

The American Society of Transplantation responded to fourteen public comment proposals released for comment on January 27, 2022. The responses below were entered on the OPTN website on March 23, 2022 after seeking input from the communities of practice, the OPTN/UNOS Policy Committee and approval by the Board of Directors.

1. Pediatric Candidate Pre-Transplant HIV, HBV, and HCV Testing

The American Society of Transplantation is supportive of the proposal and offers the following comments for consideration:

We suggest using age and weight to make this determination. Consider <20kg and no recent exposures (blood transfusions, IV drugs, etc.). Additionally, the proposal should suggest a time frame prior to transplantation for this testing to be completed. We recommend documentation of results from a blood draw no older than 12 months. Potential policy language to incorporate these considerations is provided below:

Candidate samples must be drawn during the hospital admission for transplant but prior to anastomosis of the first organ unless all the following are true 1) the candidate is less than 11 years old or weighs less than 20 kg 2) samples have been drawn within the past 12 months and 3) the candidate has not had a potential exposure to one of the above infectious diseases since samples were obtained.

2. Proposal to Revise the OPTN Charter

The American Society of Transplantation is generally supportive of the proposal and offers the following comment for consideration. In the proposal, Article 1 (Organization) states, "The OPTN Contractor serves as the OPTN by contract..." whereas the National Organ Transplant Act (NOTA) states, "The OPTN Contractor operates the OPTN by contract..." The proposed wording creates ambiguity about whether work the OPTN Contractor performs outside the OPTN contract can be construed as work being done by the OPTN. Arguably, the current wording in the OPTN Charter is less ambiguous in this regard- ""The OPTN is a part of the OPTN Contractor's organization and operations."

3. Change Calculated Panel Reactive Antibody (CPRA) Calculation

The American Society of Transplantation is supportive of the proposal and offers the following comments:

We support the inclusion of HLA-DPA1/DPB1/DQA1 and the use of a larger, more diverse, and fully HLA typed stem cell donor population in the new CPRA calculation. Waiting list candidates with sensitization toward these missing HLA loci have long been disadvantaged by the loss of the relevant allocation points.

The extension of the CPRA calculation to 6 digits will provide better equity in allocating donors for the most highly sensitized patients.

We support having CPRA viewable for all candidates.

We anticipate that implementation of the new CPRA calculator will result in changes to the %CPRA for waiting list candidates. We recommend transplant programs be given a month to obtain the documentation for patients who will now be >98% CPRA due to these changes, rather than the one week proposed.

4. Ongoing Review of National Liver Review Board (NLRB) Diagnoses

The American Society of Transplantation is supportive of the proposal as written. These proposed policies are all straightforward modifications to streamline the NLRB process, clarify issues, and introduce appropriate changes to diagnoses eligible for exception points. We also support adopting the use of LI-RADS terminology.

5. Establish OPTN Requirement for Race- Neutral eGFR Calculations

The American Society of Transplantation supports this proposal. We agree with such policy, as it increases accuracy and access to transplantation for Black kidney transplant candidates. We wish to offer perspectives for consideration to ensure that this policy ultimately meets the objectives it is meant to address.

First, Race and ethnicity differ from genetic ancestry and the concept of 'race' is a social construct used to explain differences between groups of people. There is more genetic variation within versus between 'racial' groups. While the government uses 'race' to track and address disparities, it should not be used as a surrogate of biological function. Likewise, 'race' as reported in the electronic medical records has no distinction of multiracial individuals. Furthermore, we do know, as is noted in the proposal, that compared to Whites, Blacks have a higher serum creatinine at the same measured GFR. The CKD-EPI cohort had good representation of Blacks at 31.5%, and recently published data shows that removal of the race coefficient introduces a median bias of -6.1 ml/min/1.73m² for Black candidates (Diao et al, NEJM 2021). Removing the race coefficient will reduce one kind of disparity in nephrology. The only counterpoint would be if we actually start to underestimate eGFR for all Blacks that will create/ increase CKD burden for several Black individuals and potentially create a preexisting condition with consequences for medical care, drug dosing and barriers in equitable access to health, disability, life and long-term care insurance.

