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# The Role of Procurement Biopsies in Kidney Acceptance Decision Making and Kidney Discard: Perceptions of Physicians, Nurse Coordinators, and OPO Staff and Directors

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**Background.** Procurement biopsies suffer from challenges with quality and reproducibility and are linked to kidney discard. Nonetheless, procurement biopsies are obtained for the majority of kidneys in the United States, and biopsy findings are commonly relied upon in kidney acceptance decisions. **Methods.** We conducted in-depth, semistructured interviews with 30 surgeons, nephrologists, nurse coordinators, and organ procurement organization (OPO) staff and directors to assess perceptions of factors contributing to kidney discard and strategies to reduce kidney discard, with a focus on the role of procurement biopsies. Thematic analysis was used to analyze qualitative data. **Results.** Three main themes emerged: (1) participants emphasized the importance of biopsy findings in making acceptance decisions but expressed concerns about a lack of standardization and quality control; (2) participants reported large variations in the level of importance placed on biopsy findings, the level of reliance on glomerulosclerosis in particular, and the cutoffs used; and (3) participants disagreed about how often procurement biopsies should be taken, with some supporting stricter limits on which kidneys are biopsied and others preferring a biopsy for most kidney offers. **Conclusions.** These findings support the development of standard practices for which kidneys require biopsy, how the biopsy material is prepared, and how the biopsy is interpreted. Variability in kidney acceptance practices across centers and the use of biopsy findings in guiding recipient selection also lend support to policies to allocate kidneys with suboptimal histological findings to the centers that are willing to use such kidneys and the patients who could most benefit from such offers.

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Approximately 20% of deceased donor kidneys are discarded in the United States each year despite the shortage of organs for transplantation.[1] Patients who died on the waiting list between 2008 and 2015 received a median of 16 kidney offers, the majority of which were declined by transplant centers on patients' behalf because of quality concerns.[2]

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Biopsy results are the most commonly cited reason why transplant centers decline kidneys.[3] A study comparing outcomes between kidneys with optimal and suboptimal histology scores found that although kidneys with optimal scores lasted the longest, 73.2% of the deceased donor kidneys with suboptimal scores remained functional at 5 y posttransplant.[4] This suggests that transplantation with such kidneys may still offer a significant benefit to patients.

The use of procurement biopsies in kidney acceptance decision making was popularized when Gaber et al[5] found an association between glomerulosclerosis >20%, delayed graft function, and poor graft function in 1995. However, this study suffered from flaws in the research design, and the 20% threshold has not been validated in subsequent studies.[6] A 2015 systematic review of research on the relationship between procurement biopsy findings and transplant outcomes found mixed results.[7] Other research found that increases in Leuven score (a measure based on donor age and biopsy findings) were associated with increased risk of 3-y allograft failure; however, the effect was not statistically significant after controlling for kidney donor risk index.[8] This suggests that although there is an association between biopsy results and transplant outcomes, procurement biopsies may not provide added predictive value beyond the donor history.

Despite the mixed evidence, over half of deceased donor kidneys in the United States are biopsied.[7,9] Performing procurement biopsies can delay acceptance decisions and increase cold ischemic time, increasing the risk of discard. A recent study examining variations in biopsy practices of organ procurement organizations (OPOs) across the United States found that having a procurement biopsy was associated with an overall 3.5-fold increase in the odds of discard, after adjusting for kidney donor profile index (KDPI) and other donor risk factors.[9] Comparisons with the French system also suggest that use of procurement biopsies in kidney acceptance decision making may contribute to the high discard rate observed in the United States.[10] One study found that nearly 45% of kidneys discarded in the United States because of histological findings could be matched with similar kidneys that were transplanted in France, where preimplementation biopsies are taken to aid in the clinical management of patients posttransplant but are not part of kidney acceptance decision making.[11]

Studies also indicate a lack of standardization in how biopsies are performed, interpreted, and reported.[12] The reproducibility of initial biopsy findings in kidneys that underwent multiple procurement biopsies is weak.[13-15] Whether or not procurement biopsy findings are associated with graft outcomes seems to depend on the training of the pathologist performing the biopsy and the type of biopsy method.[15,16] Improving the quality of procurement biopsies could help to increase their clinical utility, but researchers have also suggested limiting the use of procurement biopsies given their strong association with discard.[8,9,11,14,15] There are few qualitative studies examining clinician and OPO perceptions on how the use of procurement biopsies in kidney acceptance decision making impacts kidney discard. Our study examined surgeons', nephrologists', nurses', and OPO staff's and directors' perceptions of the reasons kidneys are declined at the center level and strategies to reduce kidney discard at the national level, specifically focusing on the role of procurement biopsies in kidney acceptance decision making and kidney discard.

