

Public Comment Proposal

Establish Minimum Kidney Donor Criteria to Require Biopsy

OPTN Kidney Transplantation Committee

Prepared by: Kayla Temple

UNOS Policy and Community Relations Department

Contents

Executive Summary	2
Background	3
Purpose	4
Overview of Proposal	5
NOTA and Final Rule Analysis	11
Post-implementation Monitoring	13
Conclusion	13
Policy Language	15

Establish Minimum Kidney Donor Criteria to Require Biopsy

Affected Policies: 2.11.A: Required Information for Deceased Kidney Donors
Sponsoring Committee: Kidney Transplantation
Public Comment Period: January 27, 2022 – March 23, 2022

Executive Summary

A renal procurement biopsy is a diagnostic examination of tissue sample taken from a deceased donor kidney during procurement. An Organ Procurement Organization (OPO) performs procurement biopsies to identify chronic or acute organ damage and estimate potential risk to graft function.¹ Procurement biopsies are increasingly prevalent, with biopsies performed on more than half of all deceased donor kidneys recovered for transplant.² Despite this prevalence, there is considerable variation in biopsy practice, with rate of biopsy amongst OPOs ranging from 22.8 percent of deceased donor kidneys to 77.5 percent, adjusting for donor factors.³

The OPTN Policy Oversight Committee’s Biopsy Standards and Practices Workgroup identified the absence of an established minimum set of donor criteria appropriate to initiate kidney biopsy as “the most significant contributing factor negatively affecting allocation efficiency in the realm of biopsy standards.”⁴ Establishing a standard set of criteria will streamline OPO and transplant program communication and prevent unnecessary biopsies, thus increasing the efficiency of offer acceptance, reducing cold ischemic time, and possibly reducing organ discards.⁵ The Committee believes that standardization of practices will encourage appropriate transplant program offer acceptance practices for individual potential transplant recipients (PTRs) by reducing inconsistency and improving efficiency.⁶

This proposal aims to standardize biopsy practice by establishing a set of minimum donor criteria for when an OPO must perform procurement kidney biopsies. For those deceased donors meeting the criteria, that biopsy information will be critical to both organ evaluation and appropriate offer acceptance practices for individual PTRs.

This proposal defines clinical donor criteria in instances when OPOs are required to perform procurement kidney biopsy. This proposal does not limit the OPO to only performing biopsies on those donors that meet the proposed criteria. This proposal was developed in conjunction with the *Standardize Kidney Biopsy Reporting and Data Collection* proposal.

¹ Lentine et al. “Procurement Biopsies in Kidney Transplantation: More Information May Not Lead to Better Decisions,” *Journal of the American Society of Nephrology*, 32 (2021): 1835-1837

² Carpenter et al. “Procurement Biopsies in the Evaluation of Deceased Donor Kidneys,” *Clinical Journal of the American Society of Nephrology*, 13 (2018): 1876-1885.

³ Lentine et al. “Variation in Use of Procurement Biopsies and Its Implications for Discard of Deceased Donor Kidneys Recovered for Transplantation,” *American Journal of Transplantation*, 19 (2019): 2241-2251.

⁴ OPTN Policy Oversight Committee Project Recommendations Memo: Local Recovery and Biopsy Standards & Practices Workgroups. September 9, 2020.

⁵ OPTN Policy Oversight Committee Biopsy Standards Workgroup Meeting Summary. July 22, 2020.

https://optn.transplant.hrsa.gov/media/3934/20200722_poc_biopsywg_summary.pdf

⁶ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

Background

Currently, OPTN policy does not dictate when a renal procurement biopsy must be performed, nor does it describe what parameters or types of biopsy information should be reported. However the 2018 OPTN *Guidance on Requested Deceased Donor Information* recommends the recovering OPO perform a kidney biopsy for donors with “a Kidney Donor Profile Index (KDPI) score greater than 85 percent or with a significant history of hypertension, diabetes, or acute kidney injury.”⁷ Though not binding, this document was intended to provide guidance on the decision to biopsy in order to help standardize and improve transplant decision-making.

More than 50 percent of all deceased donor kidneys are biopsied upon procurement, though recent literature has shown that the quality and reliability of procurement biases varies considerably.^{8,9} With biopsies reported as the main reason for non-utilization for 37 percent of non-transplanted deceased donor kidneys, many point to procurement biopsies as a possible driver of the nearly 20 percent rate of non-utilization of kidneys in the United States.^{10,11} Many others believe these procurement biopsies provide information critical to understanding organ quality and appropriate placement of the organ.¹² Additionally, the available literature faces a number of limitations, including selection bias, limited data, and lack of consistency and standardization in histological assessment.^{13,14} In particular, it can be difficult to point to biopsy results as the main cause of non-utilization, as many donors from whom biopsies are requested have a number of risk factors that could lead to increased odds of offer decline.¹⁵ However, wide variation in biopsy practices, the absence of accessible, large-scale biopsy data, and resulting limitations to the literature have led to calls for increased standardization. The *2018 Consensus Conference to Decrease Kidney Discards* report from the National Kidney Foundation recommended increased standardization of deceased donor biopsies.¹⁶

