

# Standardize Kidney Biopsy Reporting and Data Collection One Year Monitoring Report

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## Executive Summary

This report presents data describing the reported results of deceased donor kidney procurement biopsies before and after the implementation of the Standardize Kidney Biopsy Reporting and Data Collection policy. The policy change implemented new data collection or significantly changed the data definitions or response options for data that was collected pre-policy. Therefore, a majority of the analysis only reports for the post-policy period.

Overall, there was a 4.16% increase in the number of donors recovered for transplant in the post-policy era as compared to the pre-policy era. There was a 5.3% increase in the percentage of kidneys biopsied in the post-policy era. Kidneys that were biopsied saw little change in non-use rates between the two eras, with around 49% of biopsied kidneys being not used for transplant in both policy eras. A majority of biopsied kidneys in the post-policy era utilized a wedge biopsy as the biopsy method, and did not report findings of interstitial fibrosis and tubular atrophy (IFTA), vascular disease, arteriolar hyalinosis, cortical necrosis, fibrin thrombi, or nodular mesangial glomerulosclerosis. The Committee when receiving the six month monitoring report of this policy, defined what a 'standard' biopsy result would be; the definition can be found in the methods section. In the post-policy era, 45.63% of biopsied kidneys had 'standard' biopsy results according to the Committee's definition. These kidneys with standard biopsy results were not used for transplant 21.61% of the time.

## 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 were 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 Registration (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 changed from "Percent Glomerulosclerosis"
  - On the DDR this changed from "Glomerulosclerosis Percentage" and also changed from a categorical 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 Addressed

- Increase opportunities for transplant
- Optimize Organ Use

## Committee Request

The policy will be monitored approximately 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 Globally Sclerotic Glomeruli
- Interstitial fibrosis and tubular atrophy (IFTA)
- 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.

At the Committee's August 26, 2024 meeting while receiving a presentation on the six month monitoring report of this policy, the committee requested for subsequent reports to see organ use status for all levels of the previous data requested, as well as the organ use status for biopsied kidneys that have standard biopsy results. These metrics have been added for the one year report and will be reported for the two year report as well. More information on the definition of a standard biopsy results can be seen in the methods section.

## 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 January 10, 2025. Data are subject to change based on future data submission or correction.

### Cohort:

All deceased donor kidneys recovered in the United States between September 13, 2022 and September 13, 2024 were included in this analysis.

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

- Pre-policy: September 13, 2022 to September 13, 2023
- Post-policy: September 14, 2023 to September 13, 2024

### Methods:

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

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

For the analysis below, a standard biopsy finding is defined as a kidney biopsy in which all of the following were reported for a recovered biopsied kidney:

- Percent Globally Sclerotic Glomeruli  $\leq 10\%$
- Vascular Disease = None ( $<10\%$ ) or Mild (10-25%)
- Arteriolar Hyalinosis = None or Mild to Moderate (1 Arteriole)
- Cortical Necrosis = Absent
- Fibrin Thrombi = Absent
- Nodular Mesangial Glomerulosclerosis = Absent
- IFTA  $<5\%$

## Results

### Overall Number of Donors

**Table 1** shows the number of deceased 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 approximately a 6% increase in kidneys being biopsied from the pre- to post-policy era. There was a 1.46% increase in the non-use rate in the post-policy era as compared to the pre-policy era.

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

Policy Era	Number of Donors	Number of Kidneys Recovered	Number of Biopsied Kidneys	Percent Biopsied	Number of Kidneys Recovered but Not Used for TX	Non-use Rate
Pre-policy	15,374	30,599	18,083	59.1	8,486	27.73
Post-policy	16,013	31,855	20,516	64.4	9,300	29.19

### Overall Non-use Rates

**Table 2** shows the non-use rates for deceased donor kidneys recovered in the United States by policy era and biopsy status. Overall there was little change in the non-use rates based on biopsy status

**Table 2: Non-use Rates for Deceased Donors recovered in the United States by Policy Era and Biopsy Status**

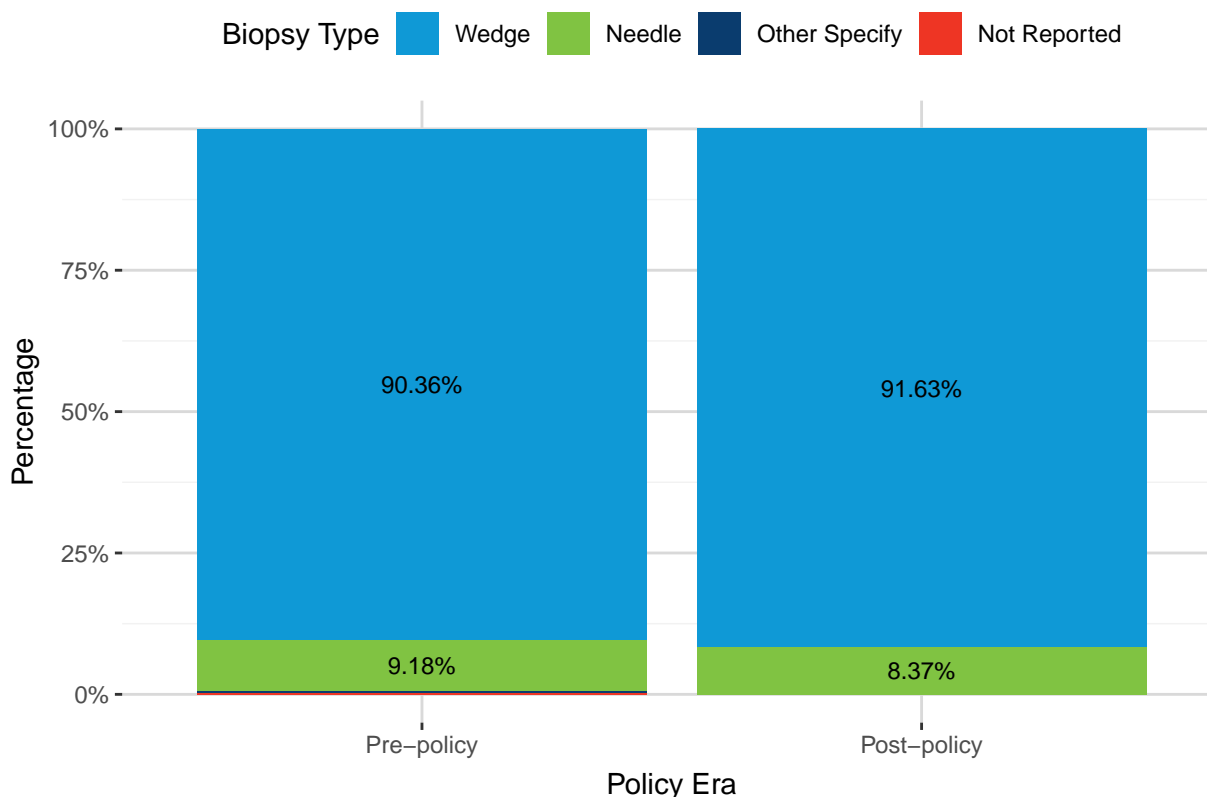
Biopsy Status	Policy Era	Not Used for TX	Used For TX	Total
Biopsied	Pre-policy	8,852 (48.95%)	9,231 (51.05%)	18,083 (100.00%)
	Post-policy	9,975 (48.62%)	10,541 (51.38%)	20,516 (100.00%)
Not Biopsied	Pre-policy	1,188 (9.49%)	11,324 (90.51%)	12,512 (100.00%)
	Post-policy	1,028 (9.07%)	10,310 (90.93%)	11,338 (100.00%)

<sup>a</sup> Note: In the pre-policy era there were 4 kidneys that did not have a biopsy status reported as well as 1 kidney in the post-policy era

## Biopsy Type

**Figure 1** and **Table 3** 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: 90.36% Post: 91.63%)

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



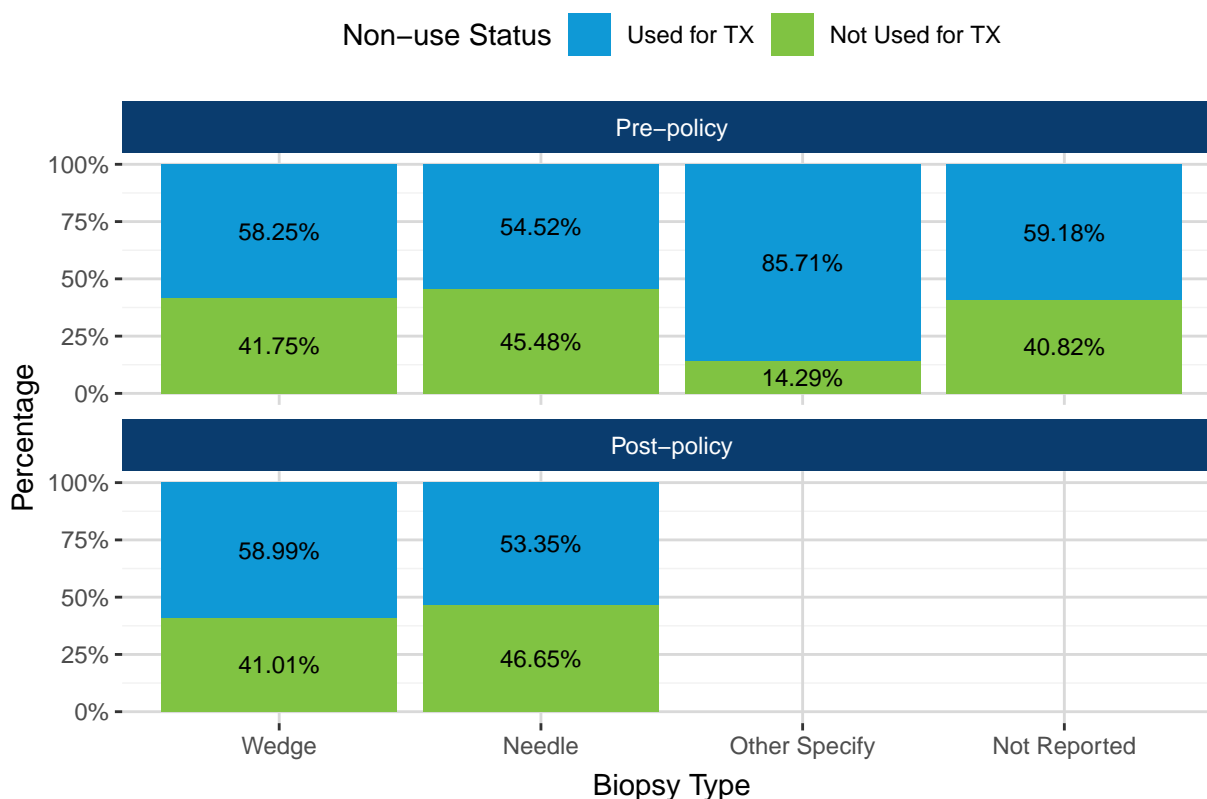
**Table 3: Count and Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Policy Era and Biopsy Type**

Biopsy Type	Pre-policy	Post-policy
Wedge	16,339 (90.36%)	18,799 (91.63%)
Needle	1,660 (9.18%)	1,717 (8.37%)
Other Specify	35 (0.19%)	0 (0.00%)
Not Reported	49 (0.27%)	0 (0.00%)
Total	18,083 (100.00%)	20,516 (100.00%)



**Figure 2** and **Table 4** show non-use rates for deceased donor kidneys recovered in the United States by policy era and biopsy status. Donor kidneys that underwent a wedge biopsy had a non-use rate of around 41-42% in both eras. Donor kidneys that underwent a needle biopsy were not used for transplant 45.48% of the time in the pre-policy era, and 46.65% of the time in the post-policy era.