## MATERIALS AND METHODS

This is a qualitative, cross-sectional study. The standards for reporting in qualitative research checklist was used to ensure quality reporting of qualitative research.[17]

### Sample and Recruitment

Participants were eligible if they were directly involved in pretransplant clinical care and kidney allocation. Participants included surgeons, nephrologists, nurse coordinators, and OPO staff and directors. Although surgeons typically make decisions about accepting kidneys for transplantation, nephrologists may be involved and can offer key insights into the acceptance practices at their transplant centers. Likewise, nurse coordinators were included based on their involvement in screening kidney offers and their ability to provide insight into the overall acceptance practices at their transplant centers. OPO staff and directors were included to provide a system-level perspective from their experiences obtaining procurement biopsies and placing kidneys with adverse histological findings.

Surgeons and nephrologists were recruited from a list of Organ Procurement and Transplantation Network (OPTN) committee members and transplant center medical directors and purposively selected to obtain a diverse sample by sex, race/ethnicity, and geographic location. Nurses from 5 transplant centers and OPO staff from 2 OPOs were identified by members of the project's Scientific Advisory Board and participated in interviews. These participants were then asked whether they would be willing to identify additional nurses or OPO staff who may be willing to participate in the study. Seven additional OPO staff and 5 additional nurses were identified in this manner. Invitations were sent via email. Interviews were conducted over the phone or via zoom per participant preference. Institutional Review Board approval was obtained from Northwestern University (STU00208614) and all participants provided verbal informed consent.

### Data Collection Methods

A research associate/project coordinator (K.S.) conducted semistructured, in-depth interviews with surgeons, nephrologists, nurse coordinators, and OPO staff and directors. Interviews were conducted during July to December, 2020. Interview guides for physicians, nurses, and OPO staff and directors were developed on the basis of the literature on the kidney allocation system and kidney discard and formative interviews with 10 transplant clinicians and administrators.[3,18] The interview guides were pilot tested through cognitive "think aloud" interviews with 3 surgeons, 3 nephrologists, 4 nurses, and 4 OPO staff and directors. Cognitive interview participants were asked to explain their thought process as they interpreted and responded to the questions; their feedback was used to enhance question clarity and order.[19]

The interviews focused on kidney acceptance decision making and strategies to reduce kidney discard at the transplant center, OPO, and national level. The physician interviews included questions about how physicians evaluate kidney quality, when a biopsy is needed, and how biopsies are used to aid in decisions about whether to accept a kidney for transplantation. The nurse interviews included questions about the process for screening kidney offers and contacting patients on the match run and the factors that commonly lead to their centers turning down kidney offers. OPO interviews included questions about

the factors that make kidneys hard to place, how OPOs determine which kidneys to biopsy, and how biopsy findings affect centers' acceptance of kidney offers. Additional questions in the physician and nurse interviews focused on patient education practices. The data on patient education were used for a separate analysis. Demographic information was collected at the end of each interview. Interviews lasted approximately 1 h and were audio-recorded. Participants were compensated $100 US. Interview guides were uploaded as supplementary materials.

### Analysis

Audio recordings were transcribed and then analyzed thematically, using inductive and deductive coding methods.[20] We reached the point of saturation—when no new themes were identified.[21] The analysis team (K.S., U.L., M.R.) engaged in reflexivity by identifying personal areas of subjectivity, potential sources of role conflict, and interests of gatekeepers in the field that could influence data collection and analysis.[22] The analysis team developed initial deductive codebooks for physicians, nurses, and OPO staff/directors based on the interview guides. After coding the first set of transcripts, the analysis team revised the codebooks, adjusting for new responses. All transcripts were then independently coded by 2 analysis team members (K.S. and U.L. or M.R.), using NVivo qualitative analysis software.[23] Analysis team members achieved an inter-rater reliability of Kappa >0.9 and met to resolve discrepancies and reach consensus for codes with Kappa <0.9. Analysis team members then identified emergent patterns in the data and generated themes from these patterns.[24]