In 2020, the OPTN Policy Oversight Committee established the Biopsy Standards and Practices Workgroup to evaluate biopsy practices, their use and efficiency in the current system, and the potential need for rules or guidance regarding biopsy practices.¹⁷ The Policy Oversight Committee’s Biopsy Standards and Practices Workgroup identified ongoing inconsistencies in biopsy practices and the quality of biopsy analysis as a major hurdle to greater allocation efficiency. Specifically, the absence of an established minimum set of donor kidney criteria to initiate kidney biopsy was found to be “the most significant contributing factor negatively affecting allocation efficiency in the realm of biopsy

⁷ OPTN Organ Procurement Organization Committee: *Guidance on Requested Deceased Donor Information*, (2018). https://optn.transplant.hrsa.gov/media/2504/opp_guidance_201806.pdf

⁸ Carpenter et al. “Procurement Biopsies in the Evaluation of Deceased Donor Kidneys,” (2018): 1876-1885.

⁹ Lentine et al. “Variation in Use of Procurement Biopsies” (2019): 2241-2251

¹⁰ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, May 24, 2021.

https://optn.transplant.hrsa.gov/media/4685/20210524_kidney_biopsy_best_practices_wg_summary.pdf

¹¹ Kasiske et al. “The Role of Procurement Biopsies in Acceptance Decisions for Kidneys Retried for Transplant,” *Clinician Journal of the American Society of Nephrology*, 9 (2014): 562-571.

¹² Angeletti et al. “Making Procurement Biopsies Important Again for Kidney Transplant Allocation,” *Nephron*, 142 (2019):

<https://www.karger.com/Article/Pdf/499452>

¹³ Lentine et al. “Procurement Biopsies in Kidney Transplantation: More Information May Not Lead to Better Decisions,” *Journal of the American Society of Nephrology*, 32 (2021): <https://jasn.asnjournals.org/content/32/8/1835>

¹⁴ Wang et al. “The Donor Kidney Biopsy and Its Implications in Predicting Graft Outcomes: A Systematic Review,” *American Journal of Transplantation*, 15 (2015): 1903-1914.

¹⁵ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, May 24, 2021.

¹⁶ National Kidney Foundation, “Report of the National Foundation Consensus Conference to Decrease Kidney Discards,” (2018).

<https://www.kidney.org/news/report-national-kidney-foundation-consensus-conference-to-decrease-kidney-discards>

¹⁷ OPTN Policy Oversight Committee Meeting Summary, June 3, 2020.

https://optn.transplant.hrsa.gov/media/3871/20200603_poc_biopsywg_summary_final.pdf

practices.”¹⁸ Currently, there is significant variation in biopsy practices, including when and often biopsies are performed. Lentine et al. found biopsy rates to be as low as 22.8 percent of deceased donor kidneys for some OPOs and as high as 77.5 percent for others, adjusted for KDPI and other donor factors that typically drive the decision to biopsy. In other words, this variation in biopsy rates across OPOs cannot be explained by differences in donor characteristics.¹⁹

The OPTN Policy Oversight Committee asked the Kidney Transplantation Committee, hereafter “the Committee” to develop a minimum set of donor criteria appropriate for biopsy. The rationale for the directive was to establish a standard set of criteria that could prevent unnecessary biopsies and analysis, thus increasing the efficiency of offer acceptance, reducing cold ischemic time, and possibly reducing organ discards.²⁰ This proposal was developed in conjunction with the *Standardize Kidney Biopsy Reporting and Data Collection* proposal, which aims to improve inconsistencies in report comprehensiveness and in analysis across OPOs.

The Biopsy Best Practices Workgroup (the Workgroup) was formed with multi-disciplinary subject matter experts and representation from the following OPTN committees and a subject matter expert in renal pathology:

- Kidney Transplantation
- Organ Procurement Organization
- Liver and Intestinal Organ Transplantation
- Data Advisory

Purpose

The purpose of this proposal is to standardize biopsy practice by establishing clear donor criteria in situations where an OPO must perform a procurement kidney biopsy. This proposal standardizes procurement biopsy and establishes requirements for procurement biopsy in situations where that information will be critical to kidney transplant programs, for both offer evaluation and appropriate program offer acceptance practices for individual PTRs. Standardization of biopsy practice will reduce variability among OPOs, streamline communication between transplant hospitals and OPOs, and could prevent unnecessary biopsies and analysis, and therefore improve allocation efficiency. Improving efficiency of offer acceptance will potentially reduce cold ischemic time and potentially reduce organ discards. The Committee presents this proposal under the principle that evaluating kidney transplant programs should utilize biopsy information to help determine whether a potential transplant recipient will receive the most benefit, as opposed to utilizing biopsy information to rule out kidneys for transplantation. This proposal does not limit the OPO to only performing biopsy on those donors that meet the proposed criteria. This proposal was developed and released in conjunction with the *Standardize Kidney Biopsy Reporting and Data Collection* proposal, which aims to standardize the biopsy information report, reporting, and improve biopsy data collection, to improve inconsistencies in report comprehensiveness and in analysis across OPOs.

