

# Standardize Kidney Biopsy Reporting and Data Collection 6 Month Monitoring Report

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## Background

On September 14, 2023 the Standardize Kidney Biopsy Reporting and Data Collection policy was implemented. This policy established the criteria that must be reported when a kidney procurement biopsy is performed. Before the implementation of this policy there was no set criteria for what information about biopsy results would be reported in the course of a transplant. With the implementation of this policy, the OPTN Kidney Transplantation Committee theorized there would be better sharing of information around the results of kidney biopsies, which would lead to more informed decision making through the offer acceptance process.

From this policy change, the following five data elements had existed in some form before the policy implementation:

- Biopsy Type
  - Removal of “Other Specify” option in response on the Deceased Donor Record (DDR)
- Number of Glomeruli
  - Phrasing of field changed from “Glomeruli Count” in the OPTN Donor Data and Matching System and “Number of Glomeruli Visualized” on the DDR
- Percent Globally Sclerotic Glomeruli
  - In the OPTN Donor Data and Matching System the data element change from “Percent Glomerulosclerosis”
  - On the DDR this changed from “Glomerulosclerosis Percentage” and also changed from an option of percentages to a numeric percentage field response
- Interstitial Fibrosis and Tubular Atrophy (IFTA)
  - Field was new addition to the OPTN Donor Data and Matching System
  - Before this change, the field was listed on the DDR as “Interstitial Fibrosis” only with different response options, that have now changed to choice of five different percentage options
- Vascular Disease
  - Changed from “Vascular Changes” on the DDR, with new response options
  - Data element was not present in the OPTN Donor Data and Matching System

The following six data elements are new additions to both the DDR as well as the OPTN Data and Matching System, meaning there was no data collected on these data elements before policy implementation:

- Tissue Preparation Technique
- Number of Globally Sclerotic Glomeruli
- Nodular Mesangial Glomerulosclerosis
- Arteriolar Hyalinosis
- Cortical Necrosis
- Fibrin Thrombi

## Strategic Plan Goal or Committee Project Addressed

- Increase the number of transplants
- Promote the efficient management of the OPTN

## Committee Request

The policy will be monitored six, 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 OPTN conventions, to account for time delay in institutions reporting data to the OPTN Computer System.

Counts and percents of biopsied deceased donor kidneys by:

- Biopsy type
- Tissue preparation technique
- Number of glomeruli observed
- Percent glomerular sclerosis

- Interstitial fibrosis and tubular atrophy
- Vascular disease
- Arteriolar hyalinosis
- Cortical necrosis
- Fibrin thrombi

Due to the nature of this policy implementation, all of the variables except for 'Biopsy Type', 'Number of glomeruli observed' and 'Percent Globally Sclerotic Glomeruli' were either not collected before the policy implementation, or were collected but had substantial changes to response options or data definitions. The consequence of this is that it is not appropriate to compare to a pre-policy cohort for a majority of variables in this analysis. Counts and percentages will be given for the post-implementation period unless appropriate to compare to a pre-policy cohort.

## Data and Methods

### Data Sources:

Donor data were submitted via the OPTN Donor Data and Matching System and on the Deceased Donor Registration (DDR).

All results are based on OPTN data as of August 16, 2024. Data are subject to change based on future data submission or correction.

### Cohort:

All deceased kidney donors recovered in the United States between March 18, 2023 and March 12, 2024 were included in this analysis.

Policy eras were defined as the following, so each era had the same amount of days:

- Pre-policy: March 18, 2023 to September 13, 2023
- Post-policy: September 14, 2023 to March 12, 2024

### Methods:

A deceased kidney donor is defined as any donor with at least one kidney recovered for the purpose of solid organ transplantation.

A biopsied deceased donor kidney is defined as any kidney for which a procurement biopsy was performed.

## Results

### Overall Number of Donors

**Table 1** shows the number of deceased kidney donors as well as deceased donor kidneys recovered by policy era. Overall, there were increases in the number of donors recovered as well number of kidneys recovered. There also was an increase in the number of kidneys biopsied as well as the percentage of kidneys biopsied, with around a 6% increase in kidneys being biopsied.

