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Deceased Donor Kidney Nonuse: A Systematic Approach to Improvement

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Background. A large number of procured kidneys continue not to be transplanted, while the waiting list remains high. **Methods.** We analyzed donor characteristics for unutilized kidneys in our large organ procurement organization (OPO) service area in a single year to determine the reasonableness of their nonuse and to identify how we might increase the transplant rate of these kidneys. Five experienced local transplant physicians independently reviewed unutilized kidneys to identify which kidneys they would consider transplanting in the future. Biopsy results, donor age, kidney donor profile index, positive serologies, diabetes, and hypertension were risk factors for nonuse. **Results.** Two-thirds of nonused kidneys had biopsies with high degree of glomerulosclerosis and interstitial fibrosis. Reviewers identified 33 kidneys as potentially transplantable (12%). **Conclusions.** Reducing the rate of unutilized kidneys in this OPO service area will be achieved by setting acceptable expanded donor characteristics, identifying suitable well-informed recipients, defining acceptable outcomes, and systematically evaluating the results of these transplants. Because the improvement opportunity will vary by region, to achieve a significant impact on improving the national nonuse rate, it would be useful for all OPOs, in collaboration with their transplant centers, to conduct a similar analysis.

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The high number and percentage of deceased-donor kidneys procured by organ procurement organizations (OPOs) but not transplanted by transplant centers continues to confound the transplant community and public. The rate of kidney nonutilization in the United States increased from 5.1% of kidneys recovered in 1988 to 19.2% in 2009.[1] Reduction of the nonuse rate would serve to ameliorate long wait times for the approximately 100 000 people on the kidney transplant waitlist. The US Department of Health and Human Services' "Advancing American Kidney Health" initiative proposed to double the number of kidney transplants in the United States by 2030 by reducing the nonuse rate,[2] and The National Academy of Medicine called for a reduction in kidney nonuse rates to 5% or less by 2026.[3]

There have been numerous efforts to address the nonuse issue. Two large-scale collaborative groups were organized by the Organ Procurement and Transplantation Network and the Center for Medicare & Medicaid Services (CMS) with the goal of reducing the nonuse rate by increasing the use of kidneys with kidney donor profile index (KDPI) >50%.[4] The National Kidney Foundation convened a national consensus conference to understand and reduce nonuse.[5]

Despite these efforts, the percentage of transplants in the United States with KDPI > 85% only increased from 7% of deceased donor transplants in 2012 to 8.8% in 2020,[1] and preliminary results from the first Organ Procurement and Transplantation Network/CMS collaborative showed no difference in kidney donor risk index of transplanted kidneys between participating and nonparticipating centers.[6] The national nonuse rate remained 20.1% in 2019 with >4000 kidneys not transplanted.[7]

One posited cause for continued high nonuse rates is that transplant physicians are overly conservative, content with doing a small number of cases relative to the need. Both the

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existence of a "weekend effect"[8] and a paper by French investigators stating 62% of kidneys not transplanted in the United States would be transplanted in France[9] are used in support of this contention. Mistaken reliance on kidney biopsies is an additional factor implicated in inappropriate kidney nonuse.[10] An alternative explanation is that transplant physicians and surgeons have not been persuaded that it is safe to transplant high-risk kidneys into older recipients based on retrospective registry studies.

With this background in mind, and with a strong desire to respond to the imperative of increasing the use of heretofore nontransplanted kidneys, we undertook an analysis of unused kidneys in our OPO service area. Goal one was to understand the interplay of factors causing nonuse including donor demographics and biopsies. Goal two was to use the information from goal one to devise a plan to increase the kidney utilization rate in our service area.