¹⁸ OPTN Policy Oversight Committee Project Recommendations Memo: Local Recovery and Biopsy Standards & Practices Workgroups. September 9, 2020.

¹⁹ Lentine et al. “Variation in Use of Procurement Biopsies” (2019): 2241-2251

²⁰ OPTN Policy Oversight Committee Biopsy Standards Workgroup Meeting Summary. July 22, 2020.

Overview of Proposal

The OPTN Kidney Committee proposes establishing a minimum set of medical donor criteria to require kidney biopsy. The criteria were developed by kidney offer-evaluating surgeons and physicians and OPO representatives responsible for allocation and donor management. These criteria will establish a set of requirements for when OPOs must perform renal procurement biopsy, but will not limit OPOs from performing procurement kidney biopsies on deceased donors that do not meet these criteria.

Donor Criteria to Require Biopsy

The Committee proposes to require the recovering OPO ensure that a procurement kidney biopsy is performed for all donors meeting any of the following criteria, excluding donors less than 18 years old:

- Anuria, or a urine output of less than 100ml in 24 hours
- Donor has received hemodialysis or other renal replacement therapy during most recent hospital admission, or in the course of donor management
- History of diabetes, including hemoglobin A1c (HbA1c) of 6.5 or greater during donor evaluation and management
- KDPI greater than 85 percent
- Donor age 60 years or older
- Donor age 50-59, and meets at least two of the following criteria:
 - History of hypertension
 - Manner of death: Cerebrovascular Accident (CVA)
 - Terminal creatinine greater than or equal to 1.5 mg/dL

These criteria include potential donor risk factors for both acute and chronic damage as described in the subsections below.

Anuria and Renal Replacement Therapy

The Committee proposes the anuria and donor receipt of renal replacement therapy criteria as potential indicators of acute renal failure, also known as acute kidney injury (AKI), and resulting acute damage.^{21,22} Anuria is clinically defined as a urine output of less than 100ml in a 24 hour period in adults, and can indicate AKI and other critical kidney injuries.^{23,24,25} Dialysis or short-term renal replacement therapy is often utilized to manage renal function and encourage recovery.²⁶

Allocation of kidneys from AKI donors particularly benefit from biopsy reporting. Stewart et al.'s mock offer study found that AKI donor offers saw a nearly fourfold increase in odds of acceptance when good biopsy findings were presented, compared to AKI donor offers with no biopsy results presented. This study also found that, for AKI donors, reporting biopsy results influenced a "ruling in" behavior, as

²¹ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

²² OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

²³ Min Choi et al. "Etiology and Outcomes of Anuria in Acute Kidney Injury: A Single Center Study" *Kidney Research and Clinical Practice*, 34 (2015): 13-9

²⁴ Peng et al. "Recovery of Renal Function in a Heart Transplantation Recipient with Over 300 Days of Iatrogenic Anuria," *Medicine*, 97 (2018) <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5944477/>

²⁵ Ivan Damjanov MD, PhD in Pathology Secrets (Third Edition) 2009, chapter 15 pg 301-328

²⁶ Goyal et al. "Acute Kidney Injury," StatPearls, 2021. <https://www.ncbi.nlm.nih.gov/books/NBK441896/>.

opposed to a “ruling out” behavior.²⁷ The Workgroup determined that biopsies can help determine degree of kidney damage and reversibility, which can help inform whether a potential transplant recipient will receive the most benefit.²⁸ Biopsy can also be utilized to differentiate acute renal damage and chronic kidney disease damage.²⁹

Creatinine thresholds were also considered throughout the development of the criteria, particularly in the context of AKI. After significant discussion on creatinine trends and indications of AKI, the Workgroup concluded that defining creatinine thresholds for acute renal failure would be beyond the scope of the project, and that creatinine thresholds without trend or context may not be an appropriate measure of AKI.³⁰

Diabetes

The Workgroup decided to include diabetes as a criterion after review of the OPTN’s *Guidance on Request Deceased Donor Information*, pointing to diabetes as a cause and potential indicator of chronic renal damage.³¹ The Workgroup determined that diabetes diagnosis timelines are inappropriate measures of duration, as onset of diabetes can predate diagnosis by years. The Workgroup also recognized that diabetes can often go undiagnosed.³² The National Kidney Foundation estimates that 8.1 million people have undiagnosed diabetes.³³ In keeping with this consideration, the Workgroup determined that an elevated HbA1c in the absence of medical history of diabetes is similarly appropriate as an indicator of risk to potential kidney graft function.³⁴ Diabetes is the most common cause of kidney failure, and in combination with high blood pressure, can lead to the development of chronic kidney disease (CKD).³⁵ Diabetes itself is also a risk factor for acute kidney injury, which increases the risk of and can lead to chronic kidney disease and chronic damage.³⁶