Another issue is that the policy is not clear as to whether eGFR or creatinine clearance needs to be indexed for body surface area (BSA). See Policy 3.6.B.i, 8.4A, 8.5G, 9.5H, 9.9B and 13.7G. For example, removing the BSA correction for a person with a BSA of 2.6 will increase his/her eGFR or creatinine clearance by 50% from the indexed value (An eGFR of 19.9 ml/min/1.73 m² will become 30 ml/min). We agree with the proposal that the transplant programs can use any method for reporting glomerular filtration rate either by direct measure or by estimating it. The formulae must not use a race-based variable. An alternative may be to encourage a cystatin C or other accurate race neutral measure of renal function for transplant referral and for waitlisting.

With regards to modifying waiting time for the kidney candidates who are already listed and could have begun accruing waiting time at an earlier date if a race-neutral eGFR calculation was used; this policy could face various challenges. It is possible that many of these patients were not referred to the transplant centers based on the eGFR in the first place, and they may not have been eligible at the time

of previous eGFR based on other considerations. Additionally, the programs with a long waiting lists would find it difficult to obtain and update a previous eGFR and convert it into a non-race based estimate. The policy is best served by being implemented prospectively.

One of the unintended consequences is the effect on living donors. In the US, living kidney donor programs need creatinine clearance or measured GFR to verify adequate donor kidney function. However, if a program uses eGFR to screen possible candidates, Black donors may be inappropriately ruled out, which would aggravate disparities in living donor transplantation for Blacks. Accordingly, we recommend that post-implementation monitoring also evaluate the impact of these changes on the availability of Black living kidney donors.

We do see a need for clear education of hospital administration, transplant and laboratory staff, and IT support to switch from the race based to race neutral eGFR calculator.

In summary, there is a need to reduce disparities in access to the kidney transplant waiting list. The current proposal is step in the right direction with removing race from the eGFR equation for wait listing. An alternative may be to require a cystatin C indexed for BSA for transplant eligibility and for wait listing. Of course, these efforts will not result in earlier referral of Blacks to a transplant center, nor will it necessarily prevent disparities in time to complete evaluation once referred to the transplant center.

6. Modify Graft Failure Definition for VCA

The American Society of Transplantation supports the clarifications and improved data collection introduced with this policy proposal; however, we do have some concerns that we believe warrant consideration.

Background:

The goal of VCA transplants varies by VCA type and among recipients of a particular VCA type. Unlike solid organ transplants, they are not expected to prolong life and for several VCA organ types there may be other options that the recipient would have considered and opted for a VCA understanding a certain outcome and treatment burden.

The brunt of this proposal is to change the definition of graft failure in VCA. It seeks to introduce "Planned Removal" as an exception to graft failure. The authors of the proposal stipulate that such intention must be declared pre-transplant or at the time of transplant.

Planned Graft Removal as an Exception to Graft Failure in VCA:

Of the currently performed VCA transplants, the only one that the transplant community would generally agree is a temporary transplant, is a uterus. The intent is to allow for one or more live births for a patient with uterine factor infertility. It is not intended to be a lifelong transplant necessitating ongoing immunosuppression. As such, this is currently the only exception to the goal of one transplant for life which all solid organ transplants strive to achieve. So, an allograft hysterectomy post live birth should not be counted as a graft failure and the proposed policy is fully supported in that regard. The converse would be true, if after the uterus transplant there is no live birth then even if that uterus was menstruating at the time of removal this would be a failure of the VCA transplant. This later situation raises an interesting question, how long should a recipient be attempting pregnancy and a live birth

before this transplant would be considered a failure. There could be significant underreporting of VCA graft failures if no hysterectomy is performed and no live birth occurs.