MATERIALS AND METHODS

OneLegacy is the federally designated OPO for 7 counties in Southern California with a population of approximately 20 million. In 2019, which was chosen as the year of study because it was the last full year before the COVID-19 pandemic, OneLegacy served 10 centers with kidney transplant programs.[11]

There were 1064 kidneys procured from 552 donors; 740 were transplanted and 324 were not transplanted. Forty-seven of the 324 (14.5%) were not offered for transplant because of absolute contraindications including cancers in the kidney, infections discovered during procurement, and abnormalities such as multicystic dysplastic kidneys. There were 5 surgical injuries (0.47%)—1 stripped ureter and 4 vascular injuries—all of which were determined to be nonrepairable by a transplant surgeon highly experienced with repair techniques. These kidneys were excluded from the study. The remaining 272 kidneys were offered for transplant and turned down by all local centers and, in turn, by all regional and national centers. Fourteen kidneys were provisionally accepted by and transported to nonlocal centers but, ultimately, not utilized due to prolonged cold ischemic times or findings on biopsies performed at the export center.

Biopsies were all wedge biopsies from the upper pole, and all were read by a single pathology group with extensive renal transplant pathology experience.

Donor records from the OPO's electronic record including coordinator notes were reviewed on all 552 donors. Also reviewed were organ offer sheets on the 272 nonused kidneys. Factors known to increase the risk of nonutilization were quantified including demographics, comorbid conditions, laboratory results, cause of death, type of donor, and biopsy findings. Risk factors for the OneLegacy donor pool were compared with national figures. We also examined the relationship between biopsy findings of glomerulosclerosis and interstitial fibrosis with the comprehensive quality score, KDPI.

Each nonutilized kidney was independently reviewed in detail by 5 transplant physicians, 2 surgeons, and 3 nephrologists to make a retrospective determination to their best judgment about the transplantability of the previously nonused kidney. Their combined experience is >100 y with over 10 000 deceased-donor transplants.

Variables were analyzed using median and interquartile range for continuous variables and proportions for categorical variables.

RESULTS

Table 1 shows the risk of nonutilization by risk factor for the 1012 kidneys that were offered for transplant. The highest risk factor was high percentage of glomerular sclerosis (GS) and/or significant interstitial fibrosis/tubular atrophy (IF/TA). High KDPI, donor age >55, positive hepatitis serology, and comorbidities of hypertension and diabetes were also associated with elevated risk of nonuse. Two-thirds of kidneys from donor after circulatory death (DCD) donors, obese donors, and donors with renal dysfunction at the time of procurement were transplanted.

Table 2 shows the donor and biopsy risk factors for nonutilized kidneys. A high percentage were from high KDPI donors, age >55, with diabetes, hypertension, or both, with elevated terminal creatinine, or cause of death cardiovascular accident (CVA) or stroke—the same risk factors seen nationally.[12] Biopsies with high levels of GS, IF/TA, or both were

TABLE 1.

Risk factors for nonuse in 1012 kidneys procured and offered for transplant

	No. kidneys	Not used, %
GS >20, IF/TA moderate–severe, or both	189	94
KDPI 86–100	258	71
Hepatitis C antibody positive	70	61
Age >55 y	277	61
Diabetes, hypertension, or both	399	52
Biopsied	531	50
Cause of death: CVA or stroke	393	42
Terminal creatinine >1.5	475	36
DCD	176	34
BMI >30 kg/m^2	349	33

BMI, body mass index; CVA, cardiovascular accident; DCD, donor after circulatory death; GS, glomerular sclerosis; IF/TA, Interstitial fibrosis/tubular atrophy; KDPI, kidney donor profile index.

TABLE 2.

Characteristics of 272 kidneys not transplanted to perceived poor kidney quality

	Nonuse, n	Nonuse, %
Age >55 y	169	62
Diabetes alone	12	4
Hypertension alone	103	38
Both	92	34
BMI >30 kg/m^2	114	42
Terminal creatinine >1.5	172	63
Biopsied	266	98
Cause of death: CVA/stroke	164	60
Hepatitis C antibody positive	43	16
DCD donor number	59	22
KDPI 86–100	184	66
Biopsy with GS >20	29	11
Biopsy with IF/TA moderate–severe	33	12
Both	115	42

BMI, body mass index; CVA, cardiovascular accident; DCD, donor after circulatory death; GS, glomerular sclerosis; IF/TA, Interstitial fibrosis/tubular atrophy; KDPI, kidney donor profile index.

TABLE 3.

