At-a-Glance

Proposal to Modify the Imminent and Eligible (I & E) Neurological Death Data Reporting Definitions

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- **Affected/Proposed Policy:** Policies 7.1.6 and 7.1.7 (Data Submission Requirements)

- **Organ Procurement Organization (OPO) Committee**

- The proposed changes clarify the data collection definitions for determining whether a death can be classified as "imminent" or "eligible." OPOs must classify a death as one of the following: Imminent Neurologic Death ("imminent"), Eligible Death ("eligible"), or neither "eligible" nor "imminent" ("neither"). The OPOs then report the "imminent" and "eligible" deaths to the OPTN. Because OPOs interpret reporting definitions differently and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

  The changes proposed by the Committee eliminate multi-system organ failure (MSOF) as an exclusionary criterion for classifying a death as "eligible" and add a list of organ-specific exclusionary criteria to give OPOs more guidance. The Committee also changed the definition of "imminent" to restrict it to those deaths that would most likely be classified as "eligible" had brain death been legally declared. This change could allow the combination of "eligible" and "imminent" deaths to mitigate the effect of the variation in brain death laws.

- **Affected Groups**
  Directors of Organ Procurement
  OPO Executive Directors
  OPO Medical Directors
  OPO Coordinators
  PR/Public Education Staff

- **Number of Potential Candidates Affected**
  There is no immediate effect on candidates or the candidate pool. The Committee anticipates that with more accurate data reporting, OPOs will be able to improve their processes and better identify donor potential.

- **Compliance with OPTN Strategic Goals and Final Rule**
  The changes support the goal to Promote the Efficient Management of the OPTN by trying to accurately capture the eligible and imminent deaths. These data will be used for better performance modeling.

- **Please Note**
  Please note that the definitions are "reporting" definitions only. They are NOT intended to be inclusive of all actual donors; therefore, they should NOT be used for screening donors or affect allocation or acceptance of organs. These criteria are not used to rule out potential organ donors and do not exclude an OPO from pursuing a donor candidate that is not classified as an Eligible Death.

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Organ Procurement Organization (OPO) Committee

Public Comment Response Period: September 21, 2012-December 14, 2012

Summary and Goals of the Proposal:

The proposed changes clarify the definitions for determining whether a death can be classified as "imminent" or "eligible." OPOs must classify a death as one of the following: Imminent Neurologic Death ("imminent,"), Eligible Death ("eligible"), or neither "eligible" nor "imminent" ("neither"). The OPOs then report the "imminent" and "eligible" (I &E) deaths to the OPTN. Because OPOs interpret reporting definitions differently and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

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Background and Significance of the Proposal:

Please note that the imminent and eligible definitions are "reporting" definitions only. They are not intended to be inclusive of all actual donors; therefore, they should not be used for screening donors or affect allocation or acceptance of organs. **These criteria are not used to rule out potential organ donors and do not exclude an OPO from pursuing a donor candidate that is not classified as an Eligible Death.**

The OPTN Contractor began collecting patient level data for all I & E deaths on January 1, 2008 in hopes that OPOs would have better performance modeling and would identify potential donors that might have otherwise been missed. The committee wrote I & E definitions and the Board approved them.

At that time, the OPO Committee sponsored two I & E training sessions to introduce the information to the community. Additionally, the AOPO Quality Council created a guidance document to help OPOs report these data accurately [Charlie Alexander, former chair of the OPO Committee provided oversight].

In spite of these efforts, OPOs have inconsistently reported these data. Because OPOs interpret reporting definitions differently (Policy 7.1), and because brain death laws vary from state to state, OPOs are inconsistent in the way they report death data.

