

Briefing Paper

Guidance on Requested Deceased Donor Information

OPTN/UNOS Organ Procurement Organization Committee

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Guidance on Requested Deceased Donor Information

Affected Policies: N/A
Sponsoring Committee: Organ Procurement Organization Committee
Public Comment Period: January 22, 2018 – March 23, 2018
Board of Director's Date: June 11-12, 2018

Executive Summary

The OPTN/UNOS Organ Procurement Organization Committee created this guidance document to address the requested deceased donor information removed from policy as part of a recent public comment proposal. This guidance document is designed to assist members in identifying additional testing and other information needed to best evaluate potential donors.

This guidance document is intended only to provide guidance for OPOs and transplant hospitals. The scope and content should reflect collaboration between OPOs and transplant programs, taking into consideration their needs and best practices. This is *not* intended to be a comprehensive list of all information necessary to evaluate organs for all donors

What problem will this resource address?

During discussions that led to the elimination of *Policy 2.12: Requested Deceased Donor Information*, there was some concern about the information not being available as a reference. The OPO Committee agreed that while the requested information should not be included in policy, the information should be available to OPOs and transplant hospitals if needed.

Why should you support this resource?

This resource addresses the concerns raised about the elimination of the requested deceased donor information from OPTN policy. While these are not policy requirements, the work group recognized that it is important to have the information available as a resource as OPOs and transplant hospitals work together to identify additional testing and other information needed to best evaluate potential donors.

How was this resource developed?

This guidance was developed during discussions with the OPO Committee's System Optimizations Work Group ("work group"). During the development of the initial proposal, the work group determined that *Policy 2.12: Requested Deceased Donor Information* should be removed from policy since the information is not required. The work group acknowledged that deceased donor information, beyond what is required in OPTN policy, may be needed for certain donors in order for transplant hospitals to evaluate potential donor organs.

In December 2017, the Board of Directors approved changes to several sections of policy. These included:

Policy 2.2 OPO Responsibilities

- Requiring host OPOs to ensure all the deceased donor information is provided according to *Policy 2.11: Required Deceased Donor Information*.
- Removing required deceased donor information that has been moved to Policy 2.11

Policy 2.11 Required Deceased Donor Information

- Increased the list of required information for all deceased donors, including the creation of broad categories for certain donor information such as donor medical history and donor management information.
- Eliminating redundant information and information that gets captured as part of the broader categories. For example, smoking history is captured as part of the medical history as well as individual lab testing results.

Policy 2.12: Requested Deceased Donor Information.

The work group agreed to remove this section of policy since the information is not required. The work group agreed that a guidance document should be developed that will outline best practices from both a transplant hospital and OPO perspective. For example, what type of donors might require additional tests outside of a normal donor evaluation? The work group used the current language in Policy 2.12 as a starting point to develop this resource. They identified several changes, such as the kidney biopsy information, that needed to be updated. They also added a new section addressing the indications and contraindications for provided liver biopsies.

How well does this resource address the problem statement?

This resource addresses the concerns raised about the elimination of the requested deceased donor information from OPTN policy. It provides a resource to assist members in identifying additional testing and other information needed to best evaluate potential donors.

Was this proposal changed in response to public comment?

Yes, the Committee made a few minor changes to the guidance document based on public comment. This guidance document was supported by all eleven regions and four professional organizations. Three of the organizations commented that the guidance document could be strengthened by inclusion of kidney biopsy reports and the use of telepathology. The Committee reviewed the recommendations and agreed to make the additions. There were a couple of recommendations to include a reference to the guidance document in policy. The Committee did not accept this recommendation because OPTN policy does not include references to documents outside of policy. There was also a recommendation to retain the use of donor wedge biopsy, however, the Committee noted that wedge biopsy was removed to allow flexibility in the method of biopsy. The Committee understands the variability in practice when it comes to kidney and liver biopsies. The Committee noted that these are guidelines and do not supersede the need for communication between transplant centers and OPOs.

Which populations are impacted by this resource?

No known impact to transplant candidates.

How does this resource impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no impact to this goal.
2. *Improve equity in access to transplants:* There is no impact to this goal.
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* There is no impact to this goal.
4. *Promote living donor and transplant recipient safety:* There is no impact to this goal.
5. *Promote the efficient management of the OPTN:* This resource promotes the efficient management of the OPTN by providing information to members without adding additional requirements.

How will the OPTN implement this resource?

This proposal will not require programming in UNetSM.

How will members implement this resource?

This guidance does not require any member action. This document will be available as a reference on the OPTN website pending approval by the Board of Directors.

Will this resource require members to submit additional data?

This proposal does not require additional data collection.

How will members be evaluated for compliance with this resource?

Guidance from the OPTN does not carry the weight of policies or bylaws. Therefore, members will not be evaluated for compliance with this document.

Guidance Document

1 RESOLVED, that the guidance document entitled Guidance on Requested Deceased Donor
2 Information, as set forth below, is hereby approved, effective June 12, 2018.