Comparison of risk factors in 1012 OneLegacy kidneys with all US kidneys (22 206)[13]

	National, %	OneLegacy, %	*P* (2 tail)
Age >55 y	24	27	0.04
Diabetes	6.5	17	<0.0002
Hypertension	34	35	0.6
BMI >30 kg/m^2	35	34	0.3
Terminal creatinine >1.5	17	47	<0.0002
Cause of death: CVA or stroke	26	39	<0.0002
HCV positive	1	7	<0.0002
KDPI 86–100	20	26	<0.0002

BMI, body mass index; CVA, cardiovascular accident; HCV, hepatitis C virus; KDPI, kidney donor profile index.

a significant factor in two-thirds of the nonutilized kidneys. Almost all were from donors with 2 or more risk factors (256/272). Cold ischemia time was >10 h at the time of last offer and was an additional factor for nonuse in 28 kidneys.

Comparison of donor risk factors between the 2019 national pool (22 206) and OneLegacy (1012) is shown in Table 3. The OneLegacy donors had a significantly higher percentage of donors' age >55, significantly higher rate of diabetes and evidence of renal injury, significantly higher percentage of deaths from CVA or stroke, higher percentage of hepatitis C virus (HCV), and significantly higher percentage of donors with high KDPI.

The relationship between KDPI and GS and between KDPI and IF/TA for transplanted and unused kidneys is shown in Figures 1 and 2. Although there was a positive correlation between KDPI and GS and between KDPI and IF/TA, the degree of correlation was insufficient to enable clinical parameters to reliably predict which kidneys would have severe biopsy findings. Biopsies with KDPI 30–60 had a 14% chance of having severe sclerosis and/or fibrosis, which is too high to rely solely on clinical factors; kidneys with KDPI from 85 to 100 had a significant chance of showing minimal sclerosis and fibrosis.

Detailed individual review of the nonutilized kidneys by the 5 reviewers identified 33 kidneys whose characteristics would be considered as transplantable in the future (12%). No individual reviewer identified >15 kidneys as transplantable; 5 kidneys were identified by all 5 reviewers as transplantable.

The rate of nonuse for weekday versus weekend and the KDPI by weekday versus weekend are shown in Table 4.

DISCUSSION

There is universal agreement that it is highly desirable to increase the number of kidney transplants and reduce the waiting time for the 100 000 people on the list and that one way to achieve this goal is by expanding the donor criteria to reduce kidney nonuse. Ambitious goals for increased kidney transplants and reduced kidney nonuse have been announced. Less clear is how this is to be achieved.

The analysis of OneLegacy nonutilized kidneys does inform a plan to reduce the nonuse rate. Because there is no weekend effect, decisions about kidney transplantability are being made on clinical judgment; the OPO is aggressively pursuing donors with risk factors for nonuse much greater than national averages and with significant degrees of renal injury that would justify nonuse, and data from the Scientific Registry of Transplant Recipients show that kidney offers were accepted at a higher rate than the national average in 2019.[14] However, none of these facts prove, nor can they prove, that the nonused kidneys were not transplantable.

One reason that the nonuse problem has proven intractable is that, even though it has been asserted that most nonused kidneys in the United States are safe to transplant, clinicians making the decisions in real time seem not to agree. Nor is there widespread enthusiasm for transplanting suboptimum kidneys into elderly recipients, despite papers promoting it,[15] possibly because it is not entirely clear which older dialysis patients really benefit from transplantation.[16]

The thought experiment of experienced local physicians reviewing procured but not transplanted kidneys appears to