## RESULTS

A total of 30 respondents participated. Participants included 9 surgeons, 6 nephrologists, 8 nurses, and 7 OPO staff and directors. The participation rate for physicians was 26% (57 physicians received an email invitation to participate in an interview; 15 completed the interview.) Five of the 7 OPO staff/directors and 3 of the 5 nurses identified by the initial nurse and OPO participants completed an interview. Participation rates were not calculated for nurses or OPO staff and directors because they were identified through snowball sampling. All 11 OPTN regions were represented. Participant demographics are presented in Table 1.

Three main themes were identified: (1) participants emphasized the importance of biopsy findings in making acceptance decisions at the center level and in placing kidneys at the OPO level but expressed concerns about a lack of standardization and quality control; (2) participants reported large variations in the level of importance placed on biopsy findings, the level of reliance on glomerulosclerosis in particular, and the cutoffs used; (3) participants disagreed on how often procurement biopsies are needed, with some supporting stricter limits on which kidneys are biopsied and others preferring to obtain a biopsy for most kidney offers. Representative illustrative quotations are presented in Table 2.

**TABLE 1.**

**Participant demographics**

| Category | N (%) |
|---|---|
| Specialty | |
| Surgeon | 9 (30) |
| Nurse | 8 (27) |
| Organ procurement organization | 7 (23) |
| Nephrologist | 6 (20) |
| Gender | |
| Male | 16 (53) |
| Female | 14 (47) |
| Race | |
| White | 22 (73) |
| Asian | 4 (13) |
| African American or Black | 2 (7) |
| Other | 2 (7) |
| Ethnicity | |
| Not Hispanic or Latino | 25 (83) |
| Hispanic or Latino | 5 (17) |
| Organ Procurement and Transplantation Network region | |
| Region 1 | 2 (7) |
| Region 2 | 3 (10) |
| Region 3 | 3 (10) |
| Region 4 | 2 (7) |
| Region 5 | 5 (17) |
| Region 6 | 2 (7) |
| Region 7 | 5 (17) |
| Region 8 | 2 (7) |
| Region 9 | 2 (7) |
| Region 10 | 2 (7) |
| Region 11 | 2 (7) |
| Clinician y of experience | |
| <10 | 6 (26) |
| 10–20 | 10 (44) |
| >20 | 7 (30) |
| Clinician center volume (kidney transplants/y) | |
| <100 | 3 (13) |
| 100–199 | 7 (30) |
| ≥200 | 13 (57) |

### Participants Emphasized the Importance of Biopsy Findings in Making Acceptance Decisions at the Center Level and in Placing Kidneys at the OPO Level but Expressed Concerns About a Lack of Standardization and Quality Control

Six of 7 nurses who discussed screening kidney offers cited biopsy findings as a key deciding factor. Ten of 15 physicians named biopsy findings as a key factor when asked how they decide to code out on a kidney offer. When asked directly about the role of biopsy in kidney acceptance practices of their centers, all 15 physicians stated that biopsy plays an important role. All of the 7 OPO staff and directors perceived that transplant centers typically place high importance on biopsy findings.

Physicians and nurses were cognizant of quality issues with procurement biopsies. The majority of physicians (n = 12) and half of nurses (n = 4) raised concerns with a lack of standardization and quality control in how biopsies are taken and interpreted, and they reported requesting biopsy slides or even redoing biopsies at their center. For example, a nurse reported that her center did not "trust" biopsy reports of all OPOs:

> *We trust [our local OPO] and their biopsy reads, but we don't trust every OPO. And so, actually being able to give us those images so that we can review them ahead of time, because I've seen us turn down kidneys based on cold time or even sometimes, less often, but like if we can't see the biopsy slides ourselves. (participant 63, female, nurse)*

Physicians and nurses also pointed out challenges with the accuracy of frozen sections, variations in the size of samples