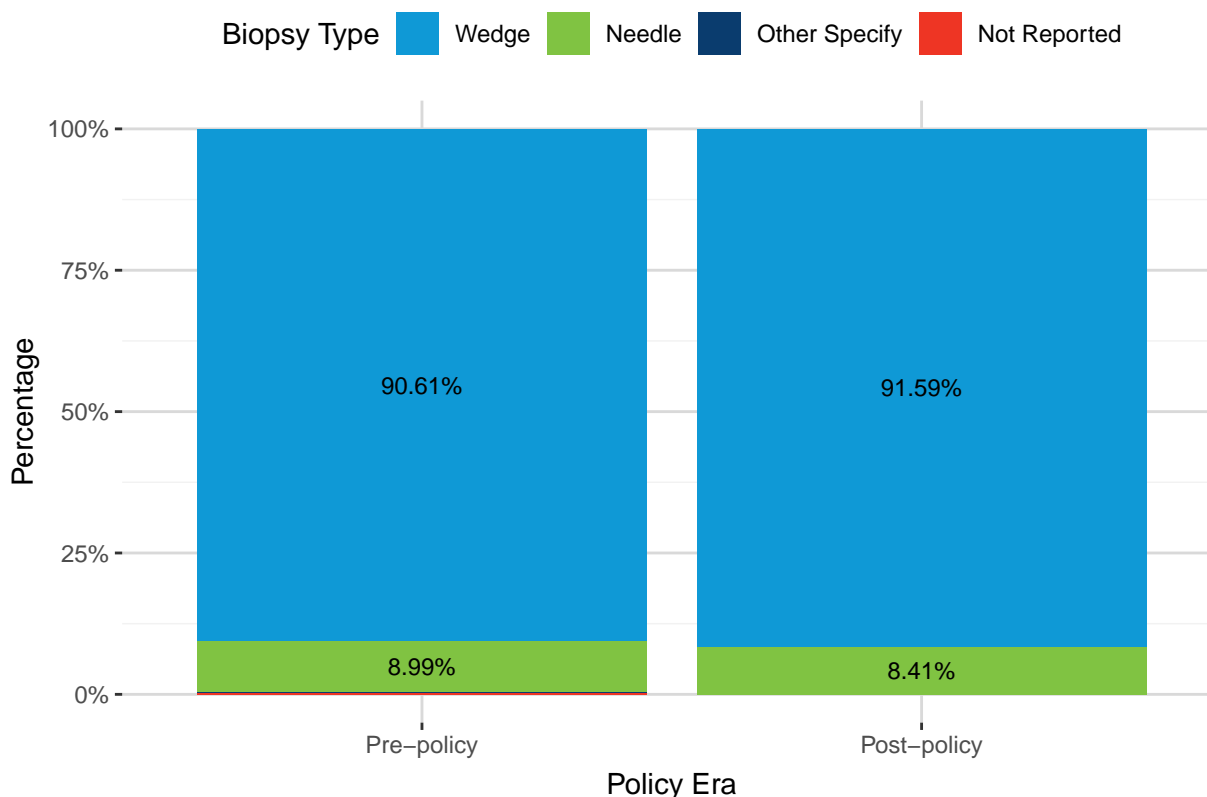
**Table 1: Number of Deceased Donors and Biopsied Kidneys Recovered in United States by Policy Era**

Policy Era	Number of Donors	Number of Kidneys Recovered	Number of Biopsied Kidneys	Percent Biopsied
Pre-policy	7,732	15,401	9,043	58.72
Post-policy	7,810	15,539	10,040	64.61

## Biopsy Type

**Figure 1** and **Table 2** show the count and percent of biopsied deceased donor kidneys recovered by policy era and biopsy type. This variable was one of the few required variables collected before the policy implementation, although it should be noted the “Other Specify” option was removed from data collection with the implementation of this policy. Overall, in both policy eras the majority of biopsied kidneys were biopsied using a wedge biopsy (Pre: 90.61% Post: 91.59%)

**Figure 1: Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Policy Era and Biopsy Type**



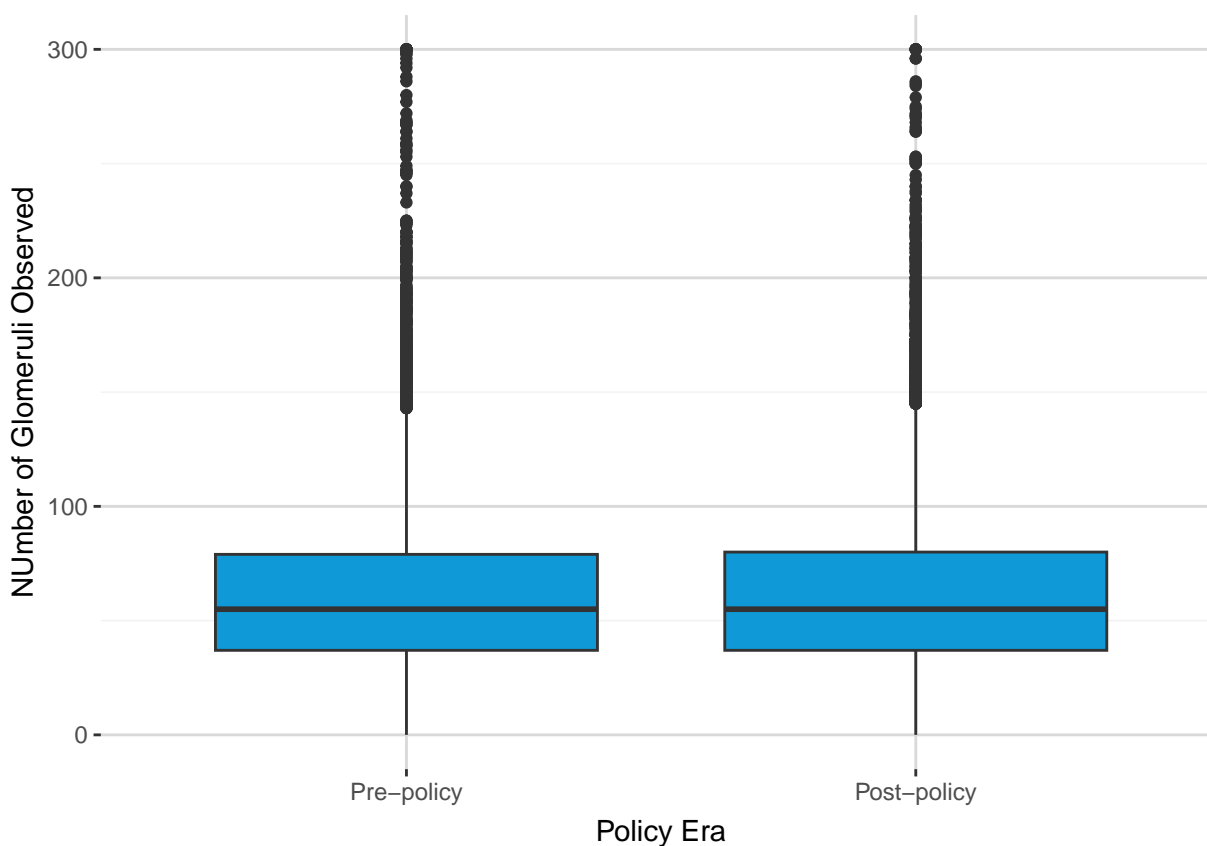
**Table 2: Count and Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Policy Era and Biopsy Type**