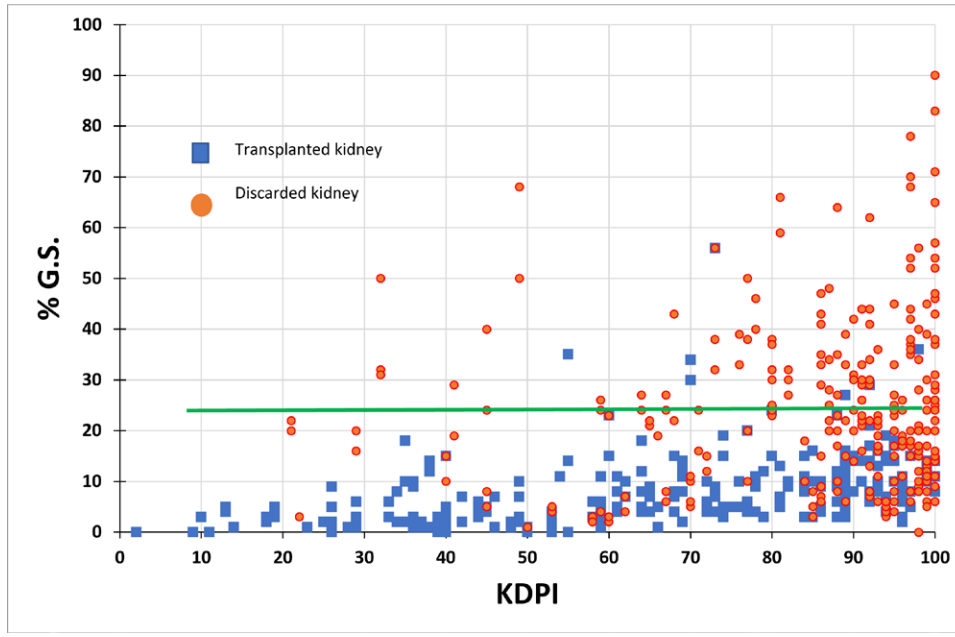

FIGURE 1. Glomerulosclerosis vs KDPI, OneLegacy kidney donors, 2019. GS, glomerular sclerosis; KDPI, Kidney Donor Profile Index.

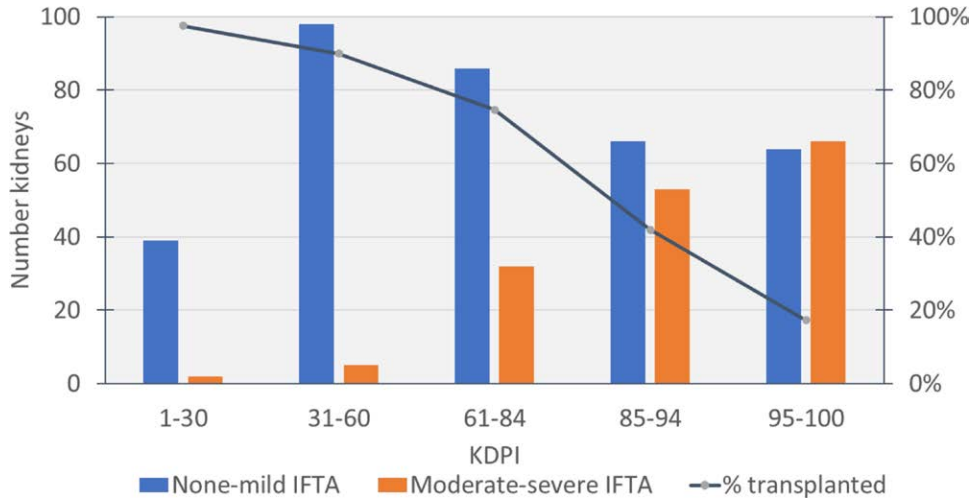

FIGURE 2. Relationship between IF/TA and KDPI and transplant percentage in OneLegacy kidney donors, 2019. IF/TA, Interstitial fibrosis/tubular atrophy; KDPI, Kidney Donor Profile Index.

TABLE 4.

Nonused kidneys by day of the week

	Transplant number	Nonused number	Nonused number, if equal by day of the week	KDPI nonused	Nonused as % of total
Sunday–Thursday	519	197	194	84.64	38
Friday–Saturday	221	75	78	85.50	34

KDPI, kidney donor profile index.

confirm this hypothesis. Despite French studies suggesting that 62% of kidneys not utilized in the United States would be transplanted in France, only 12% of kidneys were thus identified by our team of physicians, each of whom were highly motivated to reduce nonuse kidneys and highly knowledgeable about registry studies claiming safety of expanded donor criteria.[10] If highly knowledgeable and experienced transplant physicians and surgeons—highly motivated to decrease nonuse—have not significantly changed kidney acceptance criteria, they are unlikely to be persuaded or respond to regulatory pressure to cause them to perform transplants that they feel would violate their responsibility to patients. Reducing the nonuse rate to ≤5% is unlikely under these conditions. Nonetheless, this experience does inform how improvement can occur.