**TABLE 2.**

**Representative illustrative quotations**

| Physician quotes | Organ procurement organization staff quotes | Nurse quotes |
|---|---|---|
| Theme 1: lack of standardization and quality control | | |
| "... sometimes we have to, the biopsies are kind of unclear and are even good looking but the history is so extensive that we cannot completely rely on the biopsy that is done outside so we have to rereview the biopsy and rebiopsy whatever it is." (participant 32, male, surgeon) | "... the kidney once it arrived at its destination, that center rebiopsied and obtained a different result. And now at that point, I mean, to me, it's like, well, you have 2, how do you weigh them? Right, but obviously, there they went by their new biopsy result, and the kidney was discarded." (participant 62, male, OPO staff) | "... the biopsy made no sense. So, then we actually asked our OPO if they can take the slides and send it to the pathologist they usually use for the OPO. And then he reread it there and had a totally different reading, but some that was more consistent. We've also wised up to figure out you know what type of pathologist is reading this biopsy, because there's a lot of discrepancies between pathologists and their reads." (participant 47, female, nurse) |
| "... the biopsies that are done well and read by renal pathologists here and that we could look at ourselves don't really correlate well with the biopsies done elsewhere." (participant 43, male, surgeon) | | |
| "Well, biopsies are a blessing and a curse also because the biopsy always looks worse than I think the true quality of the kidney." (participant 49, male, surgeon) | | "So one of the primary concerns that we always have is that if a biopsy of a kidney has been done at a rural hospital in somewhere that's nowhere near a transplant center in the middle of the night, then the pathologist probably has to come and do it again anyway, and the sample's got 20 cells or less. I mean, like what are we really looking at here?" (participant 57, female, nurse) |
| Theme 2: variations between centers and physicians in terms of reliance on biopsy, how they use glomerulosclerosis and what cutoffs, if any, they use | | |
| "So, you know if I think the organ is really marginal and I'm uncertain that it's transplantable and the biopsy comes back pretty good, then I'm happy and I'll use that biopsy favorably. But if all the other data is positive and something that I would transplant without a biopsy and the biopsy comes back and I'm you know I don't think that it truly represents um what is a quality kidney then I ignore the biopsy." (participant 31, male, surgeon) | "... our kind of magical number where it becomes more difficult with biopsies is less than 20 percent. If it's greater than 20 percent, we have glomerulosclerosis count greater than 20 percent is when we start seeing a lot of transplant centers starting to code out." (participant 61, male, OPO staff) | "... it's generally the final creatinine and how it got there, but also then the end-all is the pathology from the biopsy." (participant 44, female, nurse) |
| "We always rely on the biopsy. It's critical. As seen from the 3 parameters, forget about the KDPI and biopsy is the most important one because it's the kidney tissue and tells us about the prognosis." (participant 46, male, surgeon) | | "So cold ischemic time and glomerulosclerosis percentage greater than um 12 or 15 I think are automatically rule-outs." (participant 34, male, nurse) |
| | | "You want glomerulosclerosis less than 20% and no necrosis on the biopsy, and no diabetic changes." (participant 53, female, nurse) |
| Theme 3: disagreement about when to biopsy and whether or not the use of procurement biopsies should be limited to reduce discard | | |
| "My personal take on this is that I think biopsies are being used to rule out kidneys, and I think we should be using them to rule in kidneys. So we should be using biopsies in a small minority of cases, where we are concerned about the kidney quality enough based on clinical characteristics that we're looking for a reason to use the kidney." (participant 51, male, nephrologist) | "... they'll request a biopsy and we rarely turn down a request to biopsy, so we don't have specific biopsy criteria, because our centers are requesting it." (participant 48, female, OPO staff) | "... so one of the strategies that we've tried to kind of be all on the same page about is staying in the game a little bit longer, and if the OPO is willing to pump or biopsy don't just code out based upon, you know, the donor's creatinine, or the presence of diabetes or age, let's wait till we have a little bit more information. And I think that has helped us because there have been some kidneys that sound really bad on paper but then when the kidneys come out the biopsy looks good, they are pumping really well, the visualization looks good and we've had great success with those." (participant 47, female, nurse) |
| "Not ask for a biopsy? I would say KDPI less than 50 with normal creatinine. Then I would be surprised to print out a biopsy. I would be happy to look at it if we did, but, you know, the better the kidney, the less the biopsy is useful." (participant 41, female, nephrologist) | "... over the age of 60, if they're DCD over the age of 50, history of stroke or cause of death is stroke, history of hypertension, an elevated creatinine greater than 1.5, history of kidney disease, sometimes there may be like a mention that there's some type of kidney disease, but their function doesn't reflect that. So usually we'll biopsy any anatomical abnormality or mass, and sometimes just by transplant center preference, because they just requested to due to their own guidelines, we typically do it." (participant 56, female, OPO staff) | |
| "I only use a biopsy to rule in an organ that is really marginal. I try and avoid when I have the option to for a local donor to get a biopsy altogether. Because I think the biopsies are you know, sort of overcall and over influence the desire to discard an organ." (participant 31, male, surgeon) | "I think they definitely impact most of our kidney discard. I just looked at our year to date data and um almost all of them were due to biopsy results." (participant 48, female, OPO staff) | "we actually go back and look at all the biopsies because we want to focus on "are we throwing away kidneys that could be transplanted?" and so we have different pathologists, we are trying to get, like one consistent pathologist that reviews all of our biopsies so that we don't have the randomization of different pathologists and different readings and so, we do that as a control to see if we are throwing away kidneys that we shouldn't be." (participant 44, female, nurse) |