**Figure 2: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Policy Era and Biopsy Status**



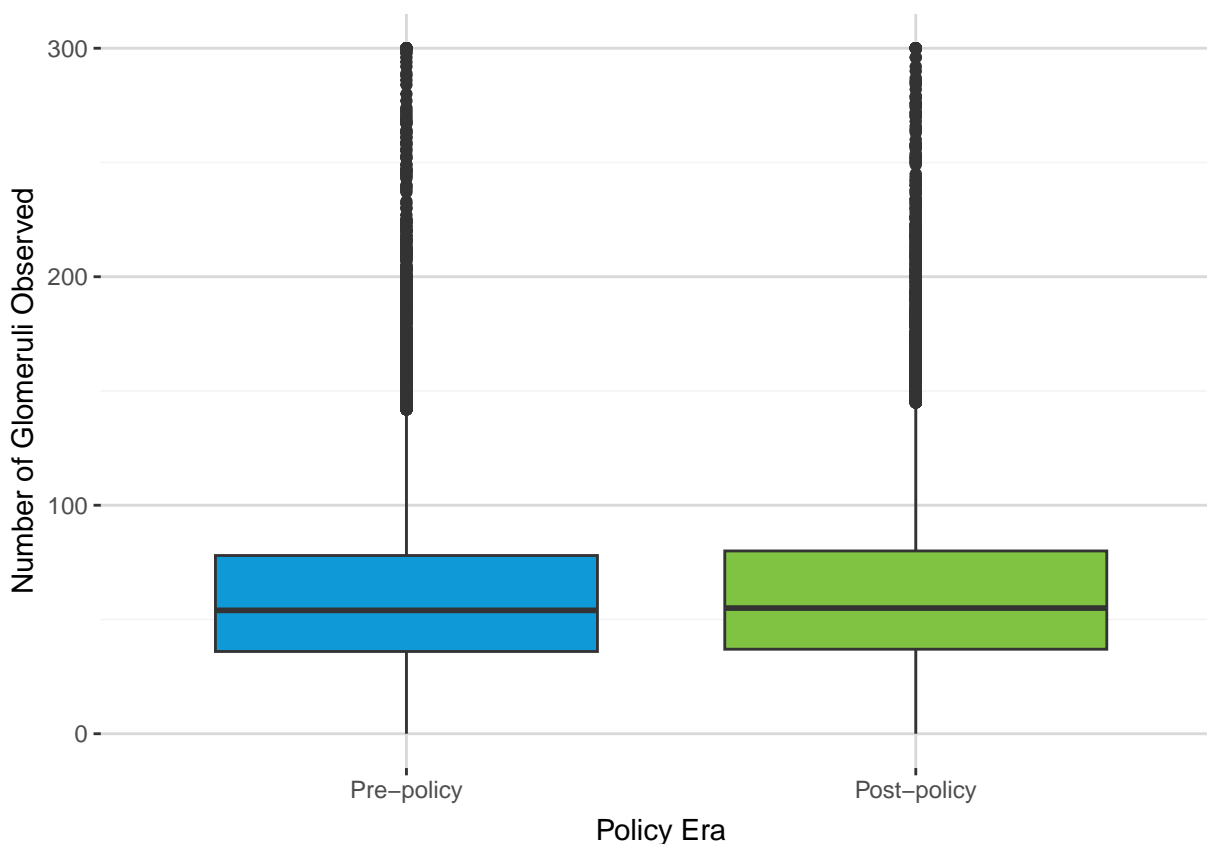
**Table 4: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Policy Era and Biopsy Status**

Biopsy Type	Policy Era	Used for TX	Not Used for TX	Total
Wedge	Pre-policy	9,517 (58.25%)	6,822 (41.75%)	16,339 (100.00%)
	Post-policy	11,090 (58.99%)	7,709 (41.01%)	18,799 (100.00%)
Needle	Pre-policy	905 (54.52%)	755 (45.48%)	1,660 (100.00%)
	Post-policy	916 (53.35%)	801 (46.65%)	1,717 (100.00%)
Other Specify	Pre-policy	30 (85.71%)	5 (14.29%)	35 (100.00%)
Not Reported	Pre-policy	29 (59.18%)	20 (40.82%)	49 (100.00%)

## Number of Glomeruli Observed

**Figure 3** and **Table 5** show the distribution 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 a slight difference between the distribution of number of glomeruli observed between the two policy eras, with a median of 54 glomeruli observed in the pre-policy era and 55 in the post-policy era.

**Figure 3: Distribution of Biopsied Deceased Donor Kidneys recovered in the United States by Number of Glomeruli Observed and Policy Era**

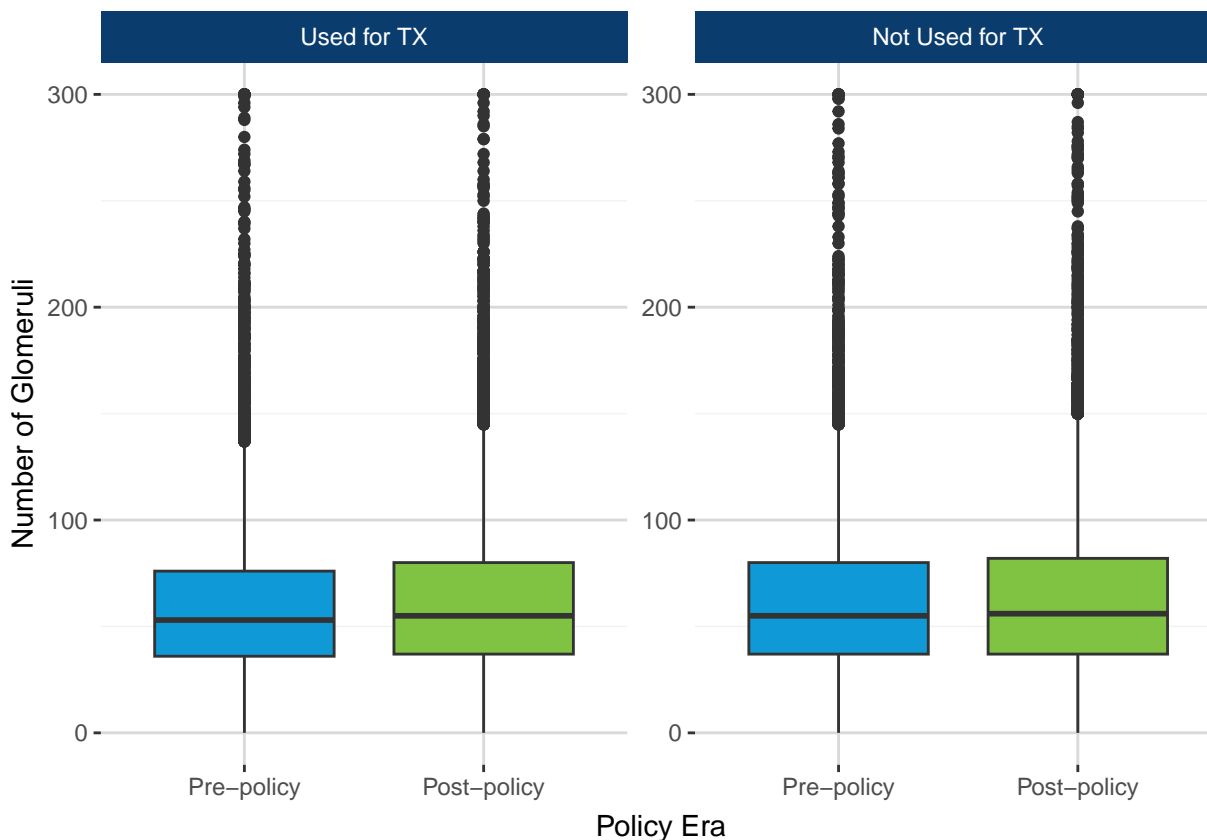


**Table 5: Distribution of Biopsied Deceased Donor Kidneys recovered in the United States by Number of Glomeruli Observed and Policy Era**

Policy Era	Number of Kidneys Biopsied	Min	25th %-tile	Median	Mean	75th %-tile	Max	Number of Not Reported
Pre-policy	18,083	0	36	54	62	78	300	77
Post-policy	20,516	0	37	55	63	80	300	77

**Figure 4** and **Table 6** show the distribution of biopsied deceased donor kidneys recovered in the United States by number of glomeruli observed and organ use status. Overall, there was little to no difference between the distribution of number of glomeruli observed and organ use status.

**Figure 4: Distribution of Biopsied Deceased Donor Kidneys recovered in the United States by Number of Glomeruli Observed and Organ Use Status**



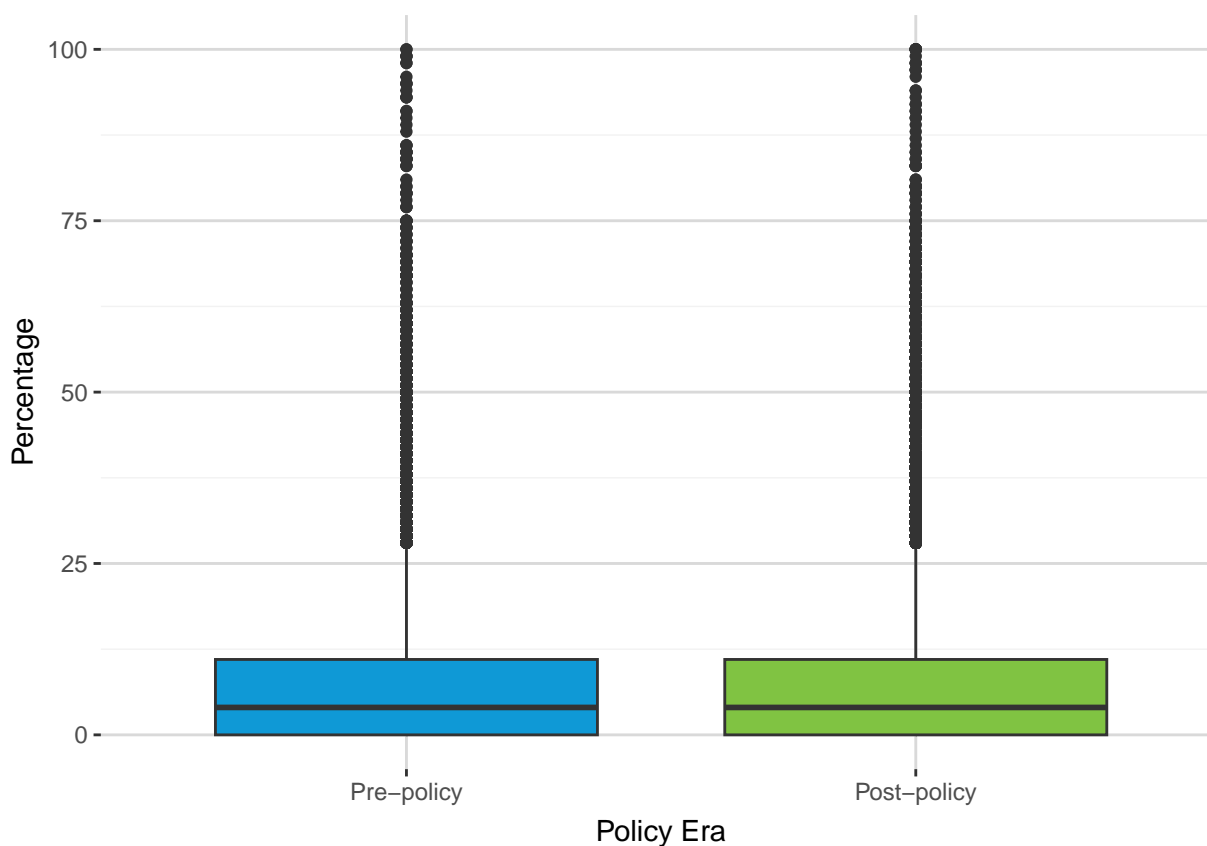
**Table 6: Distribution of Biopsied Deceased Donor Kidneys recovered in the United States by Number of Glomeruli Observed and Organ Use Status**

