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Subject: Response to OPTN's Request for Feedback

We commend the OPTN for seeking new ideas to improve the allocation and distribution of deceased donor organs. The purpose of this memo is to stimulate productive discussions and accelerate changes needed to facilitate more life-saving transplants. This memo reflects input from the National Kidney Registry (NKR) and our constituents; and is offered in response to the OPTN's request for feedback from the NKR related to the following concept papers:

- Eliminating the use of DSA and regions from kidney and pancreas distribution
- Guidance on effective practices in broader distribution

The NKR is the largest paired exchange program in the world and has facilitated over 3,200 transplants since its inception in 2007. The NKR facilitates transplants for the most difficult cases including incompatible donor-recipient pairs, high cPRA patients, patients with more time on dialysis, etc. These transplants demonstrate a 34% lower death censored graft failure rate at seven years compared to all U.S. living donor transplants. The NKR graft survival advantage is statistically significant at 3, 5- and 7-years post-transplant.

Approximately 80% of NKR facilitated transplants involve the shipment of a kidney on a commercial airline, charter flight or ground courier. The NKR has never lost a kidney or discarded a kidney due to a logistics problem or the accumulation of cold ischemic time (CIT). In 2019, the NKR expects to facilitate over 700 KPD transplants, complete over

35,000 online living kidney donor registrations and provide life and disability insurance for over 1,000 living donors.

The issues under review in the above concept papers are core to the operational success of the NKR. Because NKR draws its experience from facilitating only kidney transplants, our recommendations are not necessarily intended for, but may be applicable to, other organ systems. We believe the solutions to the problems outlined in the concept papers require a broader view of the issues, so we have provided recommendations that go beyond the initial parameters of the concept papers.

Benefits

Changes to the OPTN system have the potential to achieve the following objectives:

- **Increase the number of transplants:** The number of transplants can be increased by utilizing thousands of deceased donor kidneys that are currently being discarded.
- **Improve equity and access to transplants:** Equity and access to transplants can be improved by ensuring that the majority of waitlisted patients, regardless of where they live, experience similar wait times for a deceased donor kidney. Also, simplifying the organ allocation process so that it is easier to understand will improve the perception of equity and fairness.
- **Improve waitlisted patients' and transplant recipients' outcomes:** Reducing wait times and facilitating more transplants through the utilization of kidneys that are currently discarded will improve the outcomes for waitlisted patients and transplant recipients. Improved donor-recipient matching, and less CIT will drive better graft and patient survival rates, thus improving outcomes.
- **Promote transplant recipient safety:** Transplant recipient safety will be promoted by reducing wait times and facilitating more transplants through the utilization of kidneys that are currently being discarded.
- **Better serve the most vulnerable populations:** The most vulnerable populations will be better served by improving the accuracy of the cPRA calculation and enhancing the precision of the points awarded to hyper-sensitized patients. Approximately 1,000 100% cPRA patients – who are essentially stuck on the wait list – will have a better opportunity for a transplant.
- **Improve OPTN efficiency:** By utilizing kidneys that are currently being discarded, each additional deceased donor kidney transplant will save Medicare and private health insurance providers approximately \$500,000 per transplant (present value). Better donor-recipient matching, and less CIT will also reduce graft failure rates and save on dialysis related costs.
- **Reduce Healthcare Costs:** If 2,000+ additional kidney transplants per year can be facilitated, Medicare and private health insurance providers will save approximately \$1 billion annually. If kidney discards can be reduced, and facilitate more transplants, the savings will more than offset the costs to improve the deceased donor kidney match offer & logistics process. The OPTN should be reimbursed by Medicare and the private health insurance providers for facilitating more transplants. One approach that would better align the financial interests of the parties would be to replace the current OPTN registration fee with a higher transplant success fee.

Recommendations

We recommend that the OPTN streamline its decision-making process to better support faster decision making and implementation. Vesting more decision-making authority in senior OPTN leadership and reducing the size of the board are a few strategies that may help facilitate a more streamlined decision-making process.

We recommend that the OPTN move from the current sequential match offer process to a batch match offer process. This will speed up the kidney offer/acceptance process, reduce cold ischemic time and reduce organ discards. The batch match offer process should execute in three tiers with three hours allotted for each tier. If there are no potential match offers in a tier, the system would immediately skip to the next tier and make the next batch match offer. The first two tiers would complete in a total of six hours allowing the final batch offers to go out with only six hours of match offer related CIT. The final batch of match offers would go out nationally and allow for the placement of organs which are currently being discarded. The following is an outline of the three-tier batch match offer approach.