DCD, donation after circulatory death; KDPI, kidney donor profile index; OPO, organ procurement organization.

taken, and a lack of qualified renal pathologists to interpret biopsies at some donor hospitals:

> *... a frozen section biopsy has been proven over and over again to be poorly diagnostic of a quality organ ... as currently in place the people that are reading the biopsies are probably not fully qualified to read those biopsies. I think that it probably continues to do more harm than good in transplanting particularly these marginal organs. (participant 31, male, surgeon)*

All 7 OPO staff and directors acknowledged inconsistencies in the quality of biopsies across different OPOs. They understood why centers might feel that they need to redo biopsies in some cases. However, they expressed concern that this can lead to kidneys being unnecessarily discarded:

> *I think that the different practices at all the different OPOs result in some transplant centers, you know, implementing practices like this [redoing the biopsy], and it just seems to me*

*it seems like it would be preventable easily if we had some sort of national guidelines we all agreed on what a biopsy, who could read, you know—what would be a qualified biopsy read. All of this kind of stuff so that we don't have to retest and retest until we get a bad result. (participant 58, male, OPO)*

### Significant Variation in Level of Reliance on Biopsy Findings, Importance Placed on Glomerulosclerosis, and the Cutoffs Used, If Any

Nurses and physicians pointed out major variations in terms of how much importance different transplant centers and different physicians placed on biopsy findings. All 7 OPO staff and directors noted that adverse biopsy findings make kidneys much harder to place. However, they also found that some centers weigh biopsy more heavily than others:

*... certain programs, and certain surgeons just want to know what the clinical picture is, independent of biopsies, others are very dependent on biopsies. (participant 59, male, OPO staff)*

Physicians in the sample were split regarding how much weight they gave to biopsy findings. Just over half (n = 8) considered biopsy findings to be one of the most important factors in their kidney acceptance decision making. Physicians in this group commonly noted that biopsy is a snapshot of the tissue of the kidney, whereas KDPI is a calculation and might not indicate the true quality of the kidney:

*Biopsy for me is an even bigger deal than KDPI in regards to what the quality of the organ is, so if the biopsy is not good, then I might decline it at that point. (participant 45, female, surgeon)*

The other 7 physicians described biopsy as a piece of the puzzle but not the most important piece of information. Physicians in this group noted that they would decline offers when poor biopsy findings aligned with the donor history or the kidneys were also pumping poorly. In contrast, they were willing to use kidneys with some adverse biopsy findings if other factors were positive:

*Usually we're not turning down until we get some pump criteria, and if the kidney, the biopsy is not that great but the kidneys are pumping well, then what we consider is if that kidney is a good kidney for recipients who are coming up on the list. (participant 40, female, nephrologist)*

The weight physicians gave to biopsy findings did not seem to be related to center size; physicians at the largest transplant centers (those with yearly kidney volume >200) were likewise divided on the importance of biopsy, with 5 citing it as a primary deciding factor and 4 giving it less weight.