Non-use Status	Policy Era	Number of Kidneys Biopsied	Min	25th %-tile	Median	Mean	75th %-tile	Max	Number of Not Reported
Used for TX	Pre-policy	10,481	0	36	53	61	76	300	41
	Post-policy	12,006	0	37	55	63	80	300	37
Not Used for TX	Pre-policy	7,602	0	37	55	63	80	300	36
	Post-policy	8,510	0	37	56	65	82	300	40

## Percent Globally Sclerotic Glomeruli

**Figure 5** and **Table 7** show the distribution 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 5: Distribution of Biopsied Deceased Donor Kidneys recovered in the United States by Percent Globally Sclerotic Glomeruli and Policy Era**

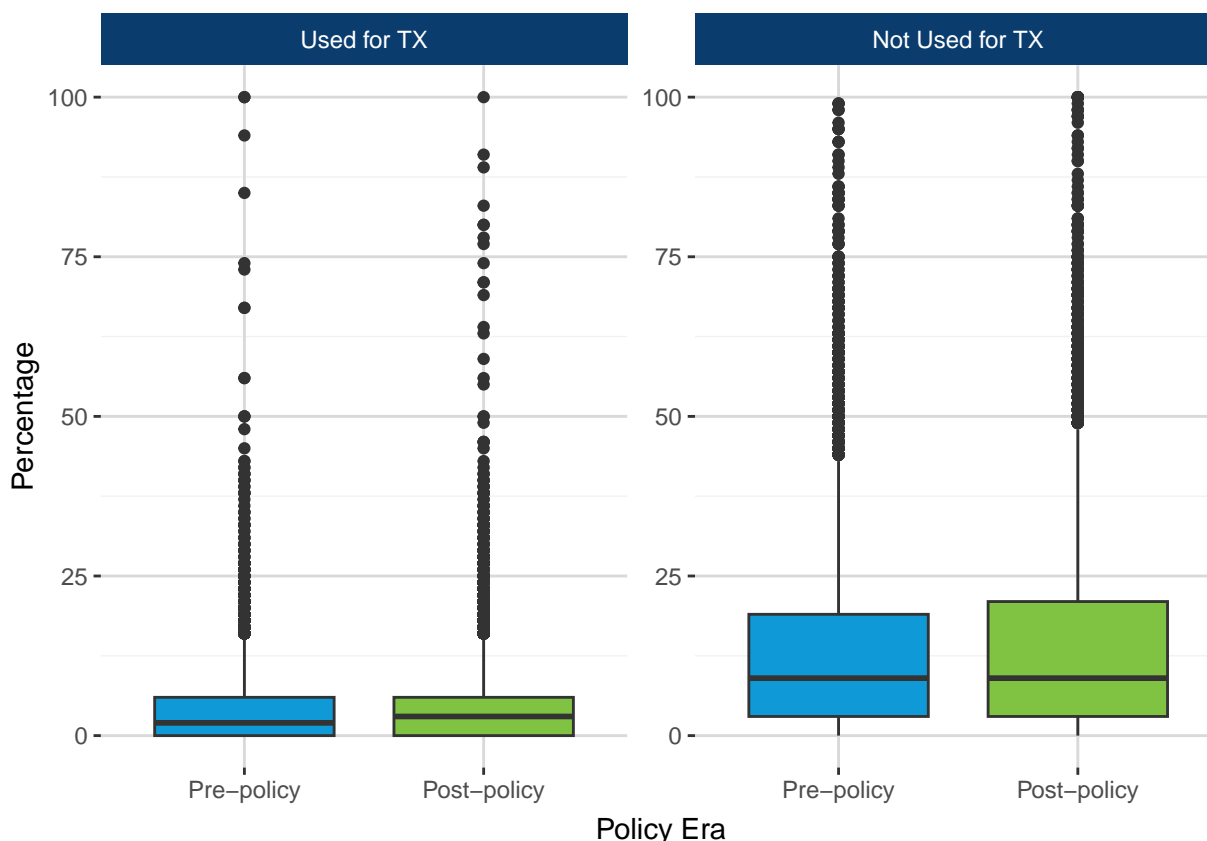


**Table 7: Distribution of Biopsied Deceased Donor Kidneys recovered in the United States by Percent Global Sclerotic Glomeruli and Policy Era**

Policy Era	Number of Kidneys Biopsied	Min	25th %-tile	Median	Mean	75th %-tile	Max	Number of Not Reported
Pre-policy	18,083	0	0	4	8	11	100	3,137
Post-policy	20,516	0	0	4	9	11	100	86

**Figure 6** and **Table 8** show the distribution of biopsied deceased donor kidneys recovered in the United States by percent globally sclerotic glomeruli and organ use status. Biopsied kidneys that were not used for transplant had a higher median percent globally sclerotic glomeruli of 8% in the pre-policy era and a median of 9% in the post-policy era, as compared to biopsied kidneys that were used for transplant, which had a median percent globally sclerotic glomeruli of 2% pre-policy and 3% post-policy.

**Figure 6: Distribution of Biopsied Deceased Donor Kidneys recovered in the United States by Percent Globally Sclerotic Glomeruli and Organ Use Status**



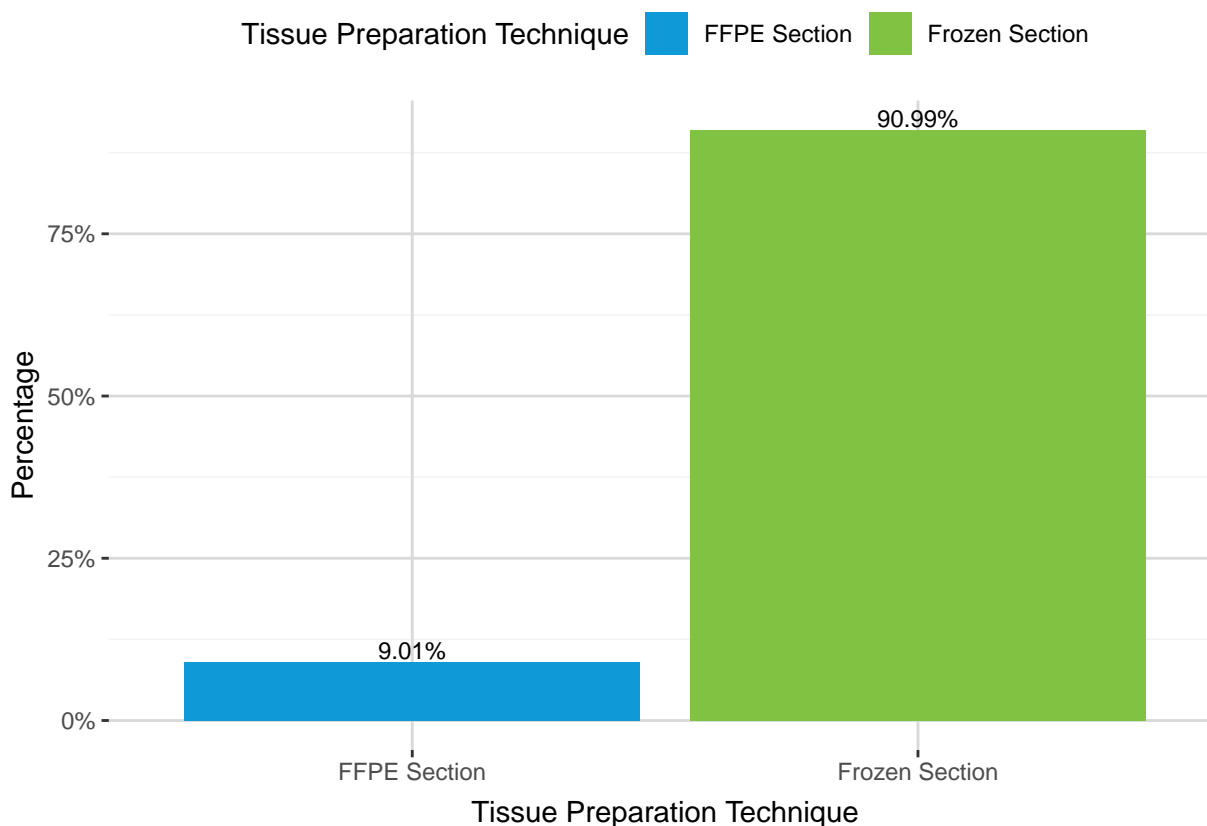
**Table 8: Distribution of Biopsied Deceased Donor Kidneys recovered in the United States by Percent Globally Sclerotic Glomeruli and Organ Use Status**

Non-use Status	Policy Era	Number of Kidneys Biopsied	Min	25th %-tile	Median	Mean	75th %-tile	Max	Number of Not Reported
Used for TX	Pre-policy	10,481	0	0	2	4	6	100	2,278
	Post-policy	12,006	0	0	3	4	6	100	44
Not Used for TX	Pre-policy	7,602	0	3	9	14	19	99	859
	Post-policy	8,510	0	3	9	15	21	100	42

## Tissue Preparation Technique

**Figure 7** and **Table 9** 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 90.99% of all biopsied kidneys using frozen sections.

**Figure 7: Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Tissue Preparation Technique**

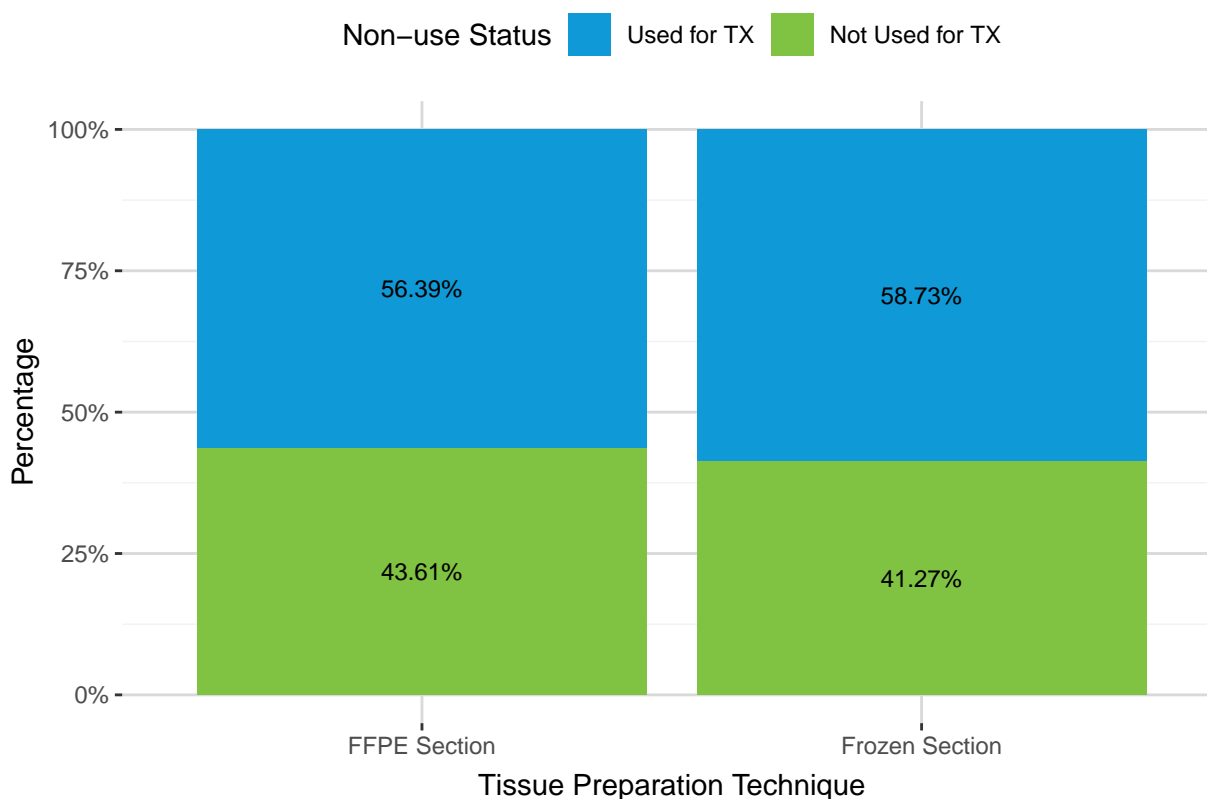


**Table 9: Count and Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Tissue Preparation Technique**

Tissue Prep Technique	Post-policy
Frozen Section	18,668 (90.99%)
FFPE Section	1,848 (9.01%)
Total	20,516 (100.00%)

**Figure 8** and **Table 10** show non-use rates for deceased donor kidneys recovered in the United States by tissue preparation technique. Donor kidneys that had a FFPE section as the method of tissue preparation technique, had a non-use rate of 43.61%. Donor kidneys that had a frozen section as the method of tissue preparation technique, had a non-use rate of 41.27%.