The other two examples given for a possible planned graft removal (abdominal wall grafts and musculoskeletal composite graft segments when transplanted for purposes of temporary coverage or to allow for the regrowth of the original tissue) do not appear to be reasonable assumptions that necessitate having this exception apply to all VCA graft types. The latter at this stage is purely theoretical, and the goal of VCA graft is to replace like with like body components as per the definition of a VCA adopted by the OPTN. The former is usually performed due to loss of abdominal wall domain and as a last resort.

Expanding intended removal to all VCA organs can result in a situation where a program will be fully compliant and avoid any form of graft failure if they list all patients with a planned removal of the organ after X years/months or even with no end date documented. Simply that the intention is to remove it. If there is an end date and the graft is functioning, there is nothing in the policy that would flag the program as of concern.

Why not list an upper extremity transplant with the intention to have it for only one year?

Relisting for Same VCA:

The addition of this as an indicator of graft failure is reasonable. It should be defined that it is the same VCA organ and same laterality. One can conceivably have a unilateral upper extremity transplant and require a contralateral transplant. Thus, it should be worded more precisely.

To avoid under reporting of graft failures, it will be important to include definitions of, and mechanisms of determining at what point decreased or limited function is no longer acceptable.

Graft Function:

VCA transplants need graft specific functional expectations to be included in the definition of graft failure. The closest example is in pancreas transplantation where insulin requirements in addition to graft removal or patient survival are included in the definition. As noted above, the different VCA transplants have different goals. Among patients receiving the same transplant, the goals can vary. For uterus it may be the easiest, to specify, live birth of a healthy infant as a possible requirement. For upper extremity and face, individualized goals and expectations should be set before the transplant and followed post-transplant to determine graft success or failure.

Would a patient with perfusing upper extremity grafts or face allograft that has no nerve regeneration be deemed a functioning graft or a graft failure? These are challenges and opportunities that will impact the acceptance of VCA transplantation into mainstream clinical practice.

Suggestions:

1. Restrict planned removal of VCA graft as exclusion from graft failure to only uterus and expand to other temporary organs as they are performed and there is acceptance from the transplant community that they are truly temporary.
2. Live birth following a uterus transplant can be considered as a defined success.

3. Include some form of minimum function for each organ to allow that organ to count as functioning.
4. Suggest that future proposals allow for individualized goals to be set before the transplant that can allow future assessment of whether the VCA graft met the individual patient's goals. These should be in addition to standardized outcomes as currently in place.

Proposed Changes to data collection:

Appendix 1 in the proposal appear to be limited to uterus transplantation. We are unclear if this was the intent. Under proposed options for primary cause of death "Maternal and obstetric mortality: other specify". If this was intended for uterus alone, then this is very appropriate. If the intent is for all VCA grafts, then it would be strongly recommended to include a wider array of causes of death such as cancer, cardiovascular, and infectious death.

7. Reinstatement of Updates to Candidate Data During the COVID-19 Emergency

The American Society of Transplantation is supportive of this proposal as written. We believe that the reinstatement of Policy 1.4 F was not only reasonable but necessary during this latest surge as an Emergency Action. The policy is compliant with the OPTN Final Rule and provides some flexibility given regional variations in COVID19 transmission.

The April 11, 2022, expiration date is reasonable pending any unforeseen future surges due to emerging new variants of COVID19.

We recommend the OPTN explore working with the CDC to obtain guidance on timing for future re-implementation of the policy, should it be needed, due to surges from emerging variants of COVID-19, rather than relying upon Executive Committee member requests for reinstatement. Further, the OPTN should apply lessons learned to formalize a general framework for emergency reduction in data reporting requirements and adjustment of outcome monitoring when a future pandemic or other national emergency similarly impacts OPO and transplant center operations or affects patient outcomes.