The eligible death definition contains a list of exclusionary criteria. A frequently misinterpreted criterion relates to MSOF defined as "the failure of 3 or more organ systems." Some OPOs report an organ as a

failed system if the organ is functioning but has some history of disease or surgery. In other words, a heart which had undergone bypass surgery might be listed as a failed system, when in reality it is a functioning organ or system. Although this heart might not be considered an acceptable organ for transplant, it is not an organ in failure. The inconsistent way OPOs apply these definitions results in data that are not useful for interpretation or process improvement. Additionally, OPOs often pursue a single organ (and sometimes multipleorgans) from donors that are considered "non-eligible" based on the definitions. In 2010, there were 589 donors that resulted in at least one organ recovered for transplant that did not meet the eligible death definition, thus resulting in inaccurate I & E data.

The Committee agreed that instead of using the number of failed systems to exclude a donor, it might be best to use the concept of "the absence of any transplantable organ" or "the presence of transplantable organ(s)." As such, a donor with any functioning organ (kidney, liver, heart or lung) that may be appropriate for transplant will be potentially identified as either an imminent or an eligible donor regardless of MSOF. After much consideration, the Committee accepted the "rule in" concept as opposed to the "rule out" model and agreed that OPOs must consider factors that "rule in" donated organs.

A data review demonstrated large inconsistencies and variations in how OPOs reported data. In order to determine why OPOs had such different reporting results, the Committee leadership contacted those OPOs that were reporting no, low, or exceptionally high rates of imminent and eligible donors. They found that some OPOs were using their own definitions and not the definition found in policy, and others were interpreting the definition differently (for example, MSOF). The Committee also considered how staff turnover could affect data reporting.

Not only is there a need for OPOs to consistently apply death definitions when reporting data, the Committee agreed that it needed to take into account the differences in the death declaration process among hospitals throughout the US. These differences affect data reporting. For example, some states require two brain death exams while others only require one. For those requiring two, if there is no possibility of gaining authorization for donation, then there may not be an incentive to perform a second brain death exam. In this scenario, the OPO would not report this patient as eligible. Yet if the OPO was in a state that required only one brain death exam, it would likely report the patient as eligible. Even in states that only require one brain death exam, individual hospitals may require two exams which could lead to inconsistent data reporting.

Some of the fundamental concepts suggested by the Committee included:

- Remove the MSOF exclusion from the definition since it is inconsistently applied. In its place should be "rule out" criteria for each individual organ system. This would result in OPOs reporting a patient as imminent or eligible if they have one organ that is transplantable, as long as that person does not have any of the other exclusionary factors. This concept is simplistic and easier to apply. This would create an inclusionary type of system because if one organ passes through the list of rule out criteria, then the donor would still be included in assessment of the OPO's "conversion" rate.

- In the definitions, the current listed age range is 0 – 70 years of age. Members commented that OPOs frequently have donors over the age of 70, so the the age limit was raised to 75 yeas of age. The lower age range for children should not be considered, however, a minimum weight should replace the age. Committee members agreed that size is a more appropriate

consideration when evaluating the pediatric population and sought guidance from the Pediatric Committee. Data was also analyzed regarding the donors over 70 to determine the effectiveness of the organs procured from that age group.

- The Committee did not reach a conclusion regarding the calculation of conversion rates, but suggested a tiered approach to performance evaluation:
  - The number of eligible deaths converted to donors;
  - Different ways of analyzing imminent deaths; and
  - A total conversion rate combining imminent and eligible deaths in the denominator to help to understand the OPO's potential.

- In defining I & E deaths, it might encourage accurate data collection to focus on individual organs, (i.e. heart, lung, liver and kidney).

The Committee accepted these fundamental concepts and formed two work groups to identify organ-specific exclusionary criteria for each organ system and make recommended changes based on these concepts. One group focused on identifying exclusionary criteria for organs above the diaphragm and the other on organs below the diaphragm.

According to the current definition, to classify a death as an eligible death, brain death must be declared, the patient must be between 0 and 70 years of age, and have none of the exclusionary conditions (i.e. active infections, malignancy) listed in the policy. To help guide the discussion, the Committee reviewed data regarding age, weight and BMI of all donors over the last 3 years. The data included the number of transplant donors and donor yield as age or weight increases. The same was done for donor BMI. The proposed criteria were based on data that determined where 99% of transplant donors fall.