Tier-1: Special Situation Offers

- Offer timing 0 – 3 hours
- Target: 1%-5% of transplants facilitated in tier-1 offers
- Offers would target approximately 0 – 5 potential matches
- National in scope: no geographic limits
- Target examples: 99.99%+ cPRA patients, great donor-recipient matches, etc.
- The patient with the highest points, that accepts, receives the offer
- No patient wait time limitations on tier-1 offers

Tier-2: Local Offers

- Offer timing 3 – 6 hours
- Target: 70%-80% of transplants facilitated in tier-2 offers
- Offers would target approximately 0 – 20 potential matches
- Ground moves only: 400 miles radius from donor recovery hospital
 - The 400-mile limit equates to about an 8-hour max drive time
 - The 400-mile limit avoids air moves that are riskier and less reliable
 - The 400-mile limit could be reduced or increased but should be standardized nationally based on the logical limits (drive time) of ground moves
- The patient with the highest points, that accepts, receives the offer
- Only offered to patient with, for example, > 4 year wait time
- Max points allocated to patients with, for example, > 5 year wait time

- The above conditions will stabilize the entire system around a 4-5 year wait time
- The wait time range (4-5 years) could gradually be narrowed (e.g. 4.3 – 4.6 years)
- A narrower wait time range would allow centers/patients to better prepare for offers and would eliminate the current incentive for patients to multi-list

Tier-3: Clearing Offers

- Offer timing 6 – 9 hours
- Target: 20%-30% of transplants facilitated in tier-3 offers
- These are the kidneys that are currently being discarded
- Waive CMS outcome related penalties for tier 3 transplants
- Reduce the SAC fee to 50% to offset extended hospital stay costs, etc.
- The first center/patient to accept the kidney, receives the offer
- National in scope: no geographic limits
- No wait time limitations

Transplant centers would be encouraged to maximize utilization of donor preferences to filter out match offers that will not be accepted, thus reducing the number of match offers requiring responses, improving the overall efficiency of the system. Center match offer declines and non-response rates would be tallied and published to provide transparency for patients. Non-responses and declines should be minimized.

Batch Match Offer Examples:

Scenario 1: Two patients are offered matches in the first batch offer and both centers/patients accept the offers. Patient 1 has a cPRA of 99.990% and is an 'A' blood type (odds of match = 1 in 10,000). Patient 2 has a cPRA of 99.990% and is a 'O' blood type (odds of match = 1 in 10,000). Since patient 2 will be drawing from a smaller donor pool and has a higher cPRA, they will accrue more points (see section on Calculated Panel Reactive Antibodies) and receive the match offer.

Scenario 2: The centers caring for the two patients in scenario 1 either decline or do not respond. After three hours, the first match offers are closed out and a second batch match offer is sent to 18 patients within 400 miles of the donor center. All of these patients have been on the wait list for some minimum amount of time (e.g. 4 years). After three hours, 4 offers have been accepted, 8 offers have been declined and 6 offers have not received a response. Out of the 4 offers that have been accepted, the patient with the highest points receives the offer.

Scenario 3: All of the offers in scenario 1 & 2 have either been declined or have not received a response. After three hours the tier 2 match offers are closed out and a third batch match offer is sent to 45 patients that are biologically compatible, preference compatible and have opted into tier 3 offers. After 45 minutes, a center accepts one of the offers and the remaining 44 offers are closed.

Eliminate Provisional Acceptances

The batch match offer process requires the elimination of the 'provisional' acceptance which is always problematic in time sensitive processes. If an offer is accepted, the kidney must go to the intended recipient. If the kidney does not go to the intended recipient and the center is above a cutoff threshold for this kind of situation (e.g. > 5% kidneys not going to intended recipient), the recipient center would pay an out of compliance fee (e.g. \$20,000). This will encourage centers to only accept offers for kidneys that are actually acceptable for patients that are available for surgery. When kidneys are frequently given to backup patients because the intended recipient fails the cross match, is not ready for surgery, etc. it undermines fairness and trust in the system. The rate of kidneys not going to intended recipients should be published to support transparency for patients.

The elimination the 'provisional' acceptance also requires all information related to the kidney to be online before the offer is made. If this information is not available or is inaccurate when the offer is made, the procuring OPO should pay the out of compliance fee. When certain critical information cannot be made available before the match offer goes out, this should be noted in the match offer and should automatically generate a root cause and correct action plan request.

Revise Calculated Panel Reactive Antibodies

The OPTN needs to change the current cPRA calculation to a 'brute force' calculation so that the cPRA is precise and can better serve hyper sensitized patients. The brute force calculation will better reflect changes in the donor pool composition and accurately differentiate between a 99.990% cPRA patient and a 99.999% cPRA patient, the later which is ten times as hard to match as the former.

The current OPTN kidney point allocation rounds a 99.51% cPRA patient up to a 100% cPRA. This point allocation needs to be enhanced to differentiate between patients with very high cPRAs (e.g. 99.9%, 99.99%, 99.999%, etc.) and point assignments must also be adjusted to reflect the expected donor pool volume for a given patient blood type.

For example, a 99.99% 'O' blood type patient is twice as hard to match as a 99.99% 'A' blood type patient. Currently, the OPTN kidney cPRA point allocation ignores the patient blood type and rounds to the nearest percent (e.g. 98%, 99%, 100%). This approach is far too imprecise to equitably serve the thousands of hyper sensitized patients on the wait list.