**Figure 8: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Tissue Preparation Technique**



**Table 10: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Tissue Preparation Technique**

Tissue Prep Technique	Used for TX	Not Used for TX	Total
FFPE Section	1,042 (56.39%)	806 (43.61%)	1,848 (100.00%)
Frozen Section	10,964 (58.73%)	7,704 (41.27%)	18,668 (100.00%)

## Interstitial Fibrosis and Tubular Atrophy (IFTA)

Figure 9 and Table 11 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% (61.14%).

Figure 9: Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Interstitial Fibrosis and Tubular Atrophy (IFTA)

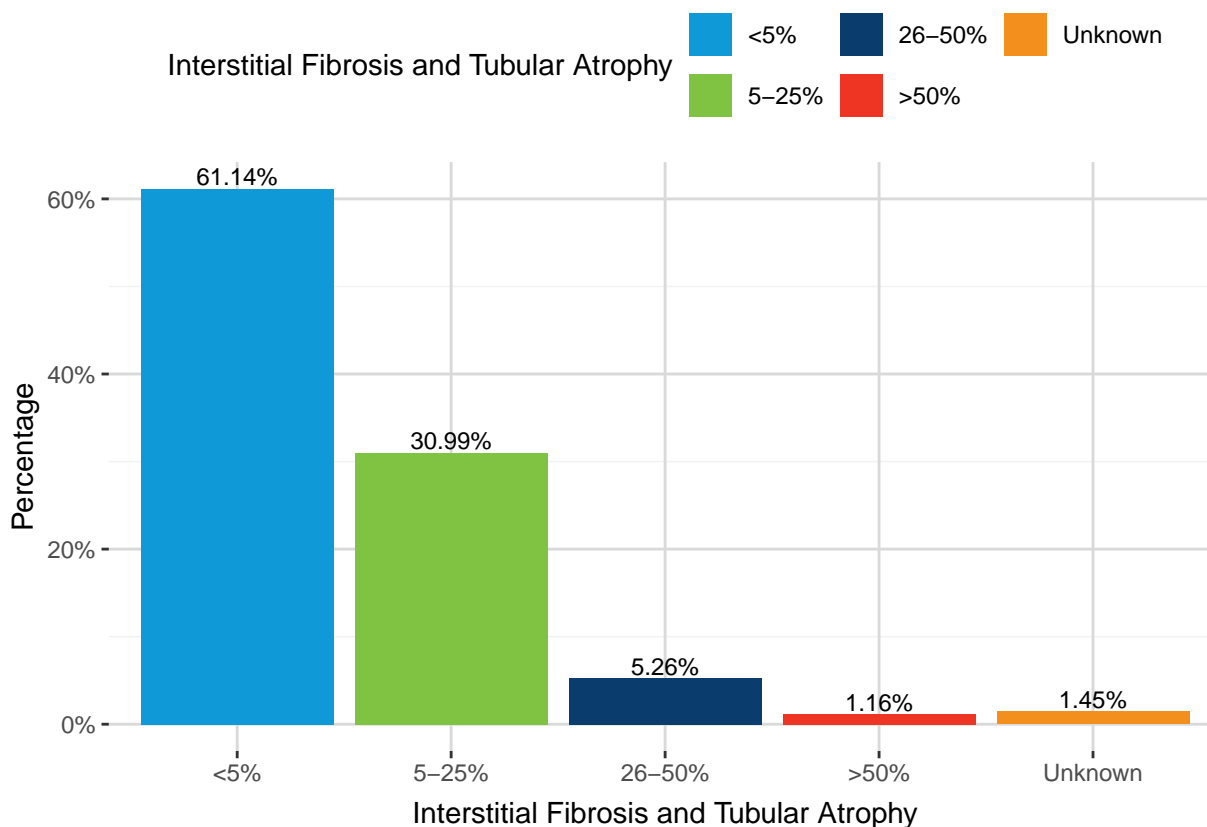


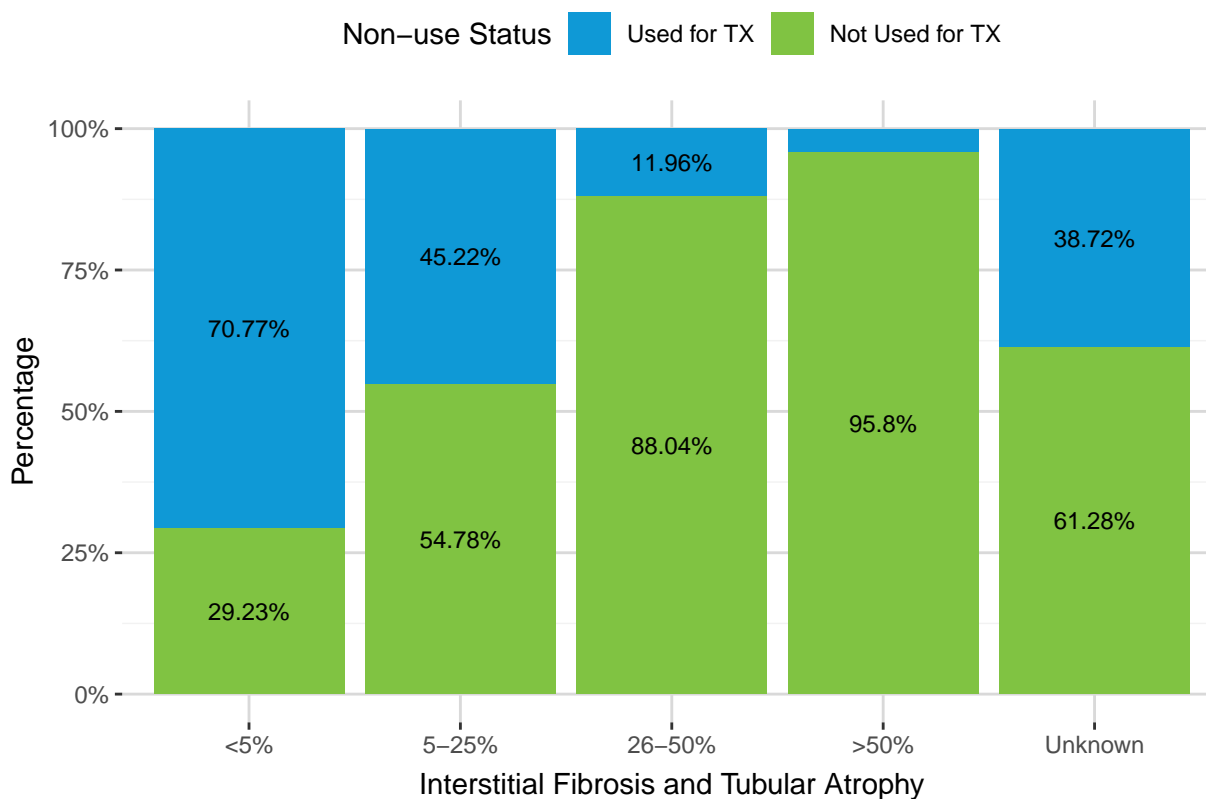
Table 11: Count and Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Interstitial Fibrosis and Tubular Atrophy (IFTA)

Interstitial Fibrosis and Tubular Atrophy	Post-policy
<5%	12,544 (61.14%)
5-25%	6,358 (30.99%)
26-50%	1,079 (5.26%)
>50%	238 (1.16%)
Unknown	297 (1.45%)
Total	20,516 (100.00%)



**Figure 10** and **Table 12** show non-use rates for deceased donor kidneys recovered in the United States by IFTA status. Donor kidneys with an IFTA >25% had the highest non-use rates, 88.04% for kidneys with an IFTA of 26-50% and 95.80% for kidneys with an IFTA of >50%.

**Figure 10: Non-use Rates for Deceased Donor Kidneys recovered in the United States by IFTA**



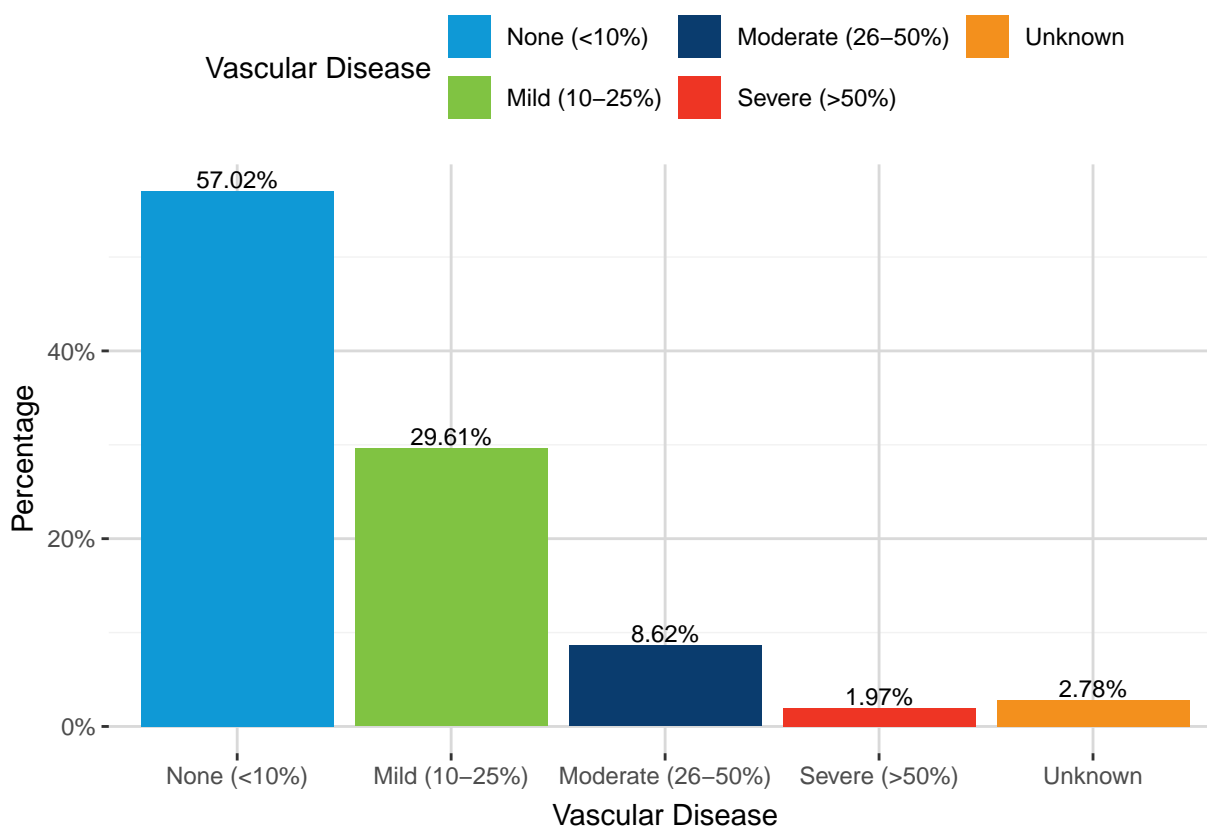
**Table 12: Non-use Rates for Deceased Donor Kidneys recovered in the United States by IFTA**