The Committee considered organ-specific criteria prior to distributing the proposal for public comment in September 2011. The Committee did not include organ-specific criteria in that proposal; however, following the review of comments received during public comment the Committee agreed to add organ-specific criteria. Since there were significant changes from the original proposal the Committee agreed that it should be distributed for public comment in the fall of 2012.

The Committee discussed the criterion, "No candidates on the list/exhausted the list," that appears on each organ specific list. After considering multiple alternatives, the members agreed that a death should not be reported as an imminent or eligible death when an OPO evaluates and/or recovers an organ and no one will accept it.

Prior to the release of the original proposal in September 2011, the Committee considered raising the age of the eligible donor but opted not to do so at that time. After reconsidering this following the public comment period the Committee raised the age from 70 to 75 years old or younger. The Committee used the "99th percentile rule" to determine the overall age cutoff as well as the age cutoff for the individual organ systems. This was determined by looking at the age of transplant donors over the last 4 years for all transplant donors and for each organ.

Type of donor and 99th percentile of age (last 4 years)
All Transplant Donors: 76
Kidney Transplant Donors: 70

Liver Transplant Donors: 77
Heart Transplant Donors: 58
Lung Transplant Donors: 65

Collaboration:

The Committee sought input from each of the organ-specific committees and the Pediatric Transplantation Committee during the development of the original proposal.

Alternatives considered:

- The Committee considered whether clearly defining MSOF would sufficiently encourage better data reporting. However, as they investigated the issue, they realized that the MSOF definition did not fully describe a potential donor's condition. As such, they eliminated MSOF as an exclusionary criterion and added much more detailed organ-specific information.

- The Committee considered using the number of failed systems to exclude a donor (MSOF), but opted to use the concept of "the absence of any transplantable organ" or "the presence of transplantable organ(s)." As such, a donor with any functioning organ that may be appropriate for transplant will be potentially identified as either an imminent or an eligible donor regardless of MSOF.

- After much consideration, the Committee accepted the "rule in" concept as opposed to the "rule out" model and agreed that OPOs must consider factors that "rule in" donated organs. As such, it developed a list of exclusionary conditions that was much more definitive than "organ system failure."

- The Committee considered multiple criteria that were ultimately not included in the list. Some of the criteria that were considered included renal artery stenosis, Glomerular Filtration Rate < 80, hemophilia, and Troponin > 10. The Committee spent considerable time defining "exhausting the list" and considered many factors when doing so.

- Members also considered instances when a potential donor from whom no organs can be placed should not be considered an imminent or eligible death. There are situations when a potential donor meets the requirements for the eligible definition, is consented and managed as a donor, but cannot proceed to organ recovery. This situation could be caused by
  - if no one is willing to accept the organs,
  - if the donor is taken to the OR but organs are declined, or
  - if organs are recovered but not able to be transplanted.

- The Committee originally agreed to a minimum weight of 5 kg; however, the Pediatric Transplantation Committee considered a minimum weight of 3 kg be used. After discussion and based on the data analyzed, the Committee concluded that 5 kg should be used.

Strengths

The proposal more clearly defines the imminent & eligible death definitions for reporting data. It will provide a better guideline for how to report a death as imminent or eligible for more consistent data reporting and provide valuable data for process improvement and donor potential.

Weaknesses

These changes will require education/training for individuals who are responsible for reporting these data. Also, individual data recording systems may need to be modified which may incur a cost to the member.

Intended consequences include improved accuracy and consistency in data reporting that will be beneficial for process improvement and identification of donor potential.

Unintended consequences include:

- The possibility that OPOs will consider these as "absolute donor rule out" definitions rather than just "reporting" definitions. These definitions are not intended to say an OPO cannot recover organs from this donor.