High KDPI and Expanded Criteria

The Workgroup consulted the literature extensively throughout the development of these criteria, including a mock offer study by Stewart et al. and a large sample analysis study by Lentine et al.³⁷ Stewart et al. point to a “ruling out” behavior related to biopsy findings for non-AKI, low serum creatinine donors.³⁸ These donors saw a threefold increase in odds of acceptance when offers were presented with no biopsy results reported, as opposed to poor biopsy results.³⁹ The odds of acceptance did not increase significantly for these donors when a good biopsy result was reported as opposed to no

²⁷ Stewart et al. “Can Behavioral Research Improve Transplant Decision-Making? A Mock Offer Study on the Role of Kidney Procurement Biopsies,” *Kidney360*, 1 (2020): 36-47

²⁸ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

²⁹ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

³⁰ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

³¹ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

³² OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

³³ National Kidney Foundation, “Diabetes and Chronic Kidney Disease,” Newsroom, 2016.

<https://www.kidney.org/news/newsroom/factsheets/Diabetes-And-CKD>

³⁴ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

³⁵ National Kidney Foundation, “Diabetes and Chronic Kidney Disease,” 2016.

³⁶ Mon-Wei Yu et al. “Acute Kidney Injury and Progression of Diabetic Kidney Disease,” *Advanced Chronic Kidney Disease*, 25 (2018):

<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5898826/>

³⁷ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, September 14, 2021.

https://optn.transplant.hrsa.gov/media/xyab1tww/20210914_kidney_biopsy_best_practices_wg_summary.pdf

³⁸ Stewart et al. “Can Behavioral Research Improve Transplant Decision-Making?” (2020): 36-47.

³⁹ Ibid

biopsy.⁴⁰ Lentine et al. found that, after adjusting for OPO and donor factors, biopsy was associated with more than three times the likelihood of discard, an association that was most pronounced for low KDPI kidneys (less than 20 percent).⁴¹ There was minimal impact of biopsy on odds of acceptance for high KDPI kidneys.⁴² Similarly, the median odds ratio that an identical graft would be discarded decreased when a biopsy was performed for kidneys KDPI greater than 85, from 1.98 without biopsy to 1.74 with biopsy.⁴³

After discussion and consideration of the literature, the Committee opted to include KDPI greater than 85 percent in the proposed criteria. The KDPI calculation incorporates several risk factors, and higher KDPI kidneys have greater risk to potential graft function.⁴⁴ Per OPTN data, 93.23 percent of deceased kidney donors recovered in 2019 with a KDPI of 86 or greater were biopsied.⁴⁵

The Workgroup also considered the inclusion of Expanded Criteria, defined as donors age 60 or older and donors aged 50 to 59 who meet at least two of the following risk factors: history of hypertension, cerebrovascular accident as cause of death, and terminal creatinine of 1.5 or greater. In discussing expanded criteria donors, the Workgroup determined that the ECD definition appropriately captures specific risk factors in donors who have KDPI less than 85 percent.⁴⁶ The Workgroup also concluded that ECD is inclusive of high terminal creatinine and hypertension, considering these factor amongst others to capture indication of potential damage without requiring biopsy for donors who have a single indicator but otherwise pose little risk of poor kidney function or chronic damage.^{47,48}

Proposed Criteria Development and Considerations

The Workgroup reviewed data on the demographics of deceased kidney donors for whom at least one kidney was biopsied upon procurement. **Figure 1** shows the biopsy status of deceased kidney donors recovered in 2019 by KDPI, age, history of diabetes, and ECD status. This data helped to inform the Workgroup on the kinds of donors for whom renal biopsies are typically done. In particular, biopsy rates increased as KDPI and donor age increased. Similarly, diabetic donors and donors meeting the ECD definition also had higher rates of biopsy. These patterns reveal current standards in the characteristics and types of kidney donors biopsied.