Biopsy Type	Pre-policy	Post-policy
Wedge	8,194 (90.61%)	9,196 (91.59%)
Needle	813 (8.99%)	844 (8.41%)
Other Specify	9 (0.10%)	0 (0.00%)
Not Reported	27 (0.30%)	0 (0.00%)
Total	9,043 (100.00%)	10,040 (100.00%)

## Number of Glomeruli Observed

Figure 2 and Table 3 show the count and percent of biopsied deceased donor kidneys recovered by policy era and number of glomeruli observed. This variable was one of the three that was collected between the two policy eras, that did not have major changes to the response options or data definition, therefore a comparison between the two eras can be looked at. Overall there was no difference between the distribution of number of glomeruli observed between the two policy eras, with a median of 55 glomeruli observed in both eras.

**Figure 2: Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Number of Glomeruli Observed and Policy Era**



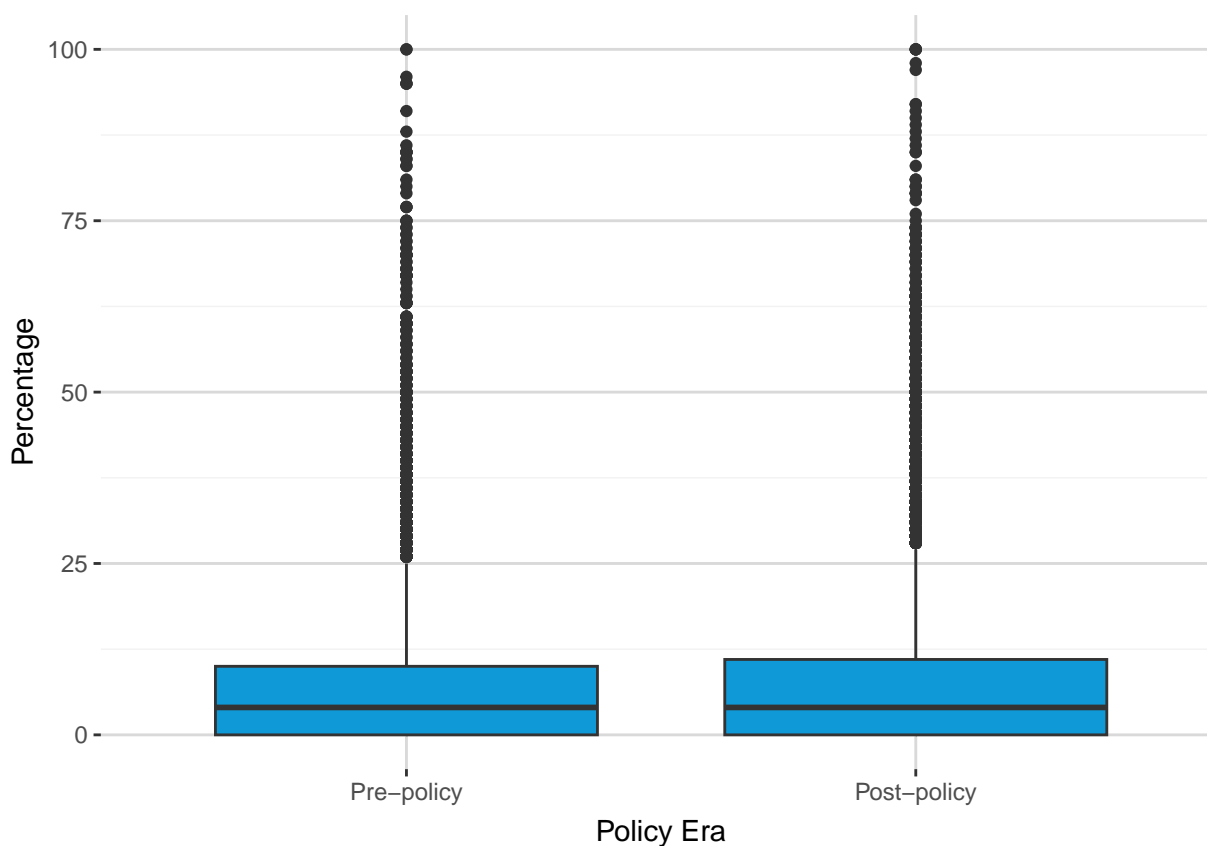
**Table 3: Count and Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Number of Glomeruli Observed and Policy Era**

