# Accelerated placement of hard-to-place kidneys: Answers to frequently asked questions from kidney transplant programs and organ procurement organizations

## Protocol 1: Pre cross clamp placement of KDPI 75-100 Kidneys

### PROTOCOL

**How will kidneys be allocated pre-recovery?**

Prior to cross-clamp of the donor, kidneys will be allocated from donors with a KDPI of 75% to 85%, through classification 26, per OPTN Policy 8.4.K Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than or Equal to 35% but Less than or Equal to 85%. Kidneys from donors with a KDPI greater than 85% will be allocated through classification 19, per OPTN Policy 8.4.L Allocation of Kidneys from Deceased Donors with KDPI Scores Greater than 85%. Concurrently, OPOs will notify programs participating in the protocol of the donor as a backup offer no less than 2 hours prior to recovery, so participating programs can begin identifying potential suitable candidates.

**How will you ensure that the expedited placement protocol does not exclude certain recipients with decreased access to transplant?**

The Work Group designed the protocol to minimize the impact on certain candidate populations with greater potential disadvantages. First, participating OPOs will be required to allocate through the priority classifications for these kidneys. These priority classifications were chosen to ensure that certain subpopulations including 0-ABDR mismatch and high CPRA candidates receive offers prior to proceeding to the expedited process. Pediatric candidates have access to, but are not prioritized in policy for, kidneys from donors with a KDPI greater than 75% (pediatrics receive priority points in the allocation of KPDI 0-35% kidneys). Finally, monitoring will track recipients of expedited kidneys and candidates bypassed.

Importantly, the work group intends for each participating OPO to partner with at least one transplant program that does not routinely accept kidneys with a KDPI greater than 75%, to test whether the protocol can improve access to transplantation for certain patients.

**How are OPOs being held accountable from proceeding to expedited placement too soon?**

Each OPO must maintain records showing compliance with the requirements of the protocol, through either the OPTN computer matching system and/or local documentation. Any data entered into OPTN computer systems may be reviewed by the OPTN, and members are required to provide documentation as requested. Deviation from the approved protocol, including bypassing priority classifications, will be monitored by the OPTN and may be reviewed by the Membership and Professionals Standards Committee (MPSC).

**How will it be ensured that implementation of this PDSA for expedited placement will honor the spirit of equity that is built into our allocation policy?**

The protocol states when an OPO may begin expedited placement. This ensures that equity is maintained for the top of the match run - which is where the most vulnerable candidates are ranked and also where most matches occur. The OPTN will also monitor adherence to priority allocation, recipients of protocol expedited kidneys, and candidates bypassed as the result of the protocol.

**How is it equitable for OPOs to create variances that allow transplant programs to just have open offers to place anywhere?**

The OPTN must always balance equity and medical utility. This is a fundamental guiding principle of the OPTN, and it is also reflected in the OPTN Final Rule. If an available organ is not used, it provides no benefit for any transplant candidate. If there is a potential situation where an available organ cannot be placed by the usual means, and if there is a sufficient rationale for alternate placement, that organ may be matched in a way to avoid non-usage.

Rescue pathway protocols are intended to test methods to successfully place organs at greater risk of non-usage. The OPTN will closely monitor the effects of all such tests, including measures of equity, and will share the results with the transplant community and the public. Any procedure found to reduce transplant equity will be discontinued and not pursued further.

**What happens if all of the high KDPI accepting centers decline?**

If each of the OPO's participating transplant programs decline the kidney offer, the protocol ends for that specific donor. The participating OPO should continue to allocate the kidney(s) and would be expected to allocate according to OPTN policies. Deviation from OPTN policies

when allocating outside of the protocol will be monitored by the OPTN and may be reviewed by the Membership and Professional Standards Committee.

**How can the expedited process be standardized for Dpnation after Circulatory Death (DCD) kidneys for all OPOs to minimize variation in practice?**

This protocol is not specific to DCD kidneys; however, the monitoring will look at the impact of the protocol on DCD kidneys by whether it was a controlled/uncontrolled DCD and whether pumping was used. Future protocols could potentially focus on DCD kidneys more specifically.

**Will the protocol require transplant programs to take steps pre-recovery to check, clear and complete cross-matching on patients?**

The protocol does not require transplant programs to take specific actions as a part of the protocol. However, the intent is that programs that agree to participate in the protocol will work hard to maintain transplant readiness for patients they anticipate will be most suitable to receive offers using the protocol. Specific plans regarding timing of crossmatching may vary between participating programs.