8. Establish Eligibility Criteria and Safety Net for Heart-Kidney and Lung-Kidney Allocation

In general, the American Society of Transplantation supports the safety net concept and the distance threshold of 500NM from the donor hospital; however, there are numerous concerns that the proposed eligibility criteria will not meet the needs of all candidates. Overall, the AST the following comments are offered for consideration:

- Based on a recent Heart-Kidney Consensus Conference publication (Am J Transplant. 2021; 00:1–9), SHK patients are more severely ill as the etiologies of renal disease are much less recoverable both from the insulting pathology and the adverse cardiac hemodynamics around the heart transplant. Acknowledging the need for consistent policy across organ transplant lines, we must also appreciate that the pathophysiology of kidney injury and damage may vary in different organ failure settings, which is important to consider in developing criteria and prioritization

- There is evidence that some candidates with a GFR of 30-40ml/min, including some who have chronic kidney disease (CKD), may benefit from SHK transplants (Shaw et al PMID: 33350052, Gallo et al PMID: 32165347).
- The proposed policy is too rigid to allow all appropriate patients access to SHK. These concerns could be addressed by an exception pathway with a review board to allow consideration of other markers of CKD such as proteinuria. The AST would support proposed changes if there were an adjudication pathway such as a review board to consider nuanced scenarios. If not, it is imperative that the OPTN study the impact of these changes on heart and lung transplant recipients shortly after implementation and promptly proposed additional modifications to address unintentional consequences that are identified.
- Status 4 heart candidates on dialysis should be included in the SHK eligibility criteria and there should also be consideration for outpatient status 5 and 6 candidates on dialysis. Active heart candidates with an eGFR less than 30 ml/min should be eligible for SHK regardless of their assigned heart status.
- Multi-organ transplants disadvantage kidney alone candidates, including pediatric kidney disease patients. We recommend that modeling be performed to ensure that the proposed policy does not further exacerbate this.

9. Redesign Map of OPTN Regions

The American Society of Transplantation offers the following comments in response to the concept paper on redesigning the map of OPTN regions:

- The AST appreciates the need to periodically review OPTN regional structure; however, we are concerned that OPTN has not sufficiently outlined the anticipated benefits and guiding principles for fair representation. Without this clarity, it is difficult to support any of the proposed maps over the current OPTN regional structure. The OPTN needs to carefully weigh the overall returns on investment of redrawing new regions. Any future proposal should provide assurances that such a shift is justified by a quantifiable benefit to patients or OPTN members. Rationale for change should include demonstrated increase to collaboration, decrease in OPTN and OPTN member cost, and improve equitable representation on the OPTN Board and Committees.
- Concerns were raised about the use of metrics to equalize regions for purposes of representation such as number of transplants, candidates waiting, donors, and OPTN members without including some measure of overall population (as a proxy for patients in end stage organ failure who do not have adequate access to the waitlist). This could be perceived as under-representing areas where the ratio of these metrics to the population of patients potentially in need of transplant are lower.

Feedback on the six maps provided:

- As the OPTN considers potential maps, please note AST would not support the regional map models with the most significant consolidation such as 4 or 6 Regions as they would be geographically unwieldy. Because of this, it seems unlikely that regional representatives would be

able to fully appreciate and “represent” the needs of their constituencies. It also could be destabilizing to make dramatic changes to the regional representation given all the significant allocation changes underway.

- It would be best to keep one consistent regional design for governance, structure, and data reporting. The creation of select specialized regional designs will add complexity without value.

10. Continuous Distribution of Kidneys & Pancreata Request for Feedback

The American Society of Transplantation is generally supportive of continuous distribution for kidney and pancreas; however, there are several concerns:

The American Society of Transplantation appreciates the OPTN's efforts to reassess kidney and pancreas allocation. This will be a substantial change from the current system, and would benefit from more extensive dialogue and analysis, potentially convening a meeting of interested stakeholders.

The goals of continuous distribution need to be better defined. Rather than just looking at broader sharing, the OPTN should also be looking at maximizing the benefits of grafts and prioritizing those that will benefit the most. Concerns about increased delayed graft function following recent allocation changes have been raised. Delayed graft function and long-term outcomes and plans to monitor these trends must be considered in any future proposal.