⁴⁰ Ibid

⁴¹ Lentine et al. "Variation in Use of Procurement Biopsies" (2019): 2241-2251

⁴² Ibid

⁴³ Ibid

⁴⁴ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

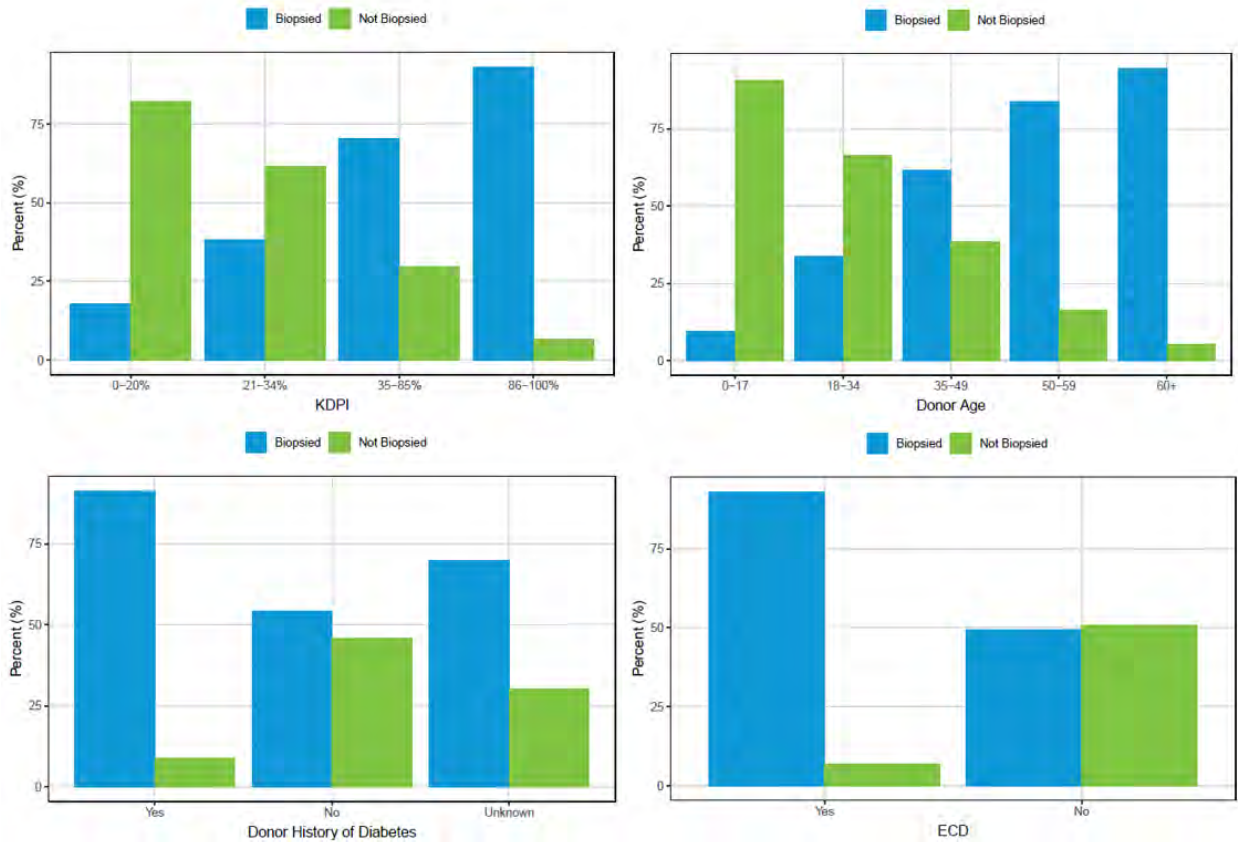
⁴⁵ See **Figure 1**

⁴⁶ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

⁴⁷ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

⁴⁸ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

Figure 1: Deceased Kidney Donors Recovered in 2019 by Biopsy and KDPI, Age, History of Diabetes, and ECD Status



In addition to literature review and clinical judgement, the minimum biopsy standards were developed based on the data shown in **Figures 1 and 2**. **Figure 2** shows the percentage of deceased kidney donors recovered in 2019 by biopsy status and whether they meet the proposed criteria, excluding anuria and renal replacement therapy.⁴⁹ The Workgroup reviewed this data to understand how many deceased kidney donors recovered in 2019 would have been biopsied under the proposed criteria, including how standardization aligns with current practices and potential impacts to the rate of biopsies performed.

⁴⁹ These elements were unable to be captured within the OPTN data

Figure 2: Deceased Kidney Donors Recovered in 2019 by Biopsy Status and Proposed Minimum Donor Criteria to Require Biopsy

