

OPTN/UNOS Policy Notice

Eligible Death Data Definitions

Sponsoring Committee: Organ Procurement Organization (OPO)
Policy Affected: 1.2 (Eligible Death and Imminent Neurological Death Definitions)
Public Comment: September 2012
Effective Date: January 1, 2017

Problem Statement

The OPTN/UNOS Board of Directors approved changes to the imminent and eligible death definitions during its June 2013 meeting. The OPO Committee subsequently delayed the effective date in order to allow the Centers for Medicare & Medicaid Services (CMS) time to make corresponding regulatory changes. CMS recently published CMS regulatory changes in the Federal Register that proposed replacing the current definition of eligible death at *42 CFR §486.302* with the revised OPTN definition. The final CMS language included inconsistencies between the two sets of definitions; therefore, the OPO Committee proposed several changes to the OPTN definition of eligible death to be in alignment with CMS regulations. No changes were made to the definition of imminent neurological death as approved at the June 2013 Board meeting.

Summary of Changes

- Addition of language addressing HIV positive organs to align with the CMS definition. This change should not have a significant impact on the number of eligible deaths but was necessary to align with CMS regulations.
- Addition and deletion of language to better align with the CMS definition. These are not substantive changes that impact the determination of an eligible death.
- Correction of an inadvertent change to the age threshold for heart and lung donors.

What Members Need to Do

OPO staff must review this policy change and apply these definitions when reporting imminent and eligible death data on the Death Notification Records form. OPOs should use the new definitions when reporting deaths that occur on January 1, 2017 or later. For all deaths that occur prior to January 1, 2017, OPOs should use the definitions that are in effect through December 31, 2016.

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, and should not affect allocation or acceptance of organs. These criteria are not used to exclude potential organ donors and do not prevent an OPO from pursuing a donor candidate that is not classified as an eligible death.

Affected Policy Language:

New language is underlined (example) and language that is removed is struck through (~~example~~).

1 1.2 Definitions

- 2 The definitions that follow are used to define terms specific to the OPTN Policies.

3

4 **Eligible death**

5 For reporting purposes of DSA performance assessments, an eligible death for deceased organ donation
6 is defined as the death of a patient who meets *all* the following characteristics:

7

8 • Is 75 years old or less

9 • Is legally declared dead by neurologic criteria according to ~~the current standards of accepted medical~~
10 ~~practice and state or local law~~

11 • Has body weight of 5 kg or greater

12 • Has a body mass index (BMI) of 50 kg/m² or less

13 • Has at least one kidney, liver, heart or lung that is deemed to meet the eligible data definition as
14 defined below:

15 ○ The kidney would initially meet the eligible data definition unless the donor meets *any* of the
16 following criteria:

17 • Greater than 70 years old

18 • Age 50-69 years with history of type 1 diabetes for more than 20 years

19 • Polycystic kidney disease

20 • Glomerulosclerosis greater than or equal to 20% by kidney biopsy

21 • Terminal serum creatinine greater than 4.0 mg/dL

22 • Chronic renal failure

23 • No urine output for 24 hours or longer

24 ○ The liver would initially meet the eligible data definition unless the donor meets *any* of the
25 following criteria:

26 • Cirrhosis

27 • Terminal total bilirubin greater than or equal to 4 mg/dL

28 • Portal hypertension

29 • Macrosteatosis greater than or equal to 50%

30 • ~~For~~ fibrosis greater than or equal to stage II

31 • Fulminant hepatic failure

32 • Terminal AST/ALT greater than 700 U/L

33 ○ The heart would initially meet the eligible data definition unless the donor meets *any* of the
34 following criteria:

35 • ~~Greater than 60 years old or older~~

36 • 45 years old or older with a history of 10 or more years of HTN or 10 or more years of type 1
37 diabetes

38 • History of coronary artery bypass graft (CABG)

39 • History of coronary stent/intervention

40 • Current or past medical history of myocardial infarction (MI)

41 • Severe vessel diagnosis as supported by cardiac catheterization (that is more than 50
42 percent occlusion or 2+ vessel disease)