Physicians were also divided in terms of how much importance they placed on the presence of glomerulosclerosis compared with other histological findings. Among the physicians who placed high overall importance on biopsy, not all considered glomerulosclerosis to be the most important factor. The 7 physicians who cited specific glomerulosclerosis cutoffs varied in terms of the percentage of glomerulosclerosis that would cause them to decline a kidney offer. At the lower end, there were 3 physicians in the 10% to 15% range; one reported a threshold of 10% to 12%, one expressed concerns starting at 10% to 15%, and another used a 15% general threshold, which could go slightly up or down depending on other findings. The median was 20%, with 2 physicians using this cutoff. Another physician gave a cutoff point of 25%. Finally, 1 physician made decisions based on a cumulative scoring system including glomerulosclerosis and also stated that over 30% glomerulosclerosis would be an automatic decline. Additionally, some of the nurses (n = 3) reported that their centers include glomerulosclerosis in their filters, meaning that kidneys are automatically screened out on the basis of glomerulosclerosis, and these offers are not seen by physicians. The filters cited ranged from as low as 15% up to 40%.

On the other hand, 8 physicians did not provide specific glomerulosclerosis cutoffs. Commonly they highlighted the importance of findings such as arteriosclerosis over glomerulosclerosis:

*Part of the biopsy of high KDPI kidneys, or long duration of hypertension or diabetes, is to rule out significant chronic damage which is already noticeable, which is arteriosclerosis. We don't necessarily use glomerulosclerosis, it's one of the criteria but it's not the sole most important criteria. (participant 51, male, nephrologist)*

Physicians also used biopsy findings to guide appropriate recipient selection. Rather than turning down a kidney with biopsy results indicating mild or moderate chronic changes, some physicians would consider the kidney specifically for an older patient who cannot tolerate an extended waiting time:

*... if we find that the kidney is transplantable, then we make the decision to transplant the right kidney to the right recipient. Again, if I have a 72-year-old male with a cardiovascular disease, hypertension, diabetes, every medical problem, but still approved to be a transplant candidate, I know this patient has 80 percent mortality rate a year of not having it. So, if I transplant in this patient a kidney that maybe from the biopsy, it may not be the best kidney to work, but it's a graft that's gonna function.... (participant 46, male, surgeon)*

### Participants Disagreed About How Often Procurement Biopsies Should Be Taken and Whether or Not the Use of Procurement Biopsies Should Be Limited to Reduce Discard

All 15 physicians believed that biopsies are helpful when making decisions about the most marginal kidneys and considered biopsy findings when evaluating KDPI >85 kidney offers. However, there was disagreement with regard to how frequently biopsies should be taken. Opinions ranged from believing biopsies should be used only to rule in offers that would not be acceptable on the basis of history alone, to being happy to look at biopsy information when provided, but requiring it only for kidneys with high KDPI or extensive history, and to preferring a biopsy on kidneys from all but the youngest and healthiest donors. Some physicians worried about biopsies being taken when a decision could be made without 1 and used justify turning down offers:

*If the patient is at a priori low risk of having CKD, and they don't have severe AKI, then there's no point in getting a biopsy. Because biopsies aren't free. You have to chop a hole in a perfectly good kidney, and then you waste time and money, and then from a system-wide standpoint, you get refusals because you biopsy inadequately or you don't have enough sample size. (participant 36, male, surgeon)*

However, other physicians were hesitant to make decisions without a biopsy, and thought OPOs should be prepared to biopsy most kidneys:

> *I think OPO's have to be equipped to get biopsies on kidneys that are anything less than completely straightforward. (participant 55, female, surgeon)*

One specific example was the question of whether biopsies should be taken on all DCD kidneys or only on a case by case basis:

> *Some people use the biopsies for all DCDs but I don't necessarily believe we need to, maybe occasionally when there is a questionable, marginal DCD but on a case by case basis. I don't think we need to do biopsy of the DCDs really. But some centers aren't opposed to it. (participant 32, male, surgeon)*

Although physicians expressed a wide range of opinions regarding how often to biopsy, all 8 of the nurses in the sample reported that their programs overall tend toward a preference for more biopsy data. All 7 of the OPOs reported that their biopsy practices varied in accordance with how their local centers used biopsy. Some OPOs had specific biopsy guidelines agreed upon with their local centers, whereas others biopsied entirely based on center request. OPOs were commonly cautious about imposing stricter biopsy criteria, and felt they had to be accommodating about center requests for biopsy to get their kidneys placed:

> *... kidney function based on lab work is fine, the kidney anatomy is fine, there's no real reason to do a biopsy, some centers will request one, and if they're requesting one we'll do one. Maybe we need to take a stance and if certain criteria are not met then there would be no reason to actually take a biopsy... I think that is part of the challenge, you know, we don't want to give up on an organ being able to be transplanted, so we wouldn't want to then tell the center 'Well, then we're not doing it, so you'll have to code out.' (participant 39, female, OPO staff)*

## DISCUSSION

Physicians, nurses, and OPO staff and directors pointed out problems with biopsy quality and reliability. Clinicians used quality control strategies such as getting biopsy slides reread by their own pathologists or redoing biopsies. However, our findings suggest a need for system-wide solutions to standardize how procurement biopsies are sampled and interpreted.

Although all clinicians in the study relied on biopsy to some extent, some placed more importance on biopsy findings than others. Additionally, the specific criteria physicians used to evaluate biopsies and the glomerulosclerosis cutoffs they used to inform decisions to decline kidney offers, if any, were highly variable. Some physicians noted that they use biopsy findings to inform candidate selection, for example offering a kidney with some chronic changes to an older candidate who is unlikely to receive another offer in the near future, rather than bypassing the kidney.

Some physicians supported limiting procurement biopsies as a strategy to reduce kidney discard. However, other physicians believed they should be able to obtain a biopsy for the majority of kidney offers. Nurses generally reported a center-wide preference for biopsy data whenever possible. OPO staff were concerned about the link between biopsy and discard but felt their OPOs had to maintain flexible biopsy criteria to meet centers' demands. A national survey of OPO biopsy practices had similar findings; of 30 OPOs with formal criteria for performing kidney procurement biopsy, 29 reported that transplant centers can request biopsies on kidneys that do not meet these criteria.[25] Although OPO staff and clinicians expressed concerns about the link between procurement biopsies and kidney discard, limiting the use of procurement biopsies remains controversial, and centers generally expect to be able to request biopsies.

Our study has strengths. Our qualitative interviews provided novel insights into perceptions on the role of procurement biopsies in kidney acceptance decision making and kidney discard from the transplant center and OPO perspectives. Our national recruitment efforts resulted in a geographically diverse sample. Study limitations include the small sample size. Nurse and OPO participants were obtained through snowball sampling, which could introduce bias. Physician participants were recruited from a list of OPTN committee members and transplant center medical directors rather than via snowball sampling; however, the participation rate was low, which could reflect a participation bias. Clinicians from higher volume centers are overrepresented.

Previous studies have suggested that increasing sample size, improving methods for obtaining biopsies, and ensuring qualified interpretation of biopsies could help to increase their predictive power and clinical utility.[4,13,14,16] Physicians, nurses, and OPO staff and directors in our study desired increased standardization and quality control in terms of biopsy sampling and interpretation. The current OPTN Kidney Committee Biopsy Best Practices Workgroup is addressing some of these issues through efforts to standardize biopsy reporting and establish national criteria for when OPOs are required to perform a biopsy.[26] However, the development of additional standards is still needed. The standardization of OPO biopsy reports alone will not address the quality control issues highlighted in our study. How biopsies are taken and who interprets biopsies must also be standardized. Additionally, OPOs may need to offer digitalized biopsy slides so that centers are able to obtain their own reads if desired. Establishing national criteria for which kidneys OPOs are required to biopsy is also a step in the right direction. However, the workgroup should examine whether additional policy measures are needed to limit centers' practice of requesting biopsies for kidneys outside of the minimum donor criteria appropriate to initiate biopsy.

The current variability in how different physicians and centers evaluate biopsy findings also lends support to the idea of fast-tracking kidneys at risk of discard because of suboptimal biopsy results to centers with a track record of accepting similar kidneys. Additionally, our findings show that physicians are using biopsy findings not only in acceptance decisions but also to guide appropriate recipient selection. Allocation policies should support this practice. Centers should be able to offer kidneys with nonideal biopsies to the candidates at their center who are most likely to benefit, even if they are not at the top of the waiting list.

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