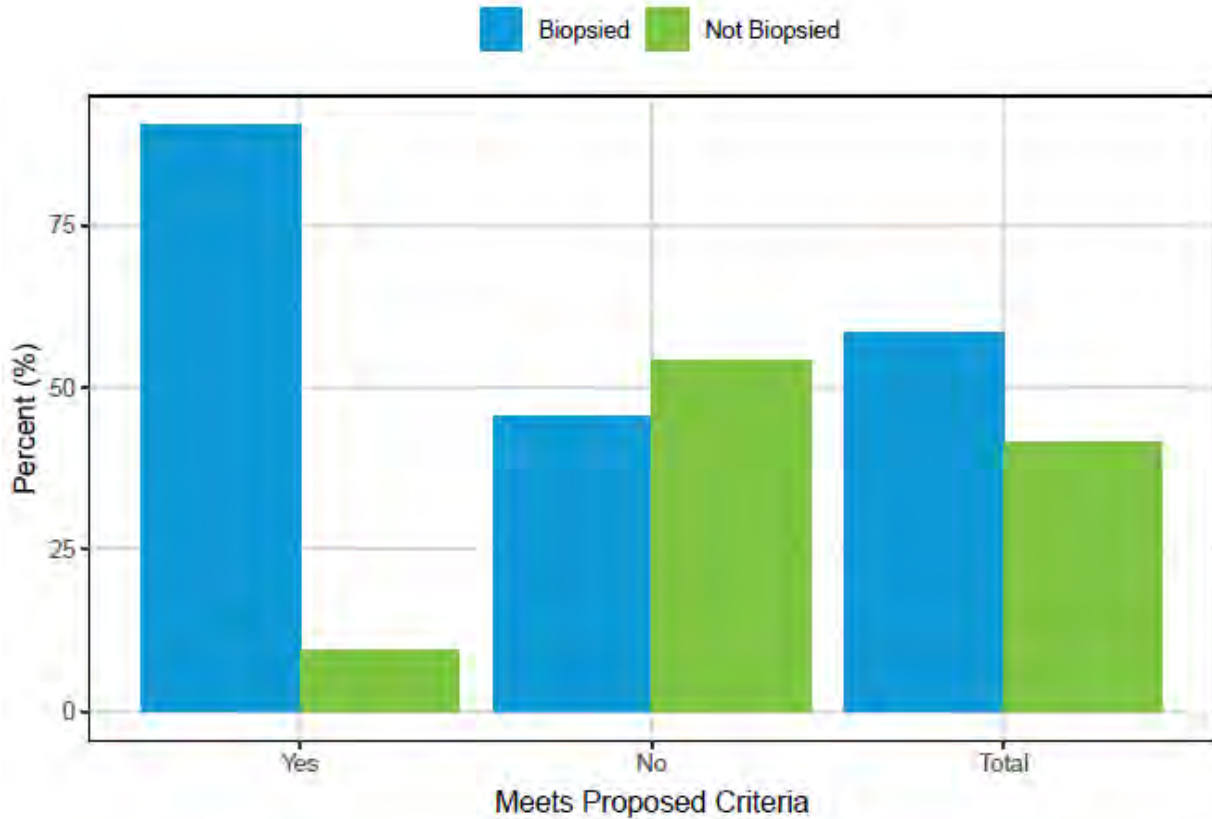


Table 1 shows the number of deceased kidney donors recovered in 2019 by biopsy status and whether they meet the proposed minimum donor criteria to require biopsy, excluding anuria and renal replacement therapy.

Table 1: Deceased Kidney Donors Recovered in 2019 by Biopsy Status and Proposed Minimum Donor Criteria to Require Biopsy

Meets Criteria	Biopsied		Not Biopsied		Total	
	N	%	N	%	N	%
Yes	2868	90.44	303	9.56	3171	100.00
No	3648	45.71	4332	54.29	7980	100.00
Total	6516	58.43	4635	41.57	11151	100.00

Per **Table 1**, procurement kidney biopsies were performed on 58.43 percent of deceased kidney donors recovered in 2019. Less than half of the procurement kidney biopsies performed in 2019 would have been considered required under the proposed minimum biopsy standards criteria. Based on this data, about 28 percent of deceased kidney donors recovered in 2019 would meet at least one of the proposed criterion. More than 90 percent of 2019 deceased kidney donors who meet the proposed criteria were biopsied.

Several Workgroup members expressed concern about excluding certain donor factors from the proposed minimum biopsy standards criteria, including nephrotic range proteinuria and history of hypertension as standalone criteria. It is important to note that these criteria do not represent the only deceased donors for whom kidney biopsy is appropriate, simply the minimum donors for whom kidney biopsy is appropriate and should be required. The Committee believes that this criteria should and does represent the true minimum of donors for whom biopsy information can be critical to appropriate placement and efficient allocation. Based on the OPTN data shown in **Figure 2**, this criteria encompasses a kidney donor pool for whom procurement biopsies are routine, but still accounts for less than half of the deceased kidney donors who are biopsied. Furthermore, **Figure 1** demonstrates high rates of biopsy for high KDPI, older, diabetic, and expanded criteria (ECD) donors. The proposed criteria contain both acute renal failure and chronic kidney damage indicators for deceased donors. Biopsy information can provide information on such potential damage, such as degree of scarring, which cannot be provided via other methods.⁵⁰ This information is critical to a holistic understanding of potential graft function, which can help determine whether a potential transplant recipient will receive the most benefit from an organ.⁵¹

The Workgroup determined that the high KDPI criterion should not include pediatric donors, as KDPI is not necessarily reflective of the risk of chronic damage or damage to kidney function for pediatric donors, particularly with small donor size and smaller renal mass contributing to higher KDPI.^{52, 53} After further discussion, the Committee decided that these criteria do not appropriately indicate risk for pediatric donors and could potentially lead to unnecessary biopsy.⁵⁴ The Committee opted to exclude all donors less than 18 years old, noting that biopsy is also rarely routine for pediatric donors.⁵⁵

Furthermore, in considering the factors proposed by the OPTN *Guidance on Required Deceased Donor Information*, the Workgroup determined that hypertension alone is not a sufficiently strong indicator of chronic damage.⁵⁶ Controlled, medication-managed hypertension may not pose significant risk to kidney function, though hypertension in consideration with other risk factors may warrant a biopsy.⁵⁷ The Workgroup similarly determined that donation after circulatory death (DCD) alone is not a sufficiently strong indicator of potential damage, as age, warm ischemic time, post-flush imaging, and other factors should be considered in evaluating potential risks to kidney function.⁵⁸ Furthermore, DCD status is already captured in the KDPI calculation.⁵⁹

Through the course of this policy's development, the Workgroup determined that biopsies should be considered as only one piece of critical information in a holistic review of an organ offer, and that

⁵⁰ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, August 23, 2021.

https://optn.transplant.hrsa.gov/media/mggiarti/20210823_kidney_biopsy_best_practices_-wg_summary.pdf

⁵¹ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, August 23, 2021.