Policy Era	Number of Kidneys Biopsied	Min	25th %-tile	Median	Mean	75th %-tile	Max	Number of Not Reported
Pre-policy	9,043	0	37	55	63	79	300	44
Post-policy	10,040	0	37	55	63	80	300	45

## Percent Globally Sclerotic Glomeruli

**Figure 3** and **Table 4** show the count and percent of biopsied deceased donor kidneys recovered by percent globally sclerotic glomeruli and policy era. This variable was one of the three that was collected between the two policy eras, that did not have major changes to the response options or data definition, therefore a comparison between the two eras can be looked at. In both the pre- and post-policy era the median percent globally sclerotic glomeruli was 4%.

**Figure 3: Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Percent Glomerular Sclerosis and Policy Era**



**Table 4: Count and Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Percent Glomerular Sclerosis and Policy Era**

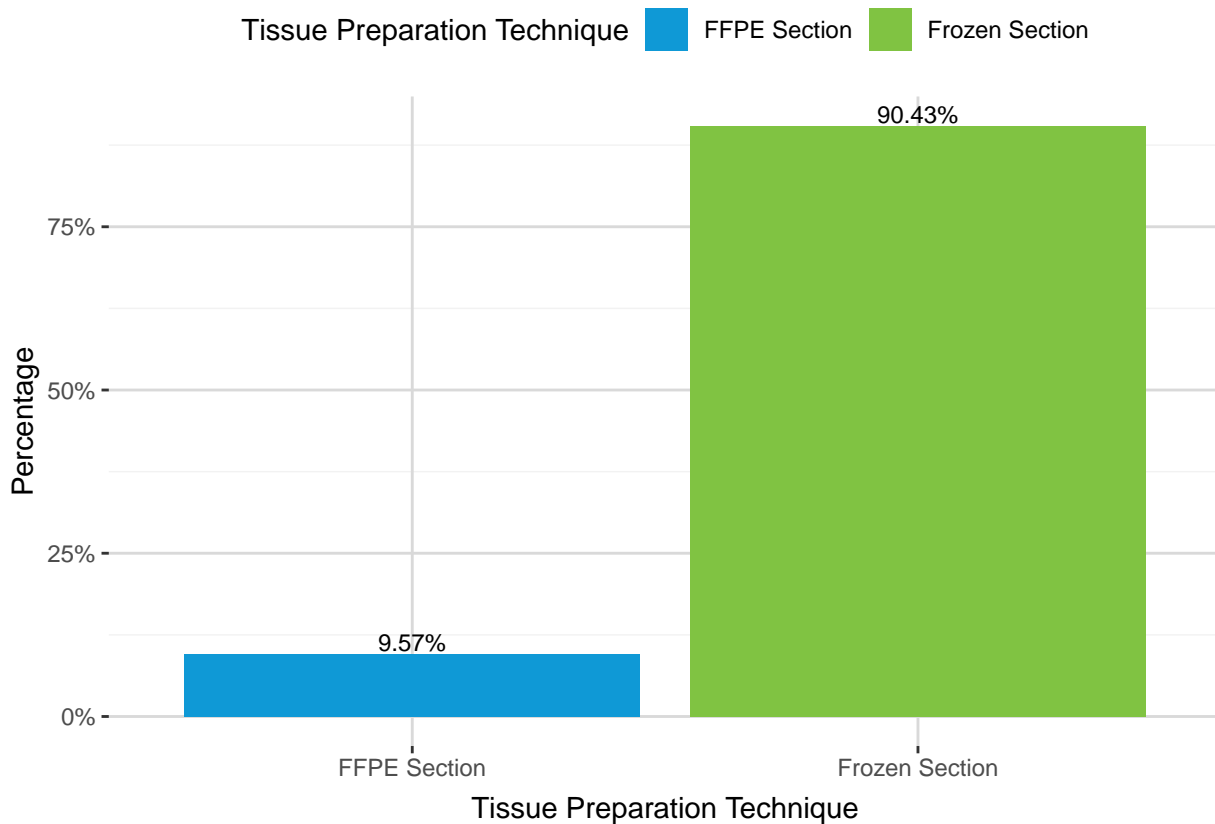
Policy Era	Number of Kidneys Biopsied	Min	25th %-tile	Median	Mean	75th %-tile	Max	Number of Not Reported
Pre-policy	9,043	0	0	4	8	10	100	1,434
Post-policy	10,040	0	0	4	8	11	100	48



### Tissue Preparation Technique

Figure 4 and Table 5 show the count and percent of biopsied deceased donor kidneys recovered by tissue preparation technique. Before the implementation of this policy, data on tissue preparation technique was not collected, therefore there is no pre implementation cohort for comparison. The analysis of this variable and any others that were not collected pre-implementation will only look at data after the implementation of the policy. The vast majority of biopsies used frozen sections as the tissue preparation technique with 90.43% of all biopsied kidneys using frozen sections.