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4 Guidance on Requested Deceased Donor Information

5 Introduction

6 The OPTN/UNOS Organ Procurement Organization created this guidance document in order to
7 provide additional information on deceased donor information and testing. This guidance
8 document is designed to assist members in identifying additional testing needed to best
9 evaluate potential donors.

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11 This guidance document is intended only to provide guidance for OPOs and transplant
12 programs. The scope and content reflects necessary collaboration between OPOs and
13 transplant programs, taking into consideration their needs and best practices. This guidance
14 document is *not* intended to be a comprehensive list of all information necessary to evaluate
15 organs for all donors.

16

17 Kidney

18 With each kidney offer, the host OPO should provide the receiving transplant program with the
19 following biopsy information for kidneys with a Kidney Donor Profile Index (KDPI) score greater
20 than 85% and donors with a significant history of hypertension, diabetes, or acute kidney injury:

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- 22 • The biopsy sample should capture a minimum of 25 glomeruli
- 23 • A frozen or fixed section slide, or the biopsy material, may accompany the kidney
- 24 • Biopsy report, when available
- 25 • Access to telepathology, when available

26

27 Pictures of the kidney and vessels are recommended if there are noted anatomical
28 abnormalities.

29

30 If machine perfusion is used, the host OPO should provide the pump parameters, such as flow
31 and resistance.

32

33 Liver

34 A transplant program may request a pre-procurement liver biopsy for any of the following
35 indications:

- 36 • Greater than 70 years of age
- 37 • Body mass index greater than 35
- 38 • Hepatitis
- 39 • History of long-standing alcohol abuse
- 40 • History of diabetes (insulin-dependent diabetes mellitus) if greater than 5 years
- 41 • Evidence of echogenic/heterogenic (fatty) changes in the liver on imaging

42

43 Relative contraindications for pre-procurement liver biopsy:

- 44 • Disseminated intravascular coagulation/coagulopathies
- 45 • Platelet count less than 80,000 per mL
- 46 • Current aspirin or blood thinner therapy
- 47 • Hemodynamic or respiratory instability
- 48 • Active hemorrhage
- 49 • Donation after cardiac death (DCD) donor

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51 Pictures of the liver biopsy slides are recommended.

52

53 Access to telepathology, when available.

54

55 CT scan/imaging is recommended if the liver is being considered for a split.

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57 **Heart**

58 With each heart offer, the host OPO should provide the following information to the receiving
59 transplant program:

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- 61 • Coronary angiography (for male donors over 40 years old or female donors over 45
62 years old)
- 63 • Central venous pressure (CVP) or stroke volume variation (SVV), and Cardiac output/
64 Cardiac index, if available
- 65 • ECG, Echocardiogram including left ventricular (LV) systolic and diastolic dimensions,
66 Septal wall thickness (diastolic), LV posterior wall thickness (diastolic) (Transesophageal
67 echocardiography if echo not available or of poor quality)
- 68 • Cardiac enzyme panel, including troponin, creatinine phosphokinase (CPK) isoenzymes,
69 and serum creatinine kinase MB (CKMB)

70

71 A transplant program may request a left and/or right heart catheterization of the deceased donor
72 where the donor's medical or social history reveals at least *one* of the following past medical
73 histories:

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- 75 • Segmental wall motion abnormality on echo
- 76 • Troponin elevation
- 77 • Significant smoking
- 78 • History of chest pain
- 79 • Abnormal electrocardiogram (ECG) consistent with ischemia or myocardial infarction
- 80 • Additional requests for a heart catheterization may be indicated by the following:
 - 81 ○ Cocaine or amphetamine use
 - 82 ○ Diabetes (Insulin-dependent diabetes mellitus)
 - 83 ○ Hyperlipidemia
 - 84 ○ Hypertension
 - 85 ○ Strong family history of coronary artery disease
 - 86 ○ Morbid obesity/High BMI (>35)

87

88 **Note:** Transplant programs may request access to view digital imaging remotely and request a
89 copy of imaging on a disk.

90

91 **Lung**

92 With each lung offer, the host OPO should provide *all* of the following information to the
93 receiving transplant program:

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- 95 • Measurement of chest circumference at the level of nipples
- 96 • Measurement by chest x-ray vertically from the apex of the chest to the apex of the
97 diaphragm and transverse at the level of the diaphragm
- 98 • Mycology sputum smear
- 99 • Non-contrast computed tomography (CT) scan of the chest in the following situations:
100 ○ Significant smoking history
101 ○ Chest trauma with suspected pulmonary contusions
102 ○ Documentation of suspected aspiration or evidence of it upon bronchoscopy
- 103 • Every attempt should be made to obtain a bronchoscopy, however, there may be certain
104 circumstances where this is not possible, such as no qualified individual or physician
105 available, lack of equipment in certain small donor hospitals, or DCD donor situations
- 106 • The transplant program may request an echo or a Swan Ganz if suspected pulmonary
107 hypertension in donor

108

109 **Note:** Transplant programs may request access to view digital imaging remotely and request a
110 copy of imaging on a disk.

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112 **Pancreas**

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114 With each pancreas offer, the host OPO should provide images of organ if requested.

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