The alternative pathway to improvement in our service area is a more systematic prospective approach, in other words, an authentic clinical trial. The elements of such a trial would include codifying as precisely as possible the inclusion criteria for transplantable "suboptimal" donors, determining recipient criteria, extensive informed consent conversations, optimization of the organ offer process to minimize cold ischemia times, and outcomes tracking including quality of life and cognitive assessment. It should be decided in advance what will constitute an acceptable outcome for primary nonfunction and 1-y graft and patient survival.

Determining donor kidney inclusion criteria is a critical element of such a trial. The National Academy argues that 95% of currently nonutilized kidneys can be transplanted.[3] For transplant centers that accept that argument, their inclusion criteria would be donor and kidney characteristics of almost all currently nonused kidneys. Although this might be acceptable in some regions, the inclusion of some high-risk kidneys in an initial trial is likely to be unacceptable to local clinicians and institutional review boards. For these centers, a smaller trial utilizing kidneys with the safest risk profile would comprise an initial trial. Because primary nonfunction and short-term graft survival are the major outcomes, it would not take long to conduct such a trial. Then, if the first cohort of expanded criteria kidneys prove to be safe and effective, criteria could be systematically expanded in subsequent trials and still meet the goal of 5% or less nonutilizations by 2026.

To determine the safest donor cohort, the role of the biopsy must be addressed. We understand the criticisms about the biopsy: too many are done with questionable indications, results are used inappropriately to not transplant kidneys, variation exists in how biopsies are done (eg, core vs wedge), single samples are not representative, variation exists in pathology interpretation, and glomerulosclerosis and interstitial fibrosis cutoffs are arbitrary and inaccurately predict results.[17-19] This study was not done to address these criticisms. Without doubt some unnecessary biopsies were done, especially in KDPI <30% donors, and a low level of glomerulosclerosis might have been a factor in decisions to not transplant some kidneys. Nonetheless, for the purpose of informing a decision on an initial donor pool, it is only necessary to identify the highest risk of kidneys.

Several lines of reasoning lead us to conclude that it would be prudent to exclude kidneys with high degrees of glomerulosclerosis and interstitial fibrosis. Sclerosis and fibrosis are not benign. In a prospective study of patients undergoing native kidney biopsy, greater severity of interstitial fibrosis and glomerulosclerosis and interstitial fibrosis were predictors of future kidney failure; severe sclerosis and fibrosis were associated with >50% reduction in GFR within 24 mo.[20] A retrospective review of 6000 transplants showed a dose–response relationship on graft survival of even low levels of glomerulosclerosis, suggesting that 10% sclerosis may be a more appropriate cutoff than 20%.[21] Few kidneys with very high sclerosis percentage have been transplanted, so that data about the safety of transplanting such kidneys are lacking. In another French study, only 45% of their kidneys were

matchable with the US comparison group,[22] one reason being that there were few kidneys with severe biopsy findings in the French donor pool.

If high degrees of sclerosis and fibrosis are going to be a factor in excluding kidneys, then a judgment should be made about the likely validity of the biopsy results. A single academic group of experienced transplant pathologists had initially read all OneLegacy biopsies. To assure that these had not been systematically over-read, a second academic renal pathology group reread 25 biopsies with high levels of sclerosis and fibrosis, resulting in only one kidney initially read as having glomerulosclerosis >20% having <20% on reread. Two hundred twelve donors had both kidneys biopsied with 92% concordance between kidneys. Demographics are another indirect check on results. Fourteen percent of the adult population in the United States have some degree of chronic kidney disease,[23] with 10 times the rate in diabetics as nondiabetics.[24] The rate of chronic renal disease in the 7 counties served by OneLegacy is 37% higher than the national average,[25] and the prevalence of diabetes is 3 times higher than the national donor pool. Thus, a significant percentage of positive biopsies in the OneLegacy donor pool is consistent with the demography.