**Figure 4: Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Tissue Preparation Technique**



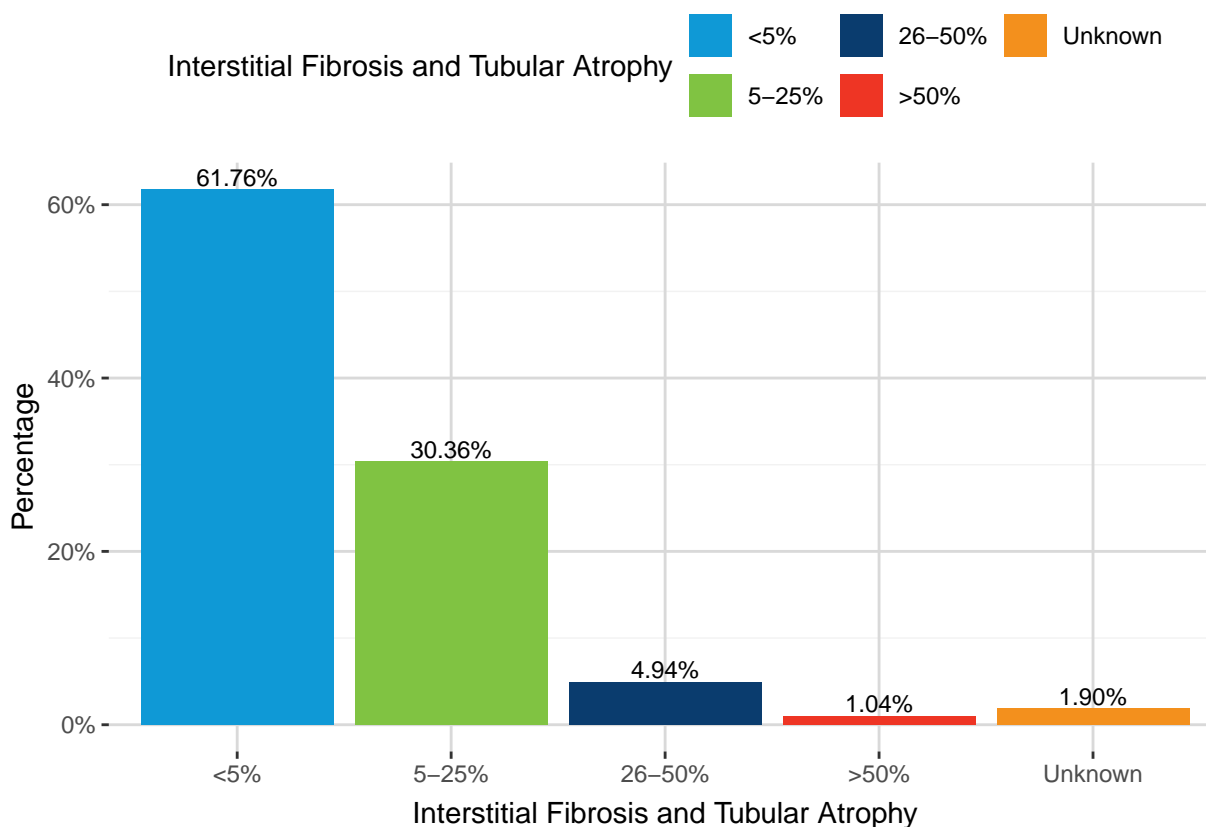
**Table 5: Count and Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Tissue Preparation Technique**

Tissue Prep Technique	Post-policy
Frozen Section	9,079 (90.43%)
FFPE Section	961 (9.57%)
Total	10,040 (100.00%)

## Interstitial Fibrosis and Tubular Atrophy (IFTA)

Figure 5 and Table 6 show the count and percent of biopsied deceased donor kidneys recovered by IFTA status. A majority of biopsied kidneys had IFTA of less than 5% (61.76%).