⁵² OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

⁵³ OPTN Guide to Calculating and Interpreting the Kidney Donor Profile Index, March 2020.

https://optn.transplant.hrsa.gov/media/1512/guide_to_calculating_interpreting_kdipi.pdf

⁵⁴ OPTN Kidney Committee Meeting Summary, November 15, 2021. https://optn.transplant.hrsa.gov/media/51kpjimp2/20211115_kidney-committee_-meeting-summary.pdf

⁵⁵ *Ibid.*

⁵⁶ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

⁵⁷ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, September 27, 2021.

https://optn.transplant.hrsa.gov/media/flacwd3t/20210927_kidney_biopsy_best_practices_-wg_summary.pdf

⁵⁸ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

⁵⁹ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

https://optn.transplant.hrsa.gov/media/4483/20210222_kidndv_biopsy_best_practices_-meeting_summary.pdf

procurement biopsies should be used to help determine whether a patient will receive the most benefit from the organ, not to unilaterally determine whether to decline an organ offer.⁶⁰ The Committee believes that standardization of practices will reduce inconsistency and improve efficiency.⁶¹

The Committee believes that establishing criteria to require biopsy will standardize procurement kidney biopsy practices, and therefore could prevent unnecessary biopsies and encourage reporting of pathology information for those organs that can benefit from increased information in allocation. This will streamline communication between OPOs and transplant centers by reducing the need for deliberation as to whether a biopsy should be performed for those donors meeting criteria.⁶² This will allow OPOs to more easily consolidate and focus pathology and coordinator resources towards the performance of necessary biopsies. The Committee predicts that this will also increase the efficiency of offer acceptance, thereby reducing cold ischemic time and organ discards.⁶³

NOTA and Final Rule Analysis

The OPTN Kidney Committee submits this project for consideration under the authority of NOTA 42 USC 247(b)(2)(E), which notes that the OPTN shall “adopt and use standards of quality for the acquisition and transportation of donated organs,” as well as the authority of the OPTN Final Rule §121.6(a), which states that “laboratory tests and clinical examinations of potential organ donors are performed to determine any contraindications for donor acceptance, in accordance with policies established by the OPTN.” This project establishes standards of quality for the acquisition of donated organs by requiring biopsy performance for donor kidneys meeting a set of medical criteria, for which biopsy data will be critical to organ and offer evaluation. This project aims to standardize and require biopsy performance for donor kidneys for which that information will be critical for both offer evaluation and appropriate acceptance practices for individual potential transplant recipients.

Member and OPTN Operations

Operations affecting Organ Procurement Organizations

This proposal will require OPOs to perform renal procurement biopsies for deceased kidney donors meeting the proposed criteria. OPOs will need to work to ensure pathology staff or services are available to perform the biopsy reading and appropriately report biopsy information to the OPTN.

Operations affecting Transplant Hospitals

Transplant programs will need to be aware of the new requirements for when deceased kidney donors must have procurement biopsies performed.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

⁶⁰ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, January 25, 2021.

⁶¹ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

⁶² OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, September 27, 2021.

⁶³ OPTN Policy Oversight Committee Project Recommendations Memo: Local Recovery and Biopsy Standards & Practices Workgroups. September 9, 2020.

Operations affecting the OPTN

This proposal will not require information technology implementation. This proposal is released by the Kidney Committee alongside a sister proposal, *Standardize Kidney Biopsy Reporting and Data Collection*, which would require UNet programming and aims to standardize the biopsy information reported, how that information is reported, and improve biopsy data collection, to reduce inconsistencies in report comprehensiveness and in analysis across OPOs.

Potential Impact on Select Patient Populations

This proposal is not expected to have impact to any specific patient populations. Impacts from improvements in allocation efficiency, streamlined communication, and potentially reduced cold ischemia times are expected to affect patient populations in equal measure.

Projected Fiscal Impact

Projected Impact on Organ Procurement Organizations

OPOs will need to utilize defined biopsy criteria and coordinate with pathology services appropriately to ensure sufficient access.

This will affect current work flow by standardizing currently variable biopsy practices across the industry and may affect the recipient surgeon's 'comfort' in accepting kidney offers for which the normal practice is routine biopsy.