Interstitial Fibrosis and Tubular Atrophy	Used for TX	Not Used for TX	Total
<5%	8,877 (70.77%)	3,667 (29.23%)	12,544 (100.00%)
5-25%	2,875 (45.22%)	3,483 (54.78%)	6,358 (100.00%)
26-50%	129 (11.96%)	950 (88.04%)	1,079 (100.00%)
>50%	10 (4.20%)	228 (95.80%)	238 (100.00%)
Unknown	115 (38.72%)	182 (61.28%)	297 (100.00%)

## Vascular Disease

**Figure 11** and **Table 13** 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 (57.02%). Of biopsied kidneys that did show some sign of vascular disease, most showed signs of mild vascular disease (29.61%).

**Figure 11: Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Vascular Disease**

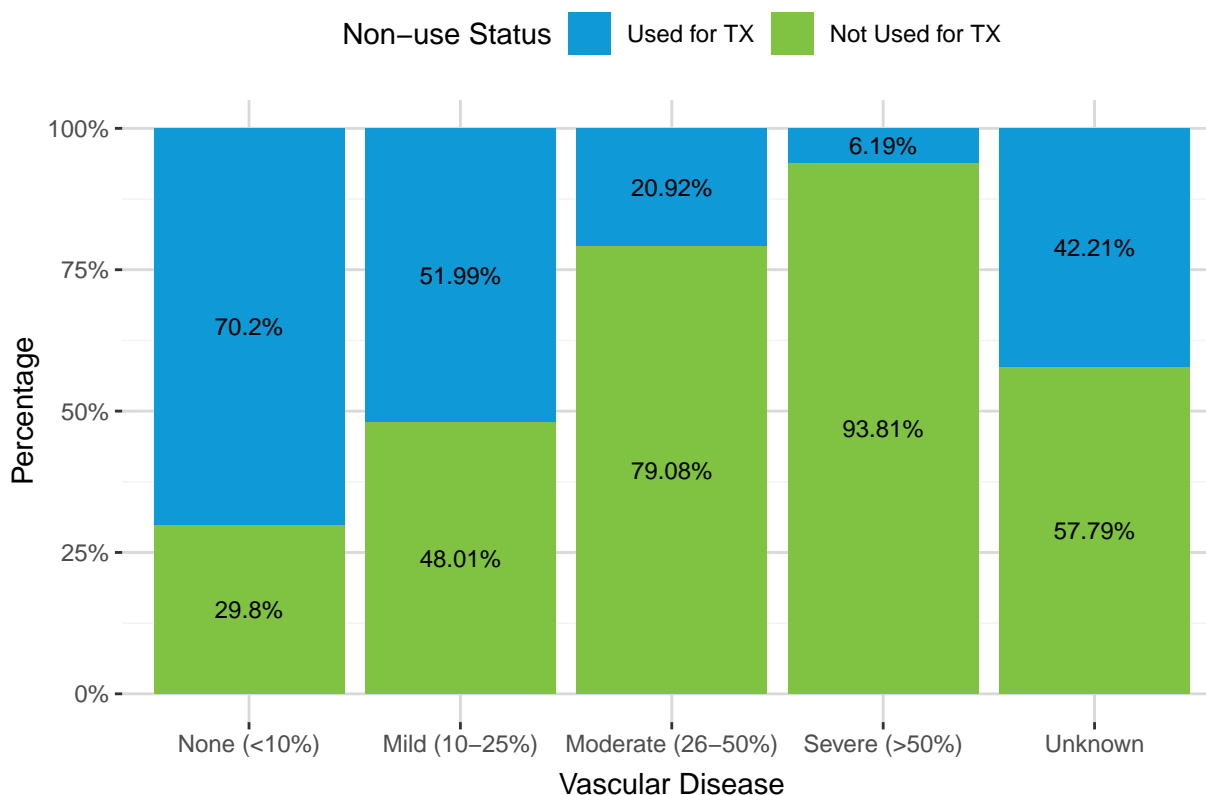


**Table 13: Count and Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Vascular Disease**

Vascular Disease	Post-policy
None (<10%)	11,698 (57.02%)
Mild (10-25%)	6,074 (29.61%)
Moderate (26-50%)	1,769 (8.62%)
Severe (>50%)	404 (1.97%)
Unknown	571 (2.78%)
Total	20,516 (100.00%)

**Figure 12** and **Table 14** show non-use rates for deceased donor kidneys recovered in the United States by vascular disease. Donor kidneys at 79.08% for kidneys with moderate vascular disease and 93.81% for kidneys with severe vascular disease.

**Figure 12: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Vascular Disease**



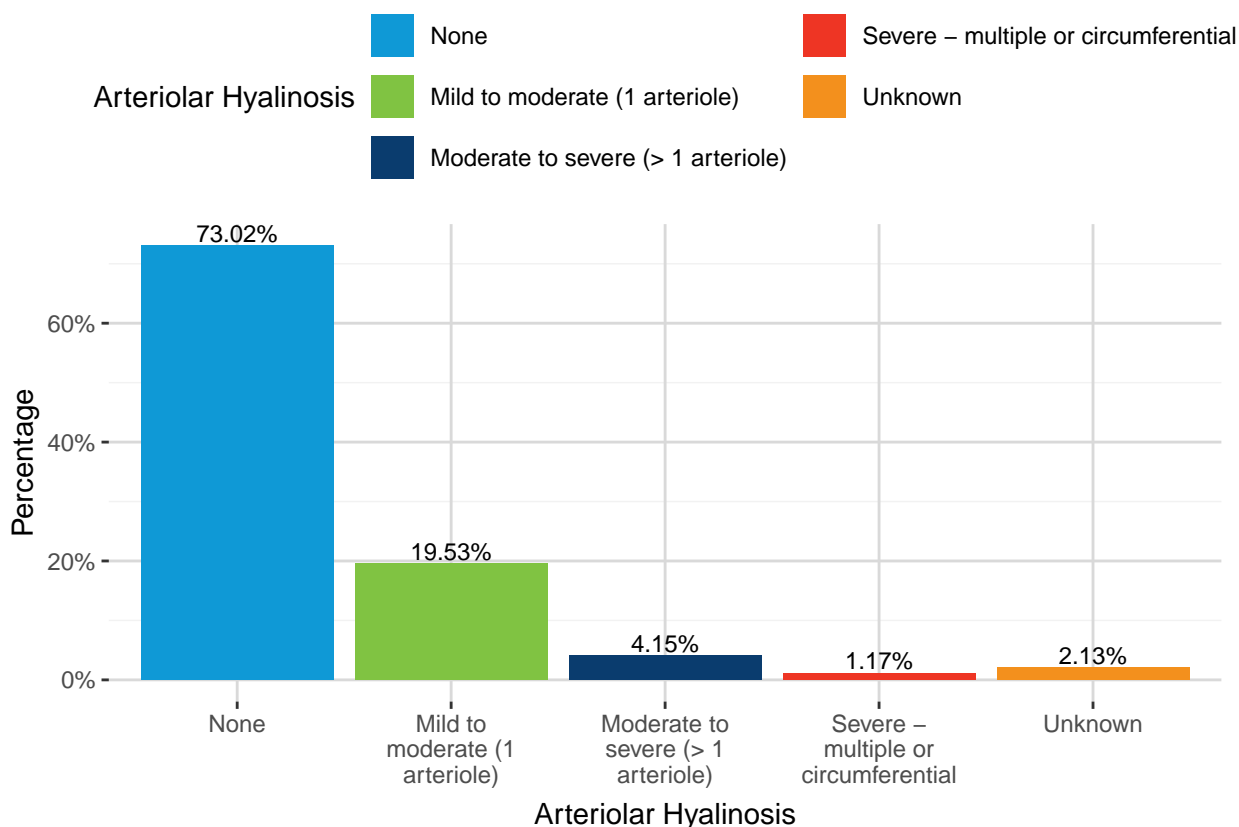
**Table 14: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Vascular Disease**

Vascular Disease	Used for TX	Not Used for TX	Total
None (<10%)	8,212 (70.20%)	3,486 (29.80%)	11,698 (100.00%)
Mild (10-25%)	3,158 (51.99%)	2,916 (48.01%)	6,074 (100.00%)
Moderate (26-50%)	370 (20.92%)	1,399 (79.08%)	1,769 (100.00%)
Severe (>50%)	25 (6.19%)	379 (93.81%)	404 (100.00%)
Unknown	241 (42.21%)	330 (57.79%)	571 (100.00%)

## Arteriolar Hyalinosis

**Figure 13** and **Table 15** 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 (73.02%). For biopsied kidneys that did show some sign of arteriolar hyalinosis, most showed signs of mild to moderate (1 arteriole) arteriolar hyalinosis (19.53% of all biopsied kidneys).