**Figure 5: Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Interstitial Fibrosis and Tubular Atrophy**



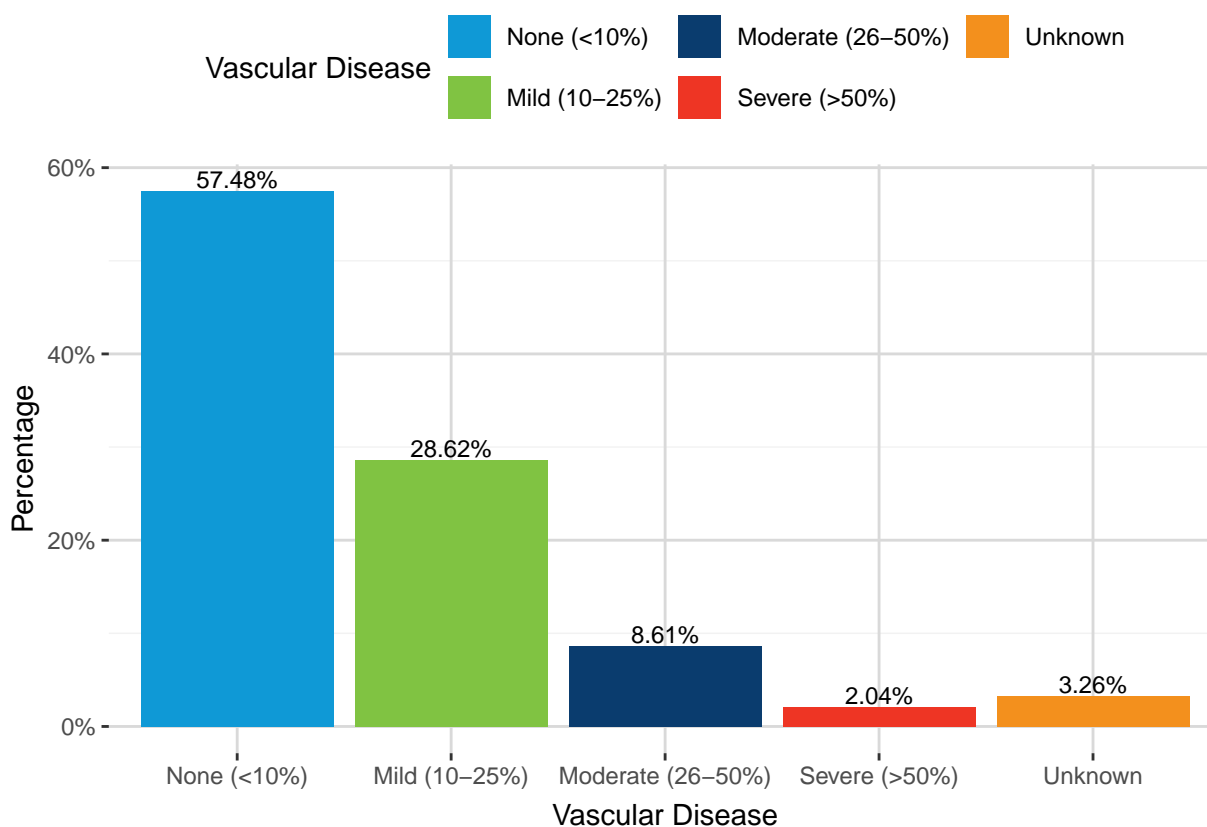
**Table 6: Count and Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Interstitial Fibrosis and Tubular Atrophy**

Interstitial Fibrosis and Tubular Atrophy	Post-policy
<5%	6,201 (61.76%)
5-25%	3,048 (30.36%)
26-50%	496 (4.94%)
>50%	104 (1.04%)
Unknown	191 (1.90%)
Total	10,040 (100.00%)

## Vascular Disease

**Figure 6** and **Table 7** show the count and percent of biopsied deceased donor kidneys recovered by vascular disease status. A majority of biopsied kidneys had no signs of vascular disease (57.48%). Of biopsied kidneys that did show some sign of vascular disease, most showed signs of mild vascular disease (28.62%).

**Figure 6: Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Vascular Disease**



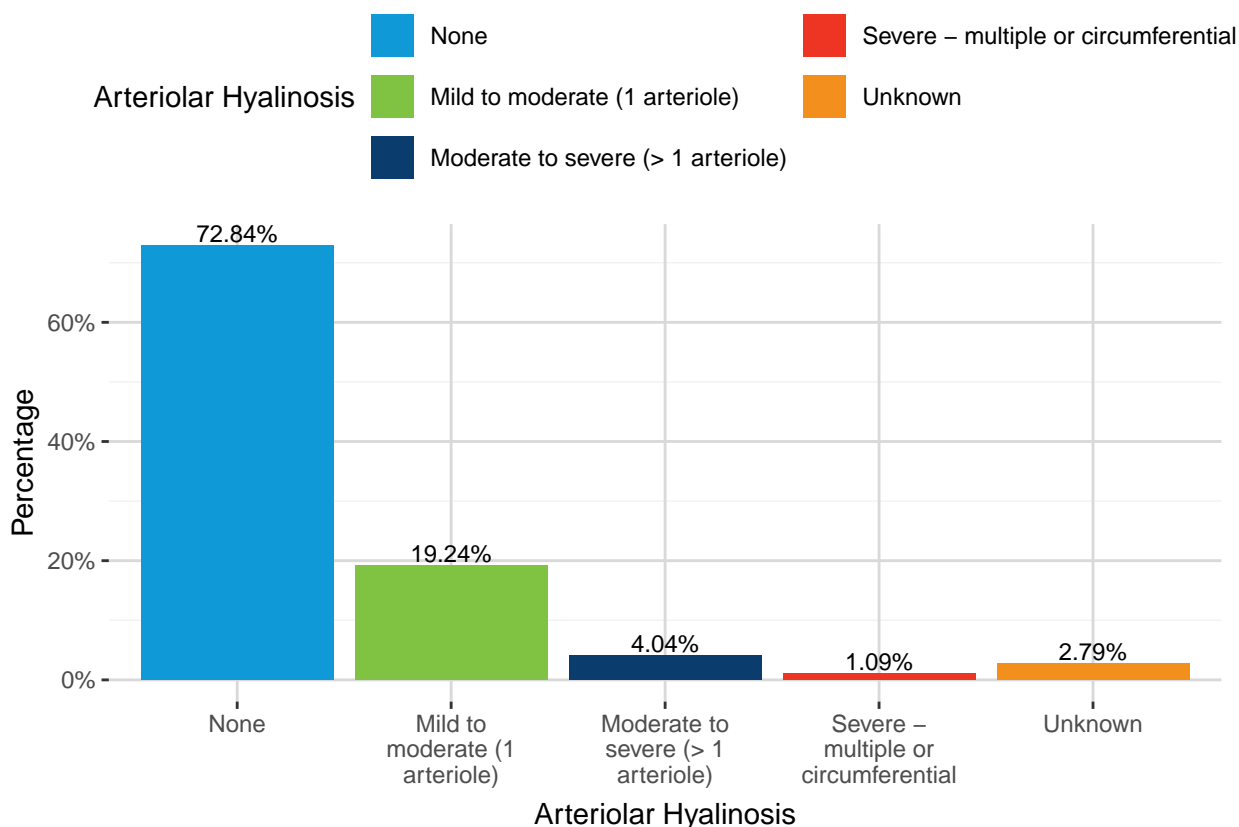
**Table 7: Count and Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Vascular Disease**