The AST's Communities of Practice also provided the following comments:

Including some of the proposed components into the new framework has the potential to exacerbate existing known inequities in kidney allocation. 1) Including travel efficiency into the framework has the potential to partially reverse recent changes in allocation to address geographic inequities. 2) We cannot ignore the hard borders that still exist between DSAs and create financial disparities that translate into geographic disparities.

Analyses leading up to the proposal need more focus on pediatric patients to ensure they will not be unfairly impacted by the changes.

It is not clear when the ceiling waiting time is reached.

We agree with points for DR matching with continual monitoring of its effects on minority communities. We also agree with change in the weightage based on data obtained. (Low weightage)

HLA matching for pancreata should follow the pattern of kidney allocation.

EPTS – We support awarding points for top 20% candidates for top 20 KDPI kidneys. We want to state that EPTS and KDPI are independent variables and there is no cross communication.

We need to have better models where these two variables have better predictability for organ and recipient survival.

- After EPTS 20% - Low weightage.
- Weightage should increase after KDPI 85%

CPRA – We agree with the nonlinear rating scale. High weightage based on cPRA >99 to get these patients transplanted

Blood Type – B and O blood type should be prioritized. Non-A1/non-A1B kidneys can be prioritized to blood groups B and O. We also agree with the rating scale in Figure 11(incorporating blood type and CPRA together and weightage based on combined score)

We agree with the binary scale for prior living donors.

EPTS, CPRA, and blood type should be considered for organ allocation.

For pediatric candidates, we agree with the high weightage rating scale recommendations.

We support high weightage for waiting time and recommend points for preemptive listing (to encourage preemptive transplants).

We agree with the rating scale and maintaining current KDPI thresholds.

We agree with the workgroup's approach to placement efficiency. High KDPI, DCD organs should be weighted higher to accelerate placement of such organs. Inner plateau should be 50 NM.

Dual transplants should be weighted in the allocation system. A clear pathway for dual transplants will help reduce the waste of organs.

We agree with the weighted scale for en bloc kidneys.

In summary, this is an exceedingly complex framework being proposed, which will make the evaluation of the impact of each component on outcomes on the efficiency of kidney allocation and the associated inequities in this system difficult to ascertain. The OPTN should carefully consider and detail in any future proposal how it plans to evaluate components the continuous distribution framework, in addition to the overall impact.

11. Establish Minimum Kidney Donor Criteria to Require Biopsy

The American Society of Transplantation does not support establishing criteria for biopsy requirements at this time. While the proposal is laudatory for the sake of national consistency, the current criteria are too broad. The Society believes that data are currently lacking to demonstrate the biopsies impact outcome. As written, the proposal will likely increase rather than decrease the number of biopsies obtained and therefore increase the number of discards due to abnormal biopsy findings.

The Society's Communities of Practice (COPs) members suggest that minimum biopsy criteria should be narrowed to kidneys from donors with KDPI>85%, diabetes, and/or anuria. COP members also suggest adding proteinuria >1g. Without this addition, there are concerns "any diabetes" could lead to numerous biopsies that wouldn't normally be requested now (e.g., well-controlled diabetes for less than 5 years in a young donor with no protein in urine and good UO).

A mandate that biopsies must be performed in a set of circumstances risks an increase in the use of procurement biopsies, which may add to cold ischemia time and potentially reduce organ utilization.

The proposal does not address the variability of reporting of procurement biopsies. Many donor hospitals do not have sufficient infrastructure to accommodate the proposed changes including a dedicated or available renal pathologist. Variable and potentially unreliable results could lead to increased discards of otherwise usable kidneys. The OPTN should consider a system of standardized central reporting of biopsies by a pathologist who specializes in reading procurement biopsies.

While we recognize the need for uniform biopsy criteria, AST cannot support this proposal until criteria are established that reduce the number of biopsies performed and do not decrease organ utilization.

