life coordinates the sharing of correspondence between donor families and the recipients of their loved ones' gifts. Information is provided to both groups about the letter-writing program and all are encouraged to begin the communication process through the OPO. Initially, only de-identified information is shared and confidentiality is maintained until the point that both donor family and recipient decide that they wish to share more personal or contact information.

Families often choose to meet after corresponding through the letter-writing program. If these circumstances present themselves, FSS will assist the families in facilitating this meeting. Often by the time recipients and donor families meet each other, they have developed a solid connection and the relationship continues to develop after the initial meeting.

II. Coordination with Law Enforcement

1. Best Practices

The outline above details best practices in coordinating organ donation with forensic investigations. In every single case, both donation and a complete forensic investigation can be conducted as has been proven true in several jurisdictions.

Philadelphia County is an excellent example of the best practices in interactions between OPOs and law enforcement. Philadelphia has a Medical Examiner who is a board-certified forensic pathologist. Gift of Life maintains regular communication with the ME's office and notifies them of each death where donation is possible. Early in the process, the ME details the information, tests, samples and other materials they will need for their investigation. Gift of Life coordinates all donation activities to conform to the requests of the ME, and as a result donation is always permitted to proceed. In the event there were to be a forensic issue warranting the presence of a pathologist, the ME or their designee would join the recovery surgeons to ensure that all evidence is collected. Immediately after organ recovery, all evidence is transported with the decedent to the ME's facility for further investigation.

The process in Philadelphia County reinforces the fact that donation does not in any way interfere with a forensic investigation. For example, organ procurement does not preclude the performance of a "complete autopsy" or interfere with the collection of trace evidence at the hospitals.⁹

⁹ J. Keith Pinckard, M.D., Ph.D., et al., Position Paper on the Medical Examiner Release of Organs and Tissues for Transplantation, National Association of Medical Examiners, Feb. 21, 2006, at 7.

2. Variation in County Practice

Unlike Philadelphia County, not all Coroners' offices have committed to ensuring donation opportunities are not lost. In those counties healthy, transplantable organs are buried against the wishes of the deceased and next-of-kin.

This variation in practice from county-to-county, coroner-to-corer, election-to-election, has no basis in forensic science or medicine. Entire states and several cities and counties have adopted processes to ensure that all forensic needs are met while permitting donation. Those jurisdictions demonstrate that a zero-denial policy is readily achievable. The National Association of Medical Examiners (NAME) just last year reaffirmed that a zero-denial policy "should be the goal of every ME/C office."¹⁰

For the past 20 years, New Jersey has had legislation requiring a Medical Examiner to attend organ recovery before limiting or denying the recovery.¹¹ This is the same requirement proposed here in Pennsylvania in Senate Bill 180. In those 20 years a Medical Examiner has never prohibited organ recovery and there has never been an instance where donation interfered with an investigation. According to NAME, the same is true nationwide—organ donation does not interfere with forensic investigations.¹² It is unconscionable that a case where donation would be allowed to proceed in one county is rejected in another because of disparate practice.

3. Effects of Coroner Declines

Based on similar experience reported in the western half of Pennsylvania, there have been approximately 55 declines since 2004 and these have increased sharply in recent years. In the first three months of 2015 there have already been 9 coroner declines. On average, 2-3 organs are transplanted from each donor while as many as 8 transplants are possible. This means that approximately 100-150 (but possibly as many as 400) people in need of a transplant were denied that opportunity because of disparate practice across counties. During this same time period more than 5,000 people died awaiting transplant in Pennsylvania.¹³

¹⁰ J. Keith Pinckard, MD, PhD, et al, NAME Position Paper: Medical Examiner Release of Organs and Tissues for Transplantation, *Academic Forensic Pathology*, V4 I4, 2014, at 7.

¹¹ N.J. STAT. ANN. § 52:17B-88.8.

¹² Pinckard, et al., at 11.

¹³ OPTN, Death Removals by Age by Year, (based on OPTN data as of May 2, 2014).