Vascular Disease	Post-policy
None (<10%)	5,771 (57.48%)
Mild (10-25%)	2,873 (28.62%)
Moderate (26-50%)	864 (8.61%)
Severe (>50%)	205 (2.04%)
Unknown	327 (3.26%)
Total	10,040 (100.00%)

## Arteriolar Hyalinosis

**Figure 7** and **Table 8** show the count and percent of biopsied deceased donor kidneys recovered by arteriolar hyalinosis status. A majority of biopsied kidneys had no signs of arteriolar hyalinosis (72.84%). For biopsied kidneys that did show some sign of arteriolar hyalinosis, most showed signs of mild to moderate (1 arteriole) arteriolar hyalinosis with 19.24% of all biopsied kidneys.

**Figure 7: Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Arteriolar Hyalinosis**



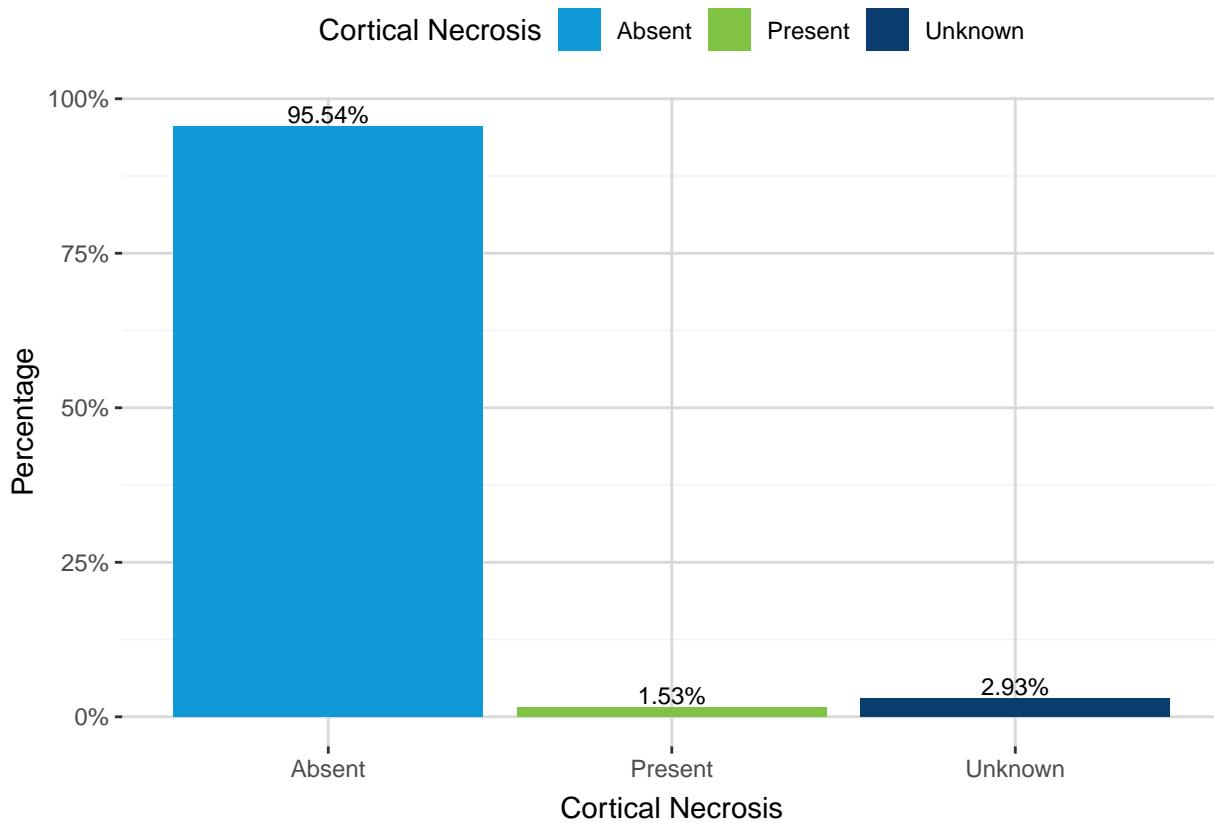
**Table 8: Count and Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Arteriolar Hyalinosis**

Arteriolar Hyalinosis	Post-policy
None	7,313 (72.84%)
Mild to moderate (1 arteriole)	1,932 (19.24%)
Moderate to severe (> 1 arteriole)	406 (4.04%)
Severe - multiple or circumferential	109 (1.09%)
Unknown	280 (2.79%)
Total	10,040 (100.00%)

## Cortical Necrosis

**Figure 8** and **Table 9** show the count and percent of biopsied deceased donor kidneys recovered by cortical necrosis status. A majority (95.54%) of biopsied kidneys were labeled as absent for signs of cortical necrosis.