- The comparison of "conversion" rates pre- and post- policy modification will be affected as it would be expected that improved accuracy of eligible death data reporting will result in some OPOs reporting more eligible deaths. This will affect conversion rate calculations. While this is noteworthy, it is not considered a negative as the true value of these data is in benchmarking OPO vs. OPO or OPO vs. national mean for like time periods. As all data submitted post implementation would be impacted, the effectiveness of benchmarking should be improved by having data that are more consistent.

Supporting Evidence and/or Modeling:

To help guide the discussion, the Committee reviewed data regarding age, weight and Body Mass Index (BMI) of all transplant donors over the last 3 years. The data included the number of transplant donors and donor yield as age or weight increases. The same type of data for donor BMI was reviewed. The proposed criteria were based on data that determined where 99% of transplant donors fall.

The Committee reviewed data to help identify organ specific exclusionary criteria such as bilirubin, liver biopsy with % micro vesicular fat, SGOT/AST, and % glomerulosclerosis. Deceased Donor Registration data of actual transplant donors from 2008 were analyzed to guide the Committee in setting the thresholds for the criteria listed above.

To help guide the discussion of which organs would be initially deemed to meet the eligible data definition, the Committee reviewed data that analyzed the match run data for kidney, liver, heart, and lung to assess when transplanted organs are placed (offers, centers).

The goal was to define "exhausting the list." Members considered the organ specific data regarding the number of offers made for an organ to be accepted. The Committee considered identifying thresholds for the number of centers contacted or the number of patients offered an organ that might replace "exhausting the list." While these data generated much discussion, it was decided that there were so many local and regional differences in the number of transplant programs and the size of the respective waiting lists that there was no one threshold that would be appropriate for all areas.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Expected Impact on Specific Patient Populations:

There is no known direct impact on transplant candidates or recipients. Accurate data collection could result in identifying potential donors that were not previously identified. This would result in an increase in the number of organs for transplant, and together with process improvement would result in better quality of organs for transplant.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

The proposed changes meet the HHS Program Goals to Promote the Efficient Management of the OPTN. Increasing the accuracy of data reporting is a process and system improvement that supports critical network functions of data collection.

Plan for Evaluating the Proposal:

I & E data will be analyzed periodically by the OPO Committee and staff to determine if there is more consistency in data reporting.

The OPO Committee will review the I & E data every six months following implementation of the policy changes.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

The Board will consider this proposal at its June 2013 Board meeting. If approved, the proposed policy changes would be effective on September 1, 2013. Members involved in data reporting should review the policy changes and make any modifications to their own protocols or policies that relate to I & E data reporting. Any individual responsible for I & E death data reporting should attend one of the education sessions that will be offered by UNOS.

This proposal will require programming in UNet^{SM}. There will be a minor change in UNet^{SM} to the Online Help Documentation; however, no changes will be required to any of the data fields.

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Standard policy notice	OPOs	e-newsletter	30 days after board meeting
Article in UNOS Update	OPOs & transplant centers	Print magazine	Earliest issue post board approval.

Short articles in the member archive	Same	e-newsletter	Every few months after board approval & as a heads up to any upcoming training.

Compliance Monitoring:

UNOS Department of Evaluation and Quality (DEQ) staff will review death referral information reported to the OPTN during OPO onsite reviews. DEQ staff will verify that OPOs are using the definitions in policy to report death referral information to the OPTN.

Policy or Bylaw Proposal:

Proposed new language is underlined (example) and the language that is proposaed for removal is struck through (~~example~~).

The Modifications to Appendix D, Section D.9 and Appendix K, Section 1 appear below with new language underlined and deleted language marked with ~~strikethroughs~~.

