Standardize Kidney Biopsy Reporting and Data Collection

OPTN Kidney Transplantation Committee
Jim Kim, MD, Committee Vice Chair
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

<table>
<thead>
<tr>
<th>Biopsy Type:</th>
<th>Wedge</th>
<th>Core Needle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tissue Preparation Technique:</td>
<td>Frozen Section</td>
<td>Formalin-Fixed Paraffin-Embedded (FFPE Section)</td>
</tr>
<tr>
<td>Number of Glomeruli:</td>
<td></td>
<td></td>
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<tr>
<td>Number of Globally Sclerotic Glomeruli:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Percent Globally Sclerotic Glomeruli:</td>
<td></td>
<td>%</td>
</tr>
<tr>
<td>Nodular Mesangial Glomerulosclerosis:</td>
<td>Absent</td>
<td>Present</td>
</tr>
</tbody>
</table>

OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK
## Proposal: Standardized Pathology Report

<table>
<thead>
<tr>
<th>Condition</th>
<th>&lt;5%</th>
<th>5-10%</th>
<th>11-25%</th>
<th>26-50%</th>
<th>&gt;50%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interstitial Fibrosis &amp; Tubular Atrophy (IFTA):</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vascular Disease (Percent luminal narrowing of most severely involved vessel):</td>
<td>None (&lt;10%)</td>
<td>Mild (10-25%)</td>
<td>Moderate (26-50%)</td>
<td>Severe (&gt;50%)</td>
<td></td>
</tr>
<tr>
<td>Cortical Necrosis:</td>
<td>Absent</td>
<td>Present</td>
<td>_________%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fibrin Thrombi:</td>
<td>Absent</td>
<td>Present</td>
<td>_________%</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Comments:</td>
<td></td>
<td></td>
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</tbody>
</table>
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 UNet\textsuperscript{SM}
  - 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 usable?

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?