12. Standardize Kidney Biopsy Reporting and Data Collection

The American Society of Transplantation is supportive of the proposal in concept and offers the following comments for consideration:

1. In the proposed standardized Pathology Report Data Fields:

- Time when the biopsy was performed should be reported and added as a data field here
- Expertise of reading pathologist should be specified- general pathologist, nephropathologist or other

2. In the proposed Data Elements and Definitions, the Fibrin thrombi should be defined further as to which capillaries it is present at (arteriolar, peritubular?)

3. In the proposed Modifications to the DDR, a category for "other" should be added for those less frequent findings that would not fit into any already specified category but may be of importance to note.

4. Identification of nodular diabetic glomerulosclerosis is likely aspirational. Early diabetic mesangial changes are difficult to recognize on frozen section, and when advanced, are typically associated with advanced chronic kidney disease and will therefore be rarely seen in donor biopsies. Nevertheless, the committee supports the initial inclusion of this field, with the expectation that a review will be performed to evaluate the utility of this measurement if future revisions to this instrument are suggested.

5. There is a risk of poor interobserver agreement at the lower end of the proposed scoring scales for Interstitial Fibrosis and Tubular Atrophy (IFTA) and vascular disease. There is some confusion in the Banff classification over IFTA, as fibrosis and atrophy have different cutoffs: no interstitial fibrosis (ci0) is scored as <5% fibrosis, while no tubular atrophy is scored as 0% atrophy. Assessment of ci to the nearest 5% is challenging even under the best circumstances and will likely be quite poor in the setting

of frozen section. It would be simpler and likely result in greater agreement to simply set no IFTA at 0% in this case. A similar argument can be made for vascular disease (cv in the Banff). In the Banff, cv0 = 0%. Small amounts of cv can also have poor interobserver agreement, as it is based on the decrease in cross-sectional area which is challenging to estimate, not the decrease in luminal diameter. Also, it is not clear why the committee chose a different threshold than the Banff schema in this case.

6. We suggest the inclusion of an additional field: arteriolar hyalinosis. Chronic diseases like hypertension and diabetes often cause greater arteriolar than arterial changes, and baseline arteriolar hyalinosis affects graft longevity (Gilbert A et al, Mod Path. 2022; 35(1):128-134). In addition, establishment of a baseline level in the procurement biopsy may assist in the interpretation of progressive chronic calcineurin inhibitor toxicity in subsequent biopsies. Suggested values include:

- 0: no arteriolar hyalinosis
- 1: mild or focal
- 2: transmural or circumferential

7. A simple indication of Nodular Mesangial Glomerulosclerosis is appropriate; however, we recommend changing the quantification to absent, present or unable to determine (and provide reason—due to technique, biopsy preparation or other limitations), the option for unknown should be removed. A concern was raised as Nodular Mesangial Glomerulosclerosis is not a commonly reported finding and may be difficult for general pathologist to identify, there are limitations to assess for this in frozen section tissue preparation technique, and this important finding should be evaluated properly.

8. It should be noted that frozen section tissue preparation is a less than optimal technique, increasing the difficulty of biopsy reads and reducing the accuracy. Accordingly, we recommend the OPTN consider approaches to encourage the routine use of formalin-fixed paraffin-embedded section for all procurement biopsies when cold-ischemic time is not impacted.

9. A .pdf sample form pre-implementation would be beneficial. Additionally, educational support for OPOs and transplant centers will be critical to ensure alignment between OPO, transplant hospitals, and the OPTN.

13. Improving Liver Allocation: MELD, PELD, Status 1A and Status 1B

The American Society of Transplantation is supportive of the need to improve the MELD and PELD calculations and offers the following comments for consideration:

We agree that the addition of sex to the MELD score calculation and the cap of creatinine at 3.0 mg/dl is a step forward to reduce the gender disparity and it will translate into transplanting more female candidates making the allocation system more equitable.