The prognostic value of highly abnormal kidney biopsies and checks on biopsy validity in the OneLegacy service area is sufficient to conclude that it would be imprudent to use kidneys with elevated levels of sclerosis and fibrosis in initial donor inclusion criteria. Excluding high fibrosis and sclerosis kidneys would yield 96 kidneys for an initial trial based on the 2019 OneLegacy nonutilized kidneys. An additional risk factor to consider is high KDPI kidneys with acute renal injury. In the largest single-center study of high KDPI donors with acute kidney injury, primary nonfunction and 1-y graft failure were higher in AKIN stage 2–3 donors, leading this experienced group to recommend caution in transplanting such kidneys.[13] In the OneLegacy nonuse kidneys, there were no high KDPI stage 3 kidneys, but there were 35 high KDPI stage 2 kidneys that would be excluded from an initial trial. The inclusion criteria in our trial are all KDPI kidneys, except those with concomitant acute renal injury, biopsies with less than moderate IF/TA, <21 GS, and no exclusion for hypertension, diabetes, or obesity. This would leave 61 high-risk kidneys available for an initial clinical trial, assuming the OPO continues to pursue donors aggressively. The nonuse rate would decline from 27% to 21%, if 100% of these were transplanted. The UCLA IRB has approved such a trial for transplanting such kidneys into recipients >65 who have given full informed consent.

Conclusions about the number and percentage of potentially transplantable nonuse kidneys cannot be extrapolated from this OneLegacy analysis to other OPOs and transplant centers. There is no sensible arbitrary reduction target, as the improvement opportunity will vary depending on the complex interplay of how aggressive an OPO is in pursuing high-risk donors, how aggressive the local transplant centers are in accepting high-risk kidneys, how the biopsy is used, the prevalence of chronic kidney disease and accompanying risk factors in the population, and perhaps most importantly, the degree of risk considered acceptable. For the purposes of comparing results, there would be advantages if OPOs had consistent donor acceptance criteria, if there were consistent biopsy practices, and if transplant centers agreed on what level of risk they are willing to accept. Recently, UNOS/OPTN has established minimum kidney donor criteria to require biopsy (established September 2022).[26] These guidelines are outlined in Table 5. However, part of the challenge of moving the country to reduce kidney nonuse is precisely the remaining lack of agreement on these questions. Even if inclusion criteria cannot be extrapolated, the method we employed can be. If all 57 OPOs in collaboration with their local transplant centers conducted a similar process, analysis of local nonuse risk factors, validation of biopsy results, and formulation of a clinical trial, and if it is done systematically in each area, rapid progress could be made across the country in meeting the goal of increasing the kidney transplant rate.

TABLE 5.

Organ procurement organization proposed criteria for kidney biopsy on deceased donors >18 y old

Criterion	Description
Urine output	<100 mL in 24 h
Hemodialysis or other renal replacement therapy	Received during most recent hospital admission or in the course of donor management
Diabetes	Any history, including hemoglobin A1c of ≥6.5 during donor evaluation and management
KDPI	>85%
Age	≥60 or 50–59 y and meets at least 2 of the following criteria: history of hypertension, manner of death is cerebrovascular accident, or terminal creatinine ≥1.5 mg/dL

KDPI, kidney donor profile index.

We acknowledge several limitations of this study. One limitation is that they are data from a single OPO. Comparison with other OPOs and other transplant centers would provide additional insights about how to expand donor criteria safely. A question that might be asked is why an outside panel was not used to review cases, as one might expect local physicians to recapitulate their existing clinical judgments. Although an outside panel would appear more objective and might have identified more transplantable kidneys, it would be less likely to change clinical practice in our service area than local physicians' review. Although it might appear that their judgments are being used to assert that our nonuse criteria in 2019 should be taken as the standard of care, because the purpose of the review was local expansion of donor criteria, the judgment of these reviewers is not intended to be applied universally nor to make a normative statement about what makes a kidney transplantable.

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