43 • Acute myocarditis or endocarditis, or both

44 • Heart failure due to cardiomyopathy

45 • Internal defibrillator or pacemaker

46 • Moderate to severe single valve or 2-valve disease documented by echo or cardiac
47 catheterization, or previous valve repair

48 • Serial echo results showing severe global hypokinesis

49 • Myxoma

50 • Congenital defects (surgically corrected or not)

51 ○ The lung would initially meet the eligible data definition unless the donor meets *any* of the
52 following criteria:

53 • ~~Age Greater than 65 years old or older~~

54 • Diagnosed with COPD

55 • Terminal PaO₂/FiO₂ less than 250 mmHg

- 56 • Asthma (with daily prescription)
- 57 • Asthma is the cause of death
- 58 • Pulmonary fibrosis
- 59 • Previous lobectomy
- 60 • Multiple blebs documented on computed axial tomography (CAT) scan
- 61 • Pneumonia as indicated on computed tomography (CT), X-ray, bronchoscopy, or cultures
- 62 • Bilateral severe pulmonary contusions as per CT

64 If a deceased patient meets the above criteria they would be classified as an eligible death unless the
 65 donor meets *any* of the following criteria:

- 66
- 67 ~~• The donor has no suitable organ for transplant (as defined above)~~
- 68 • The donor goes to the operating room with intent to recover organs for transplant and all organs are
 69 deemed not medically suitable for transplant
- 70 • The donor exhibits *any* of the following: ~~A~~active infections (with a specific diagnosis):
 - 71 ○ Bacterial: tuberculosis, gangrenous bowel or perforated bowel or intra-abdominal sepsis
 - 72 ○ Viral: HIV infection by serologic or molecular detection, rabies, reactive hepatitis B surface
 73 antigen, retroviral infections including viral encephalitis or meningitis, active herpes simplex,
 74 varicella zoster, or cytomegalovirus viremia or pneumonia, acute epstein barr virus
 75 (mononucleosis), West Nile virus infection, or SARS. However, an HIV positive organ procured
 76 for transplantation into an HIV positive recipient at a transplant hospital that meets the
 77 requirements in Policy 15.7: Open Variance for the Recovery and Transplantation of Organs from
 78 HIV Positive Donors would still meet the requirements of an eligible death, according to the
 79 OPTN Final Rule.
 - 80 ○ Fungal: active infection with cryptococcus, aspergillus, histoplasma, coccidioides, active
 81 candidemia or invasive yeast infection
 - 82 ○ Parasites: active infection with trypanosoma cruzi (Chagas'), Leishmania, strongyloides, or
 83 malaria (*plasmodium sp.*)
 - 84 ○ Prion: Creutzfeldt-Jacob disease
- 85
- 86 ~~○ The following are Ggeneral [Eexclusions to the Definition of Eligible]:~~
- 87 ~~• a~~Aplastic anemia, agranulocytosis
- 88 • Current malignant neoplasms, except non-melanoma skin cancers such as basal cell and squamous
 89 cell cancer and primary CNS tumors without evident metastatic disease
- 90 • Previous malignant neoplasms with current evident metastatic disease
- 91 • A history of melanoma
- 92 • Hematologic malignancies: leukemia, Hodgkin's disease, lymphoma, multiple myeloma
- 93 • Active fungal, ~~or~~parasitic, viral, or bacterial meningitis or encephalitis
- 94 No discernible cause of death

95 **Imminent neurological death**

96 Imminent Neurological Death is defined as the death of a patient who meets *both* of the following criteria:

- 97
- 98 • Meets the eligible death definition with the exception that the patient has not been declared legally
 99 dead by neurologic criteria according to current standards of accepted medical practice and state or
 100 local law.
- 101 • Has a severe neurological injury requiring ventilator support who, upon clinical evaluation
 102 documented in the OPO record or donor hospital chart, has no observed spontaneous breathing and
 103 is lacking at least *two* of the additional brain stem reflexes that follow:
- 104
- 105 ○ Pupillary reaction
- 106 ○ Response to iced caloric
- 107 ○ Gag Reflex
- 108 ○ Cough Reflex
- 109 ○ Corneal Reflex

- 110 ○ Doll's eyes reflex
- 111 ○ Response to painful stimuli

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

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