**Figure 13: Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Arteriolar Hyalinosis**

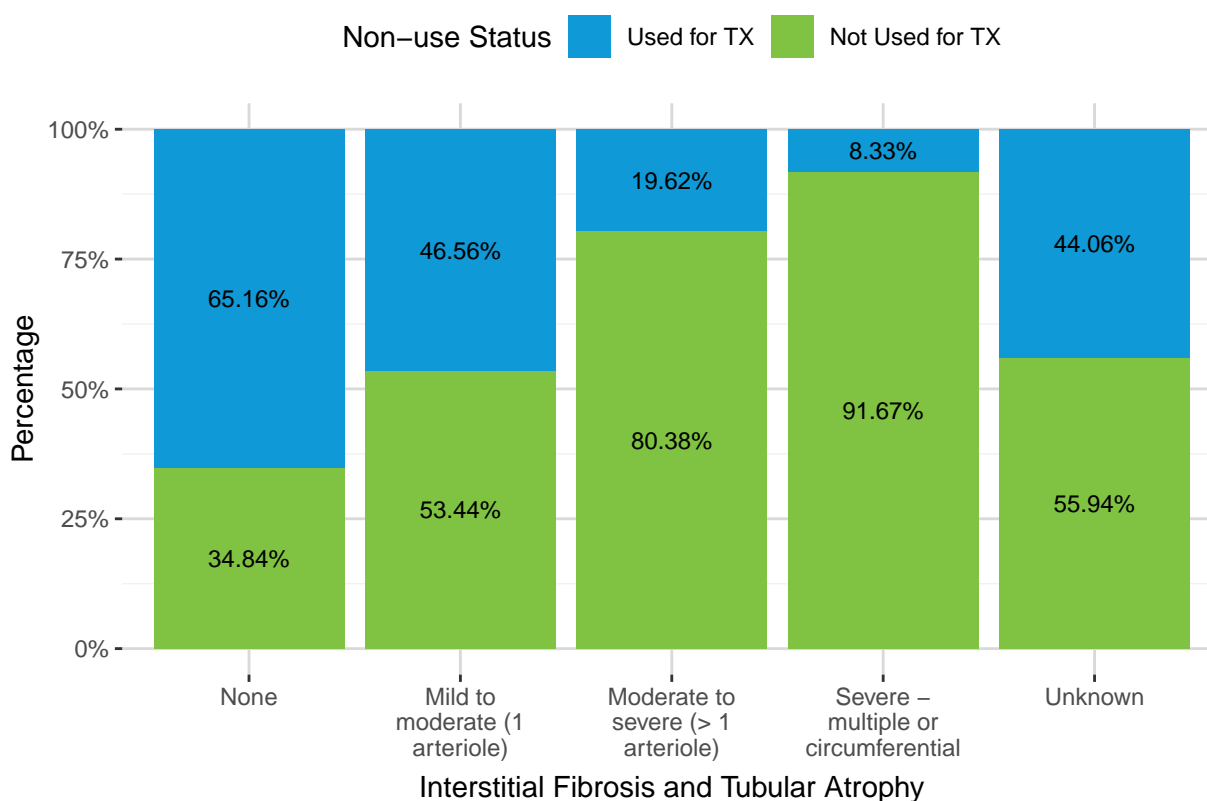


**Table 15: Count and Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Arteriolar Hyalinosis**

Arteriolar Hyalinosis	Post-policy
None	14,981 (73.02%)
Mild to moderate (1 arteriole)	4,006 (19.53%)
Moderate to severe (> 1 arteriole)	851 (4.15%)
Severe - multiple or circumferential	240 (1.17%)
Unknown	438 (2.13%)
Total	20,516 (100.00%)

**Figure 14** and **Table 16** show non-use rates for deceased donor kidneys recovered in the United States by arteriolar hyalinosis. Donor kidneys with moderate to severe (>1 arteriole) and severe arteriolar hyalinosis had the highest non-use rates, with 80.38% and 91.67% of kidneys not being used for transplant respectively.

**Figure 14: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Arteriolar Hyalinosis**



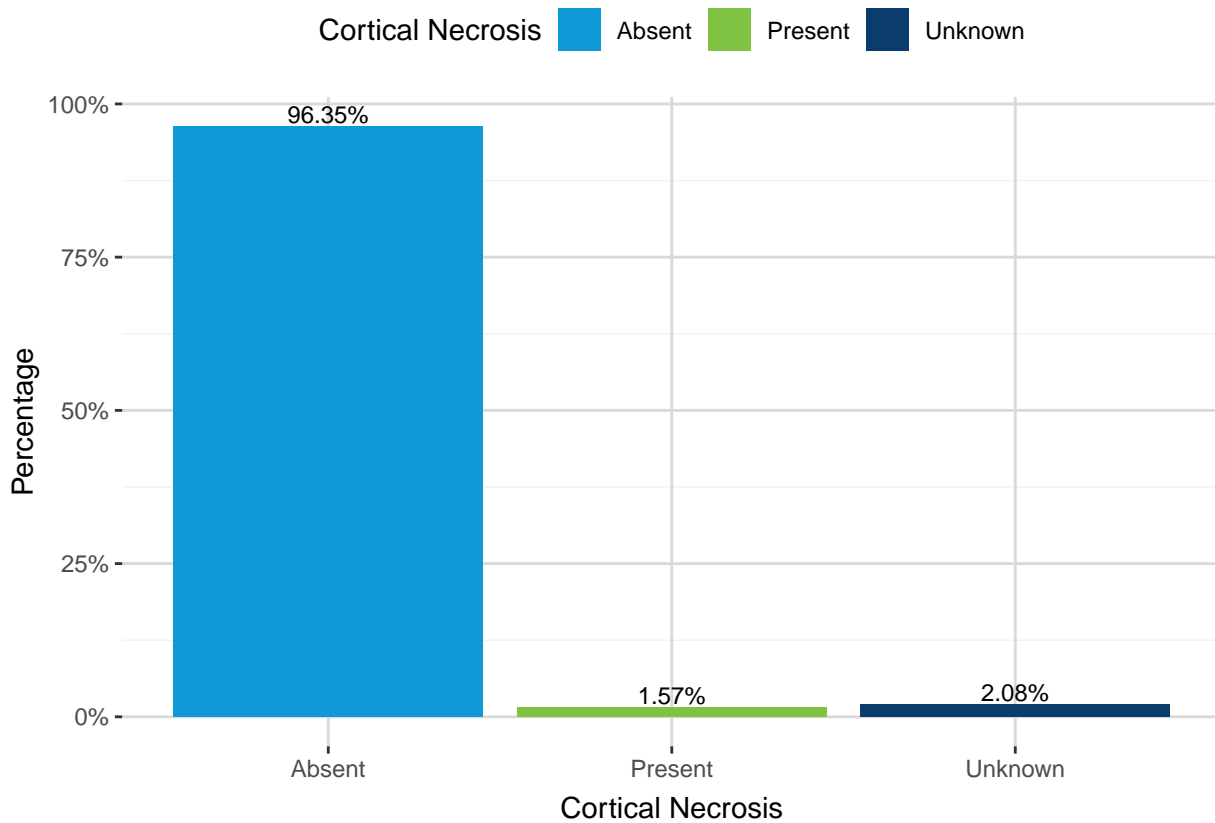
**Table 16: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Arteriolar Hyalinosis**

Arteriolar Hyalinosis	Used for TX	Not Used for TX	Total
None	9,761 (65.16%)	5,220 (34.84%)	14,981 (100.00%)
Mild to moderate (1 arteriole)	1,865 (46.56%)	2,141 (53.44%)	4,006 (100.00%)
Moderate to severe (> 1 arteriole)	167 (19.62%)	684 (80.38%)	851 (100.00%)
Severe - multiple or circumferential	20 (8.33%)	220 (91.67%)	240 (100.00%)
Unknown	193 (44.06%)	245 (55.94%)	438 (100.00%)

## Cortical Necrosis

**Figure 15** and **Table 17** show the count and percent of biopsied deceased donor kidneys recovered by cortical necrosis status. A majority (96.35%) of biopsied kidneys were labeled as absent for signs of cortical necrosis.

**Figure 15: Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Cortical Necrosis**

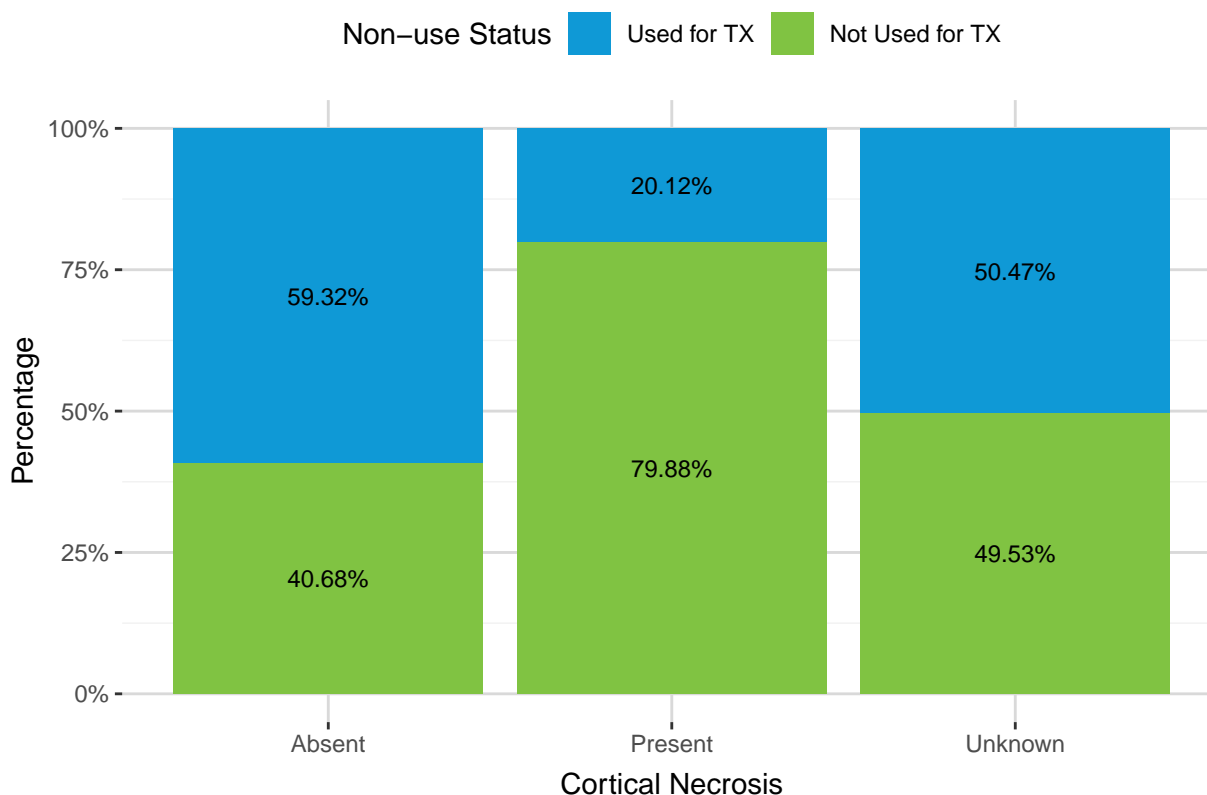


**Table 17: Count and Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Cortical Necrosis**

Cortical Necrosis	Post-policy
Absent	19,767 (96.35%)
Unknown	426 (2.08%)
Present	323 (1.57%)
Total	20,516 (100.00%)

**Figure 16** and **Table 18** show non-use rates for deceased donor kidneys recovered in the United States by cortical necrosis status. Donor kidneys absent for cortical necrosis had a non-use rate of 40.68%, whereas donor kidneys present for cortical necrosis had a non-use rate of 79.88% in the one year post-policy implementation.