We are significantly concerned about the use of albumin in the MELD 3.0 equation due to variability in serum albumin levels that may result from acutely ill hospital patients receiving IV albumin. This may unintentionally cause practitioners to question whether to infuse IV albumin when indicated, due to concerns regarding disadvantaging their patients. While albumin is an indicator for hepatic synthetic function, there are non-hepatic etiologies for albumin-wasting conditions such as nephrotic syndrome or protein-losing enteropathies that could falsely elevate candidates' MELD scores. Questions were also raised regarding which of many albumin levels would be allowed to be entered for the purposes of the

MELD calculation. AST strongly recommends consideration of alternative markers that are not limited by these issues.

Creatinine is a very poor marker in patients with chronic liver disease. We would recommend exploring the use of different measures to estimate GFR that take into account the presence of chronic liver disease.

There are likely more criteria that should be considered, e.g., bleeding episodes in pediatrics. It will be important for the OPTN to follow the impact of these changes on waiting time for candidates, particularly children, with metabolic liver disease.

14. Modify Living Donor Exclusion Criteria

The American Society of Transplantation is generally supportive of this proposal. Overall, the spirit of the proposed change is to allow the decision to proceed with living donor transplantation to be based on individualized, thoughtful discussion of the potential donor with their care team. The Society offers the following comments for consideration:

#1 Active malignancy, or incompletely treated malignancy that requires treatment, other than surveillance, or more than minimal risk of transmission

We agree with the committee's rationale to allow donor candidates with active or incompletely treated tumors that do not require current or future treatment to donate as long as they carry <0.1-1% risk of transmission to the recipient. While the risk of transmission to recipient is well defined among individuals with low grade prostate cancer and skin cancer, it may be less well defined for other tumors. We recommend transplant hospitals are reminded to include potential malignancy transmission in their recipient informed consent process.

#2 The Committee proposes modifying this exclusion criterion with the following language: "High suspicion of donor inducement, coercion, or other undue pressure"

The policy changes regarding the language around "high suspicion of donor coercion" and "high suspicion of illegal financial exchange between donor and recipient" as absolute contraindications to living donation are well aligned with the legal standards and longstanding practices of transplant centers. This is essential in assuring donors are able to make decisions to undergo such procedures voluntarily and to reduce the risk of psychosocial harm associated with living donation.

#3 The Committee proposes modifying this exclusion criterion with the following language: "High suspicion of knowingly acquiring, receiving, or otherwise transferring anything of value in exchange for any human organ".

We support the proposed modification and want to verify that donating a kidney in a KPD transaction or in exchange for a voucher is excluded from consideration as something "of value" in the transaction.

#4 Diabetes

Living kidney donation has been stagnant in the United States and we applaud the OPTN efforts to increase living kidney donation by expanding the pool of eligible potential donors. We offer the following recommendations for more precise clinical risk assessment:

- Alter terminology to avoid using “type 1” and “type 2” and consider instead “insulin dependent” and “non-insulin dependent” as DM is now understood to exist along a spectrum.

We agree with the OPTN committee’s exclusion of type 1 (insulin dependent) diabetics from consideration as living donors.

With regards to type 2 diabetes (non-insulin dependent), the committee recommends making an individualized assessment of donor demographics or comorbidities reveals evidence of end organ damage or life-time risk of complications. The recommendations are vague and are compounded by absence of a widely accepted calculator that provides accurate estimates of life-time risk of kidney disease, and mortality in living kidney donors with diabetes. In addition, there are no studies demonstrating long-term medical safety of living kidney donation among diabetics and very few studies on living kidney donors with pre-diabetes. However, “resolved” diabetes i.e., A1c < 6.5 with lifestyle modification may be an appropriate expansion esp. with the addition of an age modifier. Risk of lifetime complication from diabetes is very different in a 40-year-old compared to a 60-year-old donor. We believe this could be appropriate in select populations with shared decision making contributing to donor informed consent and careful post-donation monitoring.

#5 “Uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality”

We agree that no additional changes to the wording around “uncontrolled diagnosable psychiatric conditions requiring treatment before donation, including any evidence of suicidality” does not need to be changed to include substance abuse. Substance use disorders are considered psychiatric conditions and are thus captured in the current definition.