

Standardize Kidney Biopsy Reporting and Data Collection

*OPTN Kidney Transplantation Committee
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Background

- In 2020, the Policy Oversight Committee determined that kidney biopsy practice inconsistencies and quality of analysis are a major hurdle to greater allocation efficiency
- The POC identified two key areas for improvement:
 - Absence of minimum standard set of criteria to initiate kidney biopsy
 - Need for standardization in kidney pathology reporting
- Multi-disciplinary workgroup formed with representation from 4 OPTN Committees

Purpose of Proposal

- Standardize biopsy reporting by establishing a standard set of information to be reported when procurement kidney biopsy is performed
 - Streamline biopsy reporting and information sharing
 - Reduce inconsistencies in comprehensiveness
 - Improve allocation efficiency
 - Align biopsy data collection

Proposal:

- Committee proposes required reporting of certain data when reporting biopsy results
- Modifications to DonorNet[®] and Deceased Donor Registration (DDR) TIEDI[®] data fields and related definitions
- Data Advisory Committee (DAC) Data Element Standard of Review process

Proposal: Standardized Pathology Report

Biopsy Type:	Wedge		Core Needle	
Tissue Preparation Technique:	Frozen Section		Formalin-Fixed Paraffin-Embedded (FFPE Section)	
Number of Glomeruli:	_____			
Number of Globally Sclerotic Glomeruli:	_____			
Percent Globally Sclerotic Glomeruli:	_____ %			
Nodular Mesangial Glomerulosclerosis:	Absent	Present	Unknown	

Proposal: Standardized Pathology Report

Interstitial Fibrosis & Tubular Atrophy (IFTA):	<5%	5-10%	11-25%	26-50%	>50%
Vascular Disease (Percent luminal narrowing of most severely involved vessel):	None (<10%)	Mild (10-25%)	Moderate (26-50%)	Severe (>50%)	
Cortical Necrosis:	Absent	Present	_____ %		
Fibrin Thrombi:	Absent	Present	_____ %		
Other Comments:					

Proposal: Standardized Pathology Report

The Committee proposes the following additional biopsy parameters to be reported:

- Tissue preparation technique
- Number of globally sclerotic glomeruli
- Nodular mesangial glomerulosclerosis
- Interstitial Fibrosis and Tubular Atrophy
- Vascular Disease
- Cortical Necrosis
- Fibrin Thrombi

Rationale

- Inconsistencies in comprehensiveness and quality of biopsy analysis are major hurdle to allocation efficiency
- This proposal will standardize biopsy reporting
 - Improve consistency in analysis between OPOs
 - Streamline reporting of key donor information
 - Improve allocation efficiency
- Standardize data collection
 - Align data collection within UNetSM
 - Improve donor information

Member Actions

- OPOs will need to coordinate with pathology services to ensure necessary data and parameters are reported

What do you think?

1. Is the standardized form universally understandable and sufficiently useable?
2. How will aligning biopsy data collection in the DDR impact administrative data burden?
3. How can this form best be operationalized for OPO use?