**Figure 16: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Cortical Necrosis**



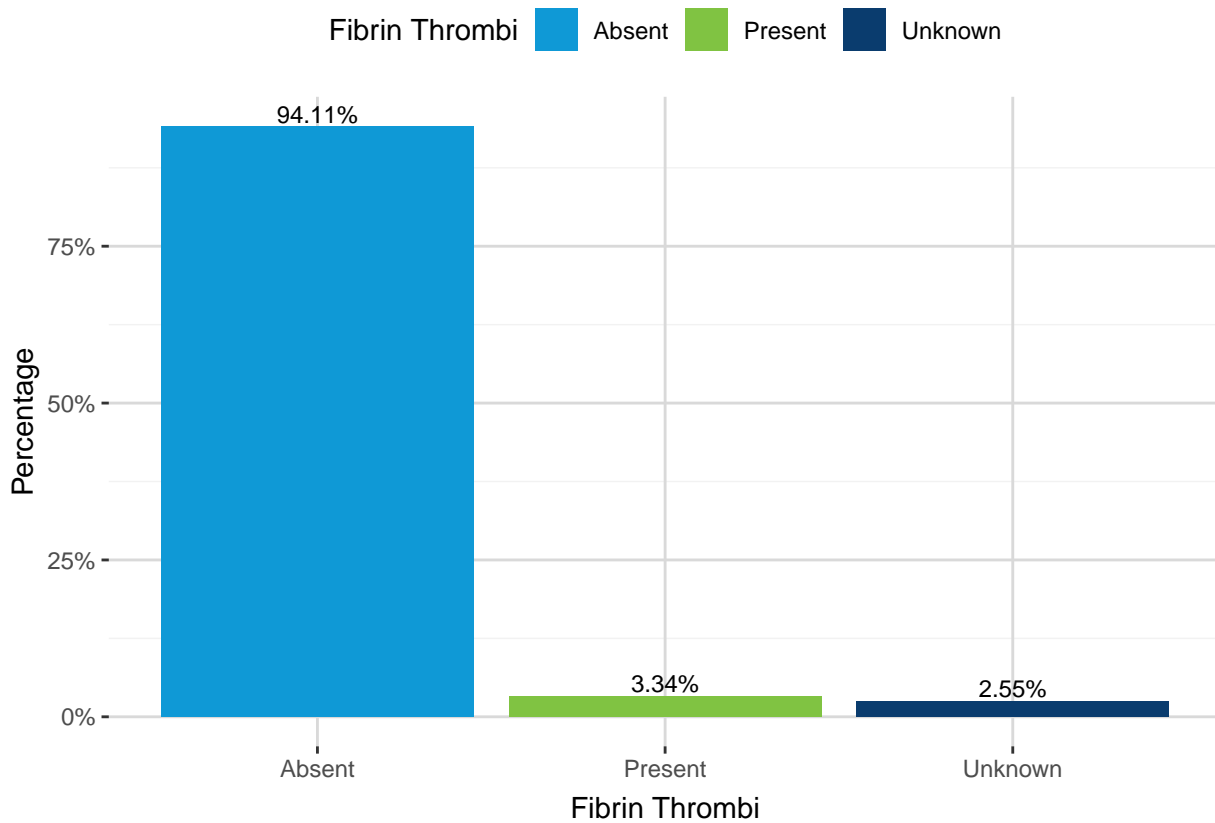
**Table 18: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Cortical Necrosis**

Cortical Necrosis	Used for TX	Not Used for TX	Total
Absent	11,726 (59.32%)	8,041 (40.68%)	19,767 (100.00%)
Present	65 (20.12%)	258 (79.88%)	323 (100.00%)
Unknown	215 (50.47%)	211 (49.53%)	426 (100.00%)

## Fibrin Thrombi

Figure 17 and Table 19 show the count and percent of biopsied deceased donor kidneys recovered by fibrin thrombi presence. A majority (94.11%) of biopsied kidneys were labeled as absent for presence of fibrin thrombi.

**Figure 17: Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Fibrin Thrombi**



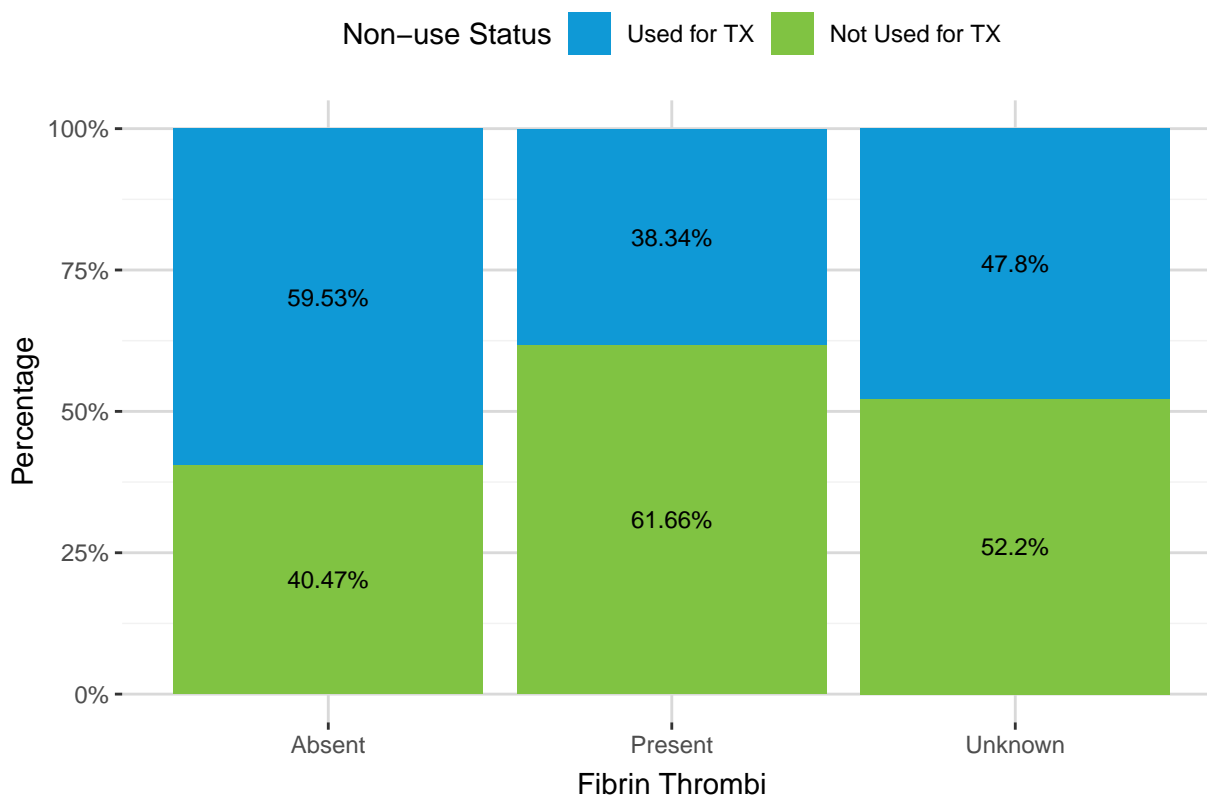
**Table 19: Count and Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Fibrin Thrombi**

Fibrin Thrombi	Post-policy
Absent	19,307 (94.11%)
Present	686 (3.34%)
Unknown	523 (2.55%)
Total	20,516 (100.00%)



**Figure 18** and **Table 20** show non-use rates for deceased donor kidneys recovered in the United States by fibrin thrombi status. Donor kidneys absent for fibrin thrombi had a non-use rate of 40.47%, whereas donor kidneys present for fibrin thrombi had a non-use rate of 61.66% in the one year after policy implementation.

**Figure 18: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Fibrin Thrombi**



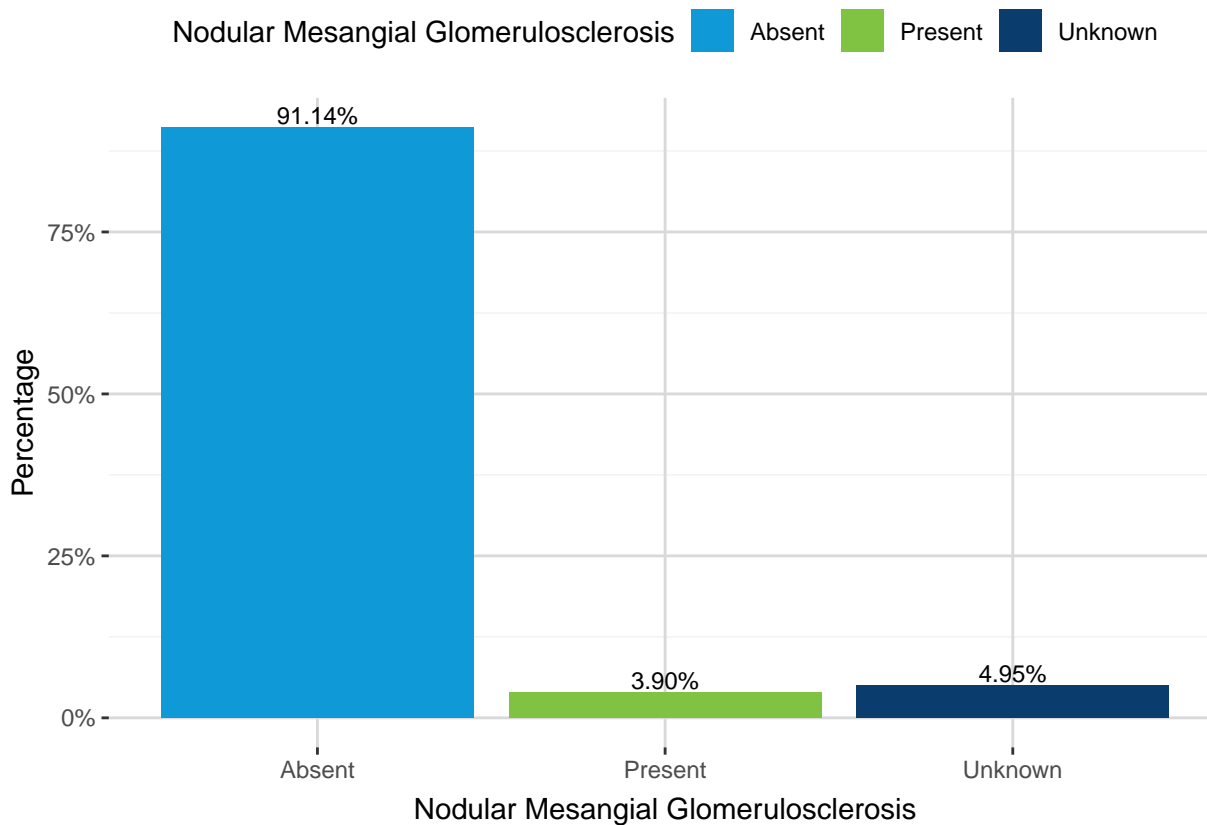
**Table 20: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Fibrin Thrombi**

Fibrin Thrombi	Used for TX	Not Used for TX	Total
Absent	11,493 (59.53%)	7,814 (40.47%)	19,307 (100.00%)
Present	263 (38.34%)	423 (61.66%)	686 (100.00%)
Unknown	250 (47.80%)	273 (52.20%)	523 (100.00%)

## Nodular Mesangial Glomerulosclerosis

**Figure 19** and **Table 21** show the count and percent of biopsied deceased donor kidneys recovered by nodular mesangial glomerulosclerosis status. A majority (91.14%) of biopsied kidneys were labeled as absent for presence of nodular mesangial glomerulosclerosis.