There will be no additional ongoing staff costs, additional hours, or increased pay for OPO, that isn't recoverable on their CMS cost report. This proposal could result in improved efficiency by focusing pathology resources on required renal procurement biopsies, which was estimated to be approximately 28 percent of deceased kidney donors meeting the proposed criteria, compared to the current 50 percent of deceased kidney donors biopsied. This data analysis was completed using a look-back to determine the number of donors that would be biopsied based on the proposed criteria. Changing donor demographics or changing criteria could affect the estimate of the annual percentage of biopsies performed.

This proposal may help generate a system in which more kidneys are transplanted due to removing potential bias from biopsy results that may or may not determine graft success or failure.

Projected Impact on Transplant Hospitals

This proposal requires transplant hospitals to provide training and education to staff in understanding which donors qualify for required biopsy performance, so that biopsy results may be expected and evaluated. This proposal is expected to take less than a month for a transplant hospital to implement.

Projected Impact on the OPTN

Preliminary estimates indicate that this will be a medium effort, and more than 400 hours may be needed for communication, educational efforts, and post-implementation monitoring.

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility laboratories.

Post-implementation Monitoring

Member Compliance

This proposal will not change current routine monitoring of OPTN members. The OPTN may review any data entered in UNetSM, and members must provide documentation as requested.

Policy Evaluation

The policy will be monitored 6, 12, and 24 months post-implementation. The following metrics, and any subsequently requested by the committee, will be evaluated as data become available. Appropriate lags will be applied, per typical UNOS conventions, to account for time delay in institutions reporting data to UNetSM and compared to an appropriate pre-policy cohort to assess performance before and after implementation of this policy.

- Counts, percents, utilization and discard rates for deceased kidney donors overall and by:
 - Minimum criteria for biopsy
 - Biopsy status
 - KDPI
 - Donor age
 - Recovering OPO

Conclusion

This proposal addresses one aspect of the Policy Oversight Committee's priority to improve standardization of procurement kidney biopsies by standardizing biopsy practice. The Kidney Committee proposes minimum clinical deceased donor criteria for when OPOs are required to perform procurement kidney biopsies. This proposal does not limit the OPO from performing renal procurement biopsy on those donors that do not meet the proposed criteria.

The Committee proposes these policy changes to standardize kidney biopsy practice for deceased donor kidneys for which that information would be critical to both organ evaluation and appropriate recipient placement. The proposed standardization will reduce variability in biopsy practices, streamline communication between transplant centers and OPOs, and prevent unnecessary biopsies and analysis, thus increasing the efficiency of offer acceptance, reducing cold ischemic time, and possibly reducing organ discards.^{64,65} Reducing inconsistency and improving efficiency will also encourage the use of biopsies in holistic review of an organ offer to determine whether a patient will receive the most benefit.⁶⁶

The Committee encourages all interested individuals to comment on this proposal in its entirety, but specifically asks for feedback on the following:

1. Are these criteria globally agreeable? Are there any criteria that should be removed or added?

⁶⁴ OPTN Policy Oversight Committee Biopsy Standards Workgroup Meeting Summary. July 22, 2020.

⁶⁵ OPTN Policy Oversight Committee Project Recommendations Memo: Local Recovery and Biopsy Standards & Practices Workgroups. September 9, 2020.

⁶⁶ OPTN Kidney Committee Biopsy Best Practices Workgroup Meeting Summary, February 22, 2021.

2. Are the timeframes and thresholds specified for anuria and renal replacement therapy suitable and reasonable?
3. Will there be unintended consequences or impacts for OPOs? For transplant centers?

Policy Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

1 2.11.A Required Information for Deceased Kidney Donors

2 The host OPO must provide *all* the following additional information for all deceased donor
3 kidney offers:

- 4
- 5 1. Anatomical description, including number of blood vessels, ureters, and approximate length
6 of each
- 7 2. Biopsy results, if performed. Biopsy must be performed for kidney donors meeting the
8 criteria below, excluding donors less than 18 years old.
- 9 3. Human leukocyte antigen (HLA) information as follows: A, B, Bw4, Bw6, C, DR, DR51, DR52,
10 DR53, DQA1, DQB1, and DPB1 antigens prior to organ offers
- 11 4. Injuries to or abnormalities of blood vessels, ureters, or kidney
- 12 5. Kidney perfusion information, if performed
- 13 6. Kidney laterality

14
15 The host OPO must perform a biopsy on deceased donor kidneys from donors that meet *at least*
16 *one* of the following criteria, excluding donors less than 18 years old:

- 17 • Anuria, or a urine output of less than 100ml in 24 hours
 - 18 • Donor has received hemodialysis or other renal replacement therapy during current
19 hospital admission or in the course of donor management
 - 20 • History of diabetes, or HbA1C of 6.5 or greater during donor evaluation or management
 - 21 • KDPI greater than 85% at time of original match run, excluding donors less than 18 years
22 old.
 - 23 • Donor age 60 years or older
 - 24 • Donor age 50-59 years, and meets at least *two* of the following criteria:
 - 25 ○ History of hypertension
 - 26 ○ Manner of death: Cerebrovascular Accident (CVA)
 - 27 ○ Terminal serum creatinine greater than or equal to 1.5 mg/dl
- 28