7.0 DATA SUBMISSION REQUIREMENTS

7.1 REPORTING DEFINITIONS

7.1.1 – 7.1.5 [No Changes]

7.1.6 Imminent Neurological Death. The OPO must maintain documentation used to exclude any patient from the imminent neurological death data definition. Imminent Neurological Death is defined as ~~a 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. For the purposes of submitting data to the OPTN, the OPO shall apply the definition of imminent neurological death to a patient that meets the definition of imminent death at the time when the OPO certifies the final disposition of the organ donation referral~~. a death of a patient:

- who meets the eligible death definition with the exception that the patient has not been declared legally dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law; and
- who has a severe neurological injury requiring ventilator support who, upon clinical evaluation documented in the OPO record or donor hospital chart, has no spontaneous breathing and has an absence of at least two additional brain stem reflexes, is considered an imminent neurological 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~~

A patient who is unable to be assessed neurologically due to administration of sedation or hypothermia protocol does not meet the definition of an imminent neurologic death.

7.1.7 ~~Although it is recognized that~~ Eligible Death Definition. The OPO must maintain documentation used to exclude any patient from the eligible data definition. ~~t~~This definition does not include all potential donors~~,~~. ~~f~~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 the following:~~ with all of the following characteristics:

- 75 years old or younger;
- Is legally declared dead by neurologic criteria in accordance with current standards of accepted medical practice and state or local law;
- Body weight 5 kg or greater;
- Body mass index (BMI) of 50 kg/m^2 or less;
- Has at least one kidney, liver, heart, or lung that is deemed to meet the eligible data definition as defined below:
    - The kidney would be initially deemed to meet the eligible data definition unless the donor has any of the following:
        - ≥ 70 years of age
        - Age > 50-years with history of Type 1 diabetes for >20 years
        - Polycystic kidney disease
        - Terminal serum creatinine greater than 4.0 mg/dl
        - Glomerulosclerosis ≥ 30% by kidney biopsy
        - Chronic renal failure
        - No urine output ≥ 24 hours
    - The liver would be initially deemed to meet the eligible data definition unless the donor has any of the following:
        - Cirrhosis
        - Direct bilirubin/total bilirubin ≥ 15mg/dl over 24 hours with no trauma or transfusion
        - Portal hypertension
        - Macrosteatosis ≥ 60% or bridging fibrosis ≥ stage III
        - Fulminant hepatic failure
        - Terminal AST or ALT > 3000 U/L
    - The heart would be initially deemed to meet the eligible data definition unless the donor has any of the following:

- > 60 years of age
- ≥ 45 years of age with a history of ≥10 years of HTN or ≥10 years of type 1 diabetes
- History of coronary artery bypass graft (CABG)
- History of coronary stent/intervention
- Current or past medical history of myocardial infarction (MI)
- Severe vessel diagnosis as supported by cardiac catheterization (e.g. >50% occlusion or 2+ vessel disease)
- Acute myocarditis and/or endocarditis
- Heart failure due to cardiomyopathy
- Internal defibrillator or pacemaker
- Moderate to severe single valve or 2-valve disease documented by echo or cardiac catheterization, or previous valve repair
- Serial echo results showing severe global hypokinesis
- Myxoma
- Congenital defects (whether surgically corrected or not)

o The lung would be initially deemed to meet the eligible data definition unless the donor has any of the following:

- > 65 years of age
- Diagnosed COPD (e.g. emphysema)
- Terminal PaO_2/FiO_2 <250 mmHg
- Asthma (with daily prescription)
- Asthma is the cause of death
- Pulmonary fibrosis
- Previous lobectomy
- Multiple blebs documented on computed axial tomography (CAT) Scan
- Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
- Bilateral severe pulmonary contusions as per CT

If a deceased patient meets the above criteria they would be classified as an Eligible Death unless the donor meets any of the following criteria:

- The donor has no organs deemed to meet the eligible death data definition (as defined above), or;
- the donor goes to the operating room with intent to recover organs for transplant and all organs are deemed not medically suitable for transplantation, or;
- if the donor exhibits any of the following:
  - ~~o~~ Active infections (with a specific diagnoses ~~[Exclusions to the Definition of Eligible]~~
  - o Bacterial: Tuberculosis, Gangrenous bowel or perforated bowel and/or intra-abdominal sepsis, ~~See "sepsis" below under "General"~~
  - o 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 Disseminated 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
- No discernable cause of death