**Our OPO currently utilizes the OPTN contractor Organ Center for kidney allocation; will this create any conflict?**

OPOs are welcome to use the Organ Center after they run through the protocol if they would like the Organ Center to allocate/exhaust the match run.

**How does this work with the same time rollout of the CMS proposed IOTA model?**

We acknowledge there are many changes taking place within the transplantation and donation communities. The Task Force feels it is important to test potential improvements to the allocation system now, regardless of other changes that may or may not take place in the future. We recognize change as a constant force, and we are committed to testing potential improvements to help the field grow. At the same time, the Task Force is involving representatives from many key constituents, including CMS, so that these efforts remain in step with new and changing requirements.

**Will consent be required to be a "pre-identified candidate," or does the program just submit a list based on their criteria?**

OPTN Policy 5.3.C requires transplant programs to obtain written, informed consent from each kidney transplant candidate willing to receive kidney offers from donors with a KDPI greater than 85%. Participation in this protocol does not require additional written informed consent from transplant candidates. Participating transplant programs are expected to proactively identify and communicate with transplant candidates likely to receive offers through this protocol. Consistent with all manners of organ allocation, transplant candidates can always accept or decline a specific offer at the time it is received.

## PARTICIPATION

**How will the participating OPOs and transplant programs be selected?**

The protocol will seek up to 5 organ procurement organization (OPO) participants, which vary in characteristics such as geographic location and population density. The OPTN will solicit interest from all OPOs, and the Task Force Expedited Placement Work Group will decide participants based on that interest. Future PDSA cycles will be used to involve more OPOs as appropriate based on monitoring.

Transplant program selection, which will vary by participating OPO, will represent a spectrum of programs. Factors for consideration include certain criteria such as distance, consideration of a "reasonable travel model", transportation modalities used, acceptable pump times and travel distances, as well as varied historical acceptance practices.

**Can a program join multiple protocols? If so, how would that be tracked?**

Yes. When additional protocols are implemented, there may be overlapping OPO and transplant program participation. Use and adherence to each protocol will be tracked by protocol-specific bypass codes.

**If a program has a low acceptance rate of high KDPI kidneys, will it have an opportunity to get a high KDPI kidney?**

Transplant program selection will vary by participating OPO and will include programs with varied historical acceptance practices.

## MONITORING

**How long before an evaluation of the project will occur in order to allow all OPOs to use these methods?**

Monitoring cycles will occur at least monthly. Under the current plan, the protocol and detailed data will be reviewed regularly by the Task Force work group, who will make recommendations to the Executive Committee about whether to continue the protocol, recruit additional participants, and iterate on the design or discontinuation of the protocol.

**How will OPO and transplant program participation be tracked/monitored for success?**

OPOs will be recruited for the protocol to get a representative group. OPOs participating in the protocol will be monitored regularly. Detailed monitoring will be OPO-specific and identified. Results will also be aggregated across all participating OPOs in order to understand the aggregated effect.

**How will data be collected to score success?**

Detailed monitoring will occur at least monthly and will include OPO specific and identified results as well as aggregated across all participating OPOs. In both instances the monitoring encompasses a set of metrics evaluating:

- the impact of protocols nationally, among participating and non-participating OPOs
- protocol usage
- effect of the protocol on allocation efficiency
- effect of the protocol on equity

Each protocol will have a unique bypass code to be used by participating OPOs. This will help track protocol usage and develop this monitoring.

**Will these kidneys be included in reported outcomes, and what happens when outcomes suffer due to hard-to-place kidney acceptance?**

The protocol will not impact any existing OPTN transplant performance metrics or the Scientific Registry of Transplant Recipients (SRTR) reporting on transplant program metrics. Calculations will continue to utilize risk-adjustment models that account for many of the same factors used to calculate the donor KDPI. For more information about the SRTR risk adjustment models visit https://www.srtr.org/tools/posttransplant-outcomes/.

**What protections will be in place to protect programs from adverse outcomes such as early graft loss, patient death, etc.?**

While these kidneys will be offered differently from standard allocation, transplant hospitals still remain in control of their own offer acceptance decisions. Protocols will be monitored, and the Task Force work group will make recommendations to the Executive Committee if unintended consequences occur. It will take time to accrue the data to monitor post-transplant outcomes like graft loss and patient death.