**Figure 19: Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Nodular Mesangial Glomerulosclerosis**

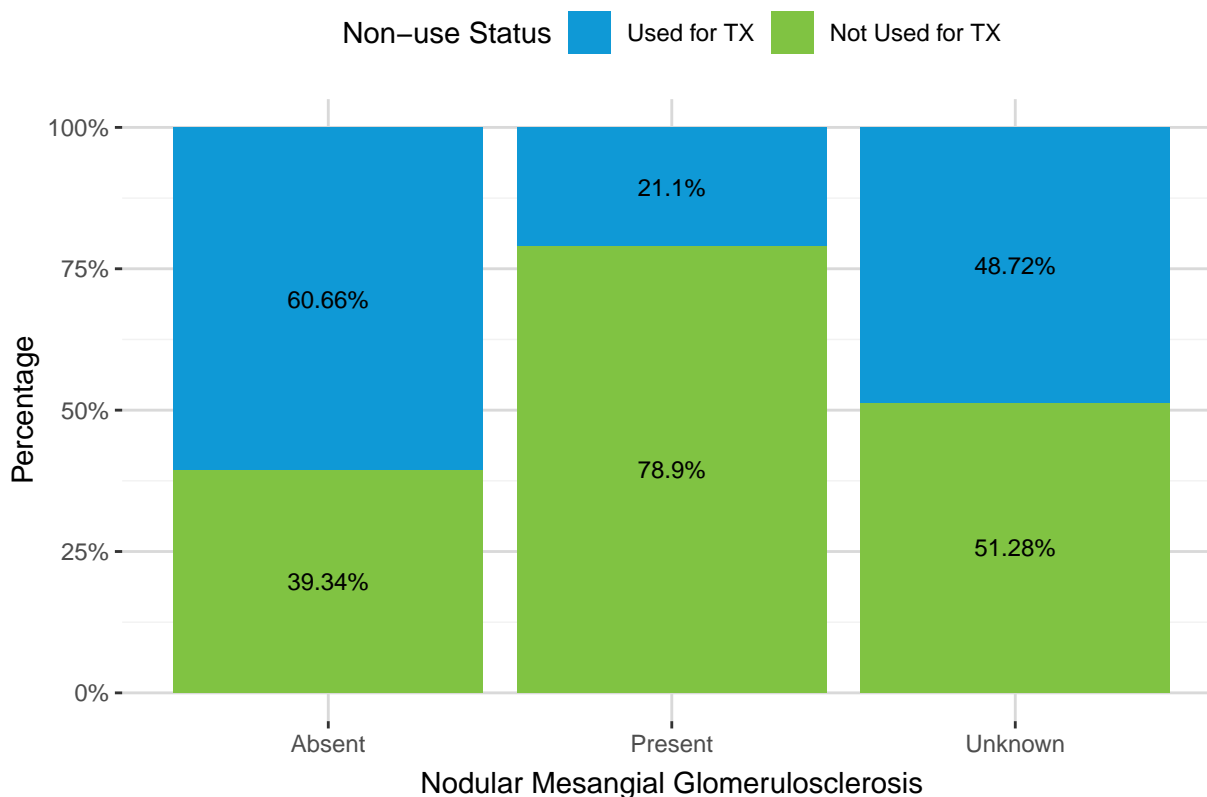


**Table 21: Count and Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Nodular Mesangial Glomerulosclerosis**

Nodular Mesangial Glomerulosclerosis	Post-policy
Absent	18,699 (91.14%)
Unknown	1,016 (4.95%)
Present	801 (3.90%)
Total	20,516 (100.00%)

**Figure 20** and **Table 22** show non-use rates for deceased donor kidneys recovered in the United States by nodular mesangial glomerulosclerosis status. Donor kidneys absent for nodular mesangial glomerulosclerosis had a non-use rate of 39.34%, whereas donor kidneys present for nodular mesangial glomerulosclerosis had a non-use rate of 78.90% in the one year post-policy implementation.

**Figure 20: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Nodular Mesangial Glomerulosclerosis**



**Table 22: Non-use Rates for Deceased Donor Kidneys recovered in the United States by Nodular Mesangial Glomerulosclerosis**

Nodular Mesangial Glomerulosclerosis	Used for TX	Not Used for TX	Total
Absent	11,342 (60.66%)	7,357 (39.34%)	18,699 (100.00%)
Present	169 (21.10%)	632 (78.90%)	801 (100.00%)
Unknown	495 (48.72%)	521 (51.28%)	1,016 (100.00%)

## Biopsy Results

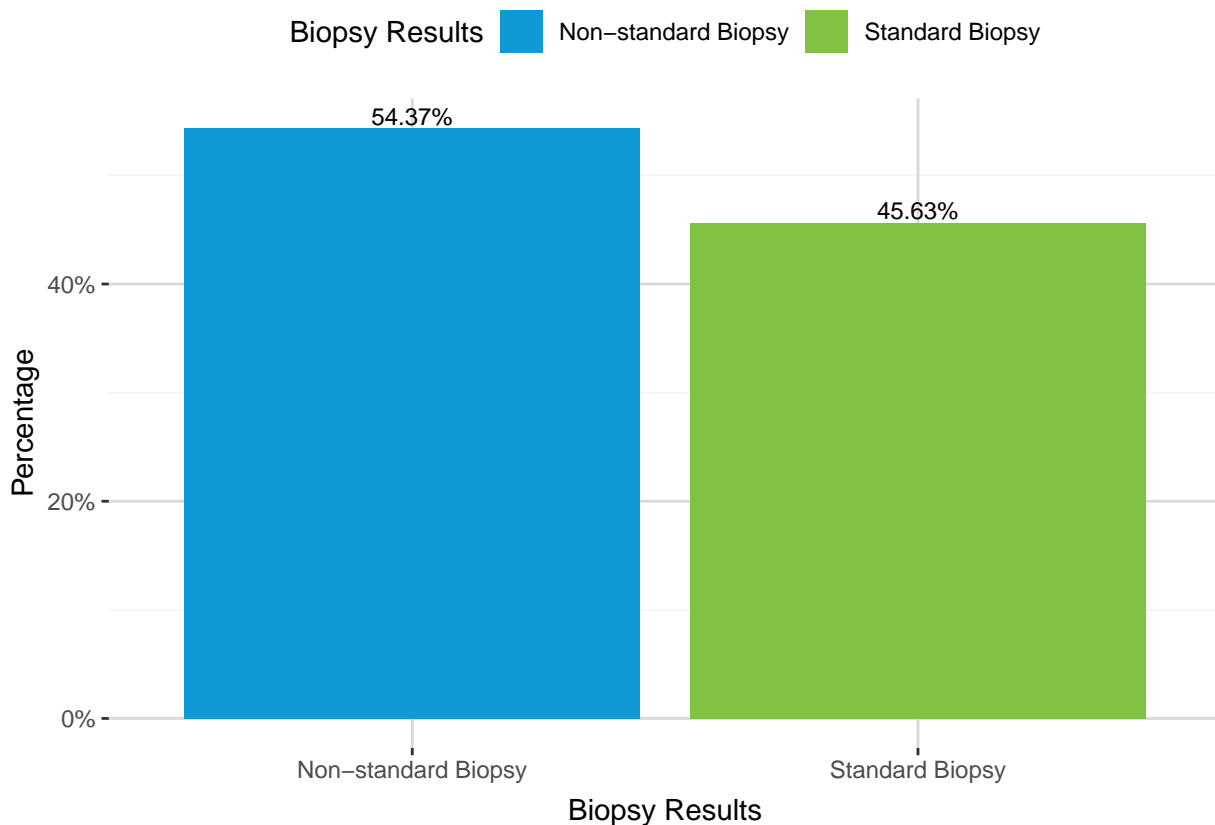
**Figure 21** and **Table 23** show the count and percentage of biopsied kidneys by biopsy results. A standard biopsy result was defined in discussion with the committee while reviewing the six month monitoring report of this policy, the committee decided on the following definition.

A standard biopsy result is defined as a biopsied kidney having the following results:

- Percent Globally Sclerotic Glomeruli  $\leq 10\%$
- Vascular Disease = None ( $<10\%$ ) or Mild (10-25%)
- Arteriolar Hyalinosis = None or Mild to Moderate (1 Arteriole)
- Cortical Necrosis = Absent
- Fibrin Thrombi = Absent
- Nodular Mesangial Glomerulosclerosis = Absent
- IFTA  $<5\%$

In total, 9,361 (45.63%) biopsied kidneys in the post-policy era met this definition of standard biopsy results.

**Figure 21: Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Biopsy Results**

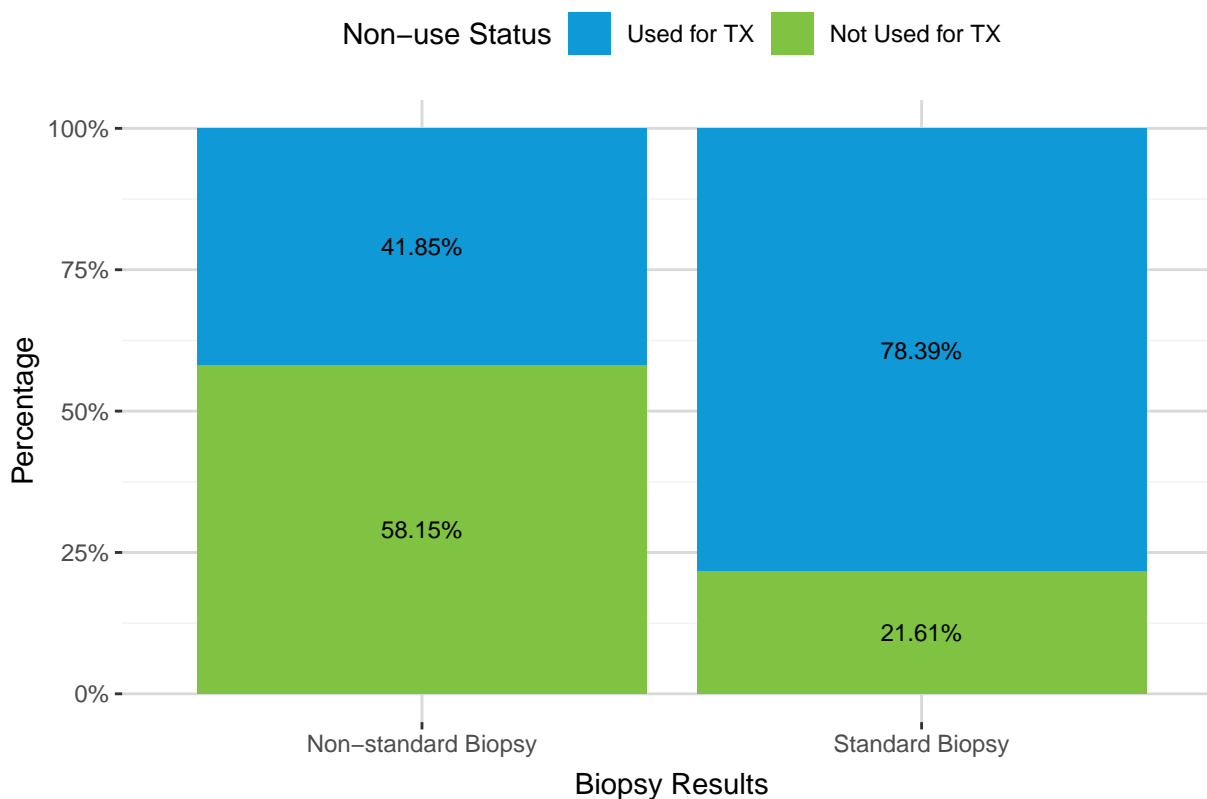


**Table 23: Count and Percentage of Biopsied Deceased Donor Kidneys recovered in the United States by Biopsy Results**

<b>Biopsy Results</b>	<b>Post-policy</b>
Non-standard Biopsy	11,155 (54.37%)
Standard Biopsy	9,361 (45.63%)
Total	20,516 (100.00%)

**Figure 22** and **Table 24** show the non-use rates for deceased donor kidneys recovered in the United States by biopsy results. Kidneys that had standard biopsy results were not used for transplant 21.61% of the time. Biopsied kidneys with non-standard biopsy results were not used for transplant 58.15% of the time.

**Figure 22: Non-use Rate of Biopsied Deceased Donor Kidneys recovered in the United States by Biopsy Results**



**Table 24: Non-use Rate of Biopsied Deceased Donor Kidneys recovered in the United States by Biopsy Results**

Biopsy Results	Used for TX	Not Used for TX	Total
Non-standard Biopsy	4,668 (41.85%)	6,487 (58.15%)	11,155 (100.00%)
Standard Biopsy	7,338 (78.39%)	2,023 (21.61%)	9,361 (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 reporting 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. Wedge biopsy was the most common biopsy type in both the pre- and post-policy eras. A majority of biopsied kidneys did not report findings of Interstitial Fibrosis and Tubular Atrophy (IFTA), vascular disease, arteriolar hyalinosis, cortical necrosis, fibrin thrombi or nodular mesangial glomerulosclerosis in the post-policy era.

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