**Figure 8: Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Cortical Necrosis**



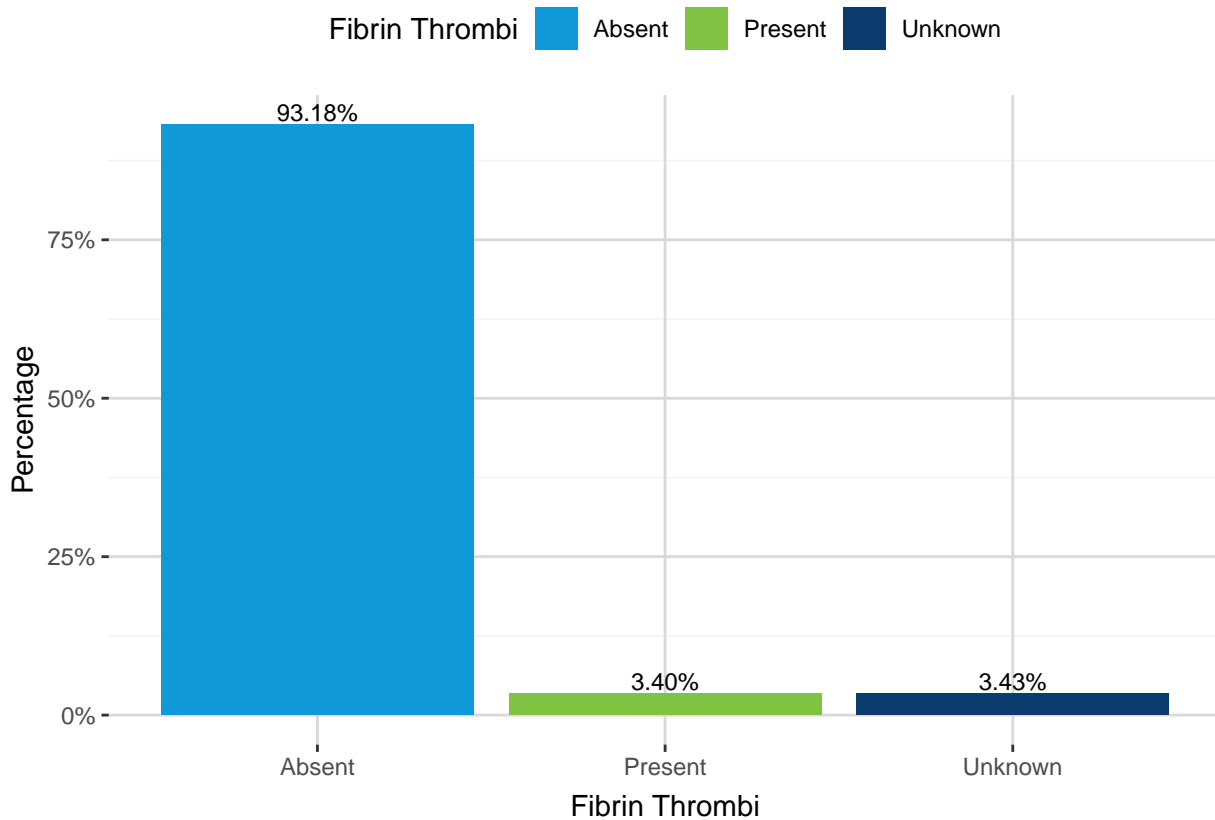
**Table 9: Count and Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Cortical Necrosis**

Cortical Necrosis	Post-policy
Absent	9,592 (95.54%)
Unknown	294 (2.93%)
Present	154 (1.53%)
Total	10,040 (100.00%)

## Fibrin Thrombi

**Figure 9** and **Table 10** show the count and percent of biopsied deceased donor kidneys recovered by fibrin thrombin presence. A majority (93.18%) of biopsied kidneys were labeled as absent for presence of fibrin thrombin.

**Figure 9: Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Fibrin Thrombi**



**Table 10: Count and Percentage of Biopsied Deceased Donor Kidneys Recovered in United States by Fibrin Thrombi**

Fibrin Thrombi	Post-policy
Absent	9,355 (93.18%)
Unknown	344 (3.43%)
Present	341 (3.40%)
Total	10,040 (100.00%)

## Conclusion

Overall, the implementation of the Standardize Kidney Biopsy Reporting and Data Collection policy involved mostly the addition of new data fields and data definitions for results of kidney biopsies. There was also redefining and changes to the fields that had previously been collected. Due to this, there is no way to compare to a previous cohort for a majority of the variables. From the new variables added, it can be seen that a vast majority of biopsies are reporting the information and there was no substantial decrease in biopsying overall, with slight increase in the number and percentage of biopsied kidneys in the six months after policy implementation as compared to the six months before policy implementation.

This policy will be monitored by the Committee again at approximately one and two years post-implementation.