We recommend enhancing the point allocation for highly sensitized patients by basing it upon the patient's expected wait time. This approach would use the more precise brute force cPRA and the expected blood compatible donor pool (e.g. projected based on the past 2-3 years) to calculate the expected wait time for each patient. This approach has helped the NKR consistently match and transplant hyper sensitized patients with cPRAs up to 99.7% on a living donor pool of only 700 donors per year. Based on the NKR experience and the larger deceased donor pool, we would expect the OPTN to consistently match and transplant patients with cPRAs up to 99.997% if the point allocation for highly sensitized patients was enhanced.

The following are expected wait time calculation examples:

- If a patient has a 99.99% cPRA (match odds = 1 in 10,000), is an 'A' blood type and the donor pool will provide approximately 12,000 blood compatible donors/year; this patient's expected wait time would be approximately 1 year (10,000/12,000). Minimal points needed to find a match.
- If a patient has a 99.999% cPRA (match odds = 1 in 100,000), is an 'A' blood type and the donor pool will provide approximately 14,000 blood compatible donors/year; this patient's expected wait time would be approximately 8 years (100,000/12,000). Maximum points needed to find a match.
- If a patient has a 99.999% cPRA (match odds = 1 in 100,000), is an 'O' blood type and the donor pool will provide approximately 6,000 blood compatible donors/year; this patient's expected wait time would be approximately 17 years (100,000/6,000). Maximum points needed to find a match.

Because many transplant centers cannot perform accurate virtual cross matching, which is critical for matching highly sensitized patients in a time sensitive environment, the OPTN should designate high cPRA centers of excellence. Any patient with a cPRA greater than the high cPRA cutoff (e.g. 98%) should be referred to one of these high cPRA centers of excellence so that the highly sensitized patients have an opportunity to receive a well-matched deceased donor transplant. As a point of reference, there are over 6,000 wait list patients with a cPRA of over 98% and approximately 1,000 patients with a cPRA of 100%.

Improve Logistics

The logistics required to support an effective batch match offer process should include the following key components:

- **RCCAP Process:** Any match offer or logistics failure should automatically generate a request for a Root Cause and Corrective Plan (RCCAP) from the organization responsible for the failure. For example, if a kidney did not get transplanted into the intended recipient, a RCCAP should be completed by either the transplant center or the OPO. A Pareto analysis should be performed on the RCCAPs monthly to initiate solutions for recurring problems that can be systematically corrected. The Pareto analysis should be published to support transparency.
- **GPS Tracking:** Utilize smart phone GPS technology for all shipped organs. Integrate GPS tracking with 'fail-safe' systems to ensure positive confirmation of all inflight organ moves (e.g. wheels-up and kidney on plane, plane landed and kidney on the move, etc.).
- **Logistics Monitoring:** Implement real-time logistics failure reporting systems that are integrated with the GPS smart phone technology and the national courier vendors. Examples of these real-time integrated monitoring systems include the NKR's swap tracker and move tracker.
- **OPO Efficiency:** There are currently 58 Organ Procurement Organizations operating individual geographic monopolies in the United States. The lack of competition in any market allows for poorly performing organizations to stay in business and underserve their markets. This is true for the OPO market as it is for all markets. To foster competition and systematically close poorly performing OPOs, a process should be created whereby the lowest performing OPOs (e.g. 2-5 per year) are merged into the strongest bordering OPOs. This would also allow OPOs to leverage economies of scale which are significant in the OPO industry.
- **National Couriers:** The OPTN, working in partnership with the OPOs, should contract with 2-4 national organ couriers to move all organs beyond the local OPO donor service areas with an option to provide services within donor service areas. These courier vendors should be positioned to back each other up. The best performing courier vendor(s) should receive the largest portion of the business so that competition is fostered and top performance is systematically rewarded. The courier contracts should include clear service standards and penalties.
- **Avoid Connector Flights:** When shipping organs via commercial air, connector flight moves should be replaced with charter or charter/commercial hybrid moves whenever possible. If there is no other option, connector flight moves should always utilize an onboard courier to mitigate the extreme risk inherent in this mode of transport.

- **Charter Flights:** The national courier vendors should manage the acquisition of charter flights to concentrate purchasing power across all OPOs. Generally, prop charters should be used for shorter distances (e.g. under 1000 miles) and jet charters should be used for longer distances (e.g. over 1000 miles). Charter/commercial hybrid moves are generally the fastest and most cost-effective method of moving a kidney more than the maximum driving distance (e.g. 400 miles). The NKR has not experienced problems with a shortage of charter flights or pilots.
- **Organ Containers:** The OPTN, working in partnership with the OPOs, should develop & deploy a standardized kidney shipping container that supports a standardized kidney pump, built-in signage and a compartment for holding a standardized GPS smart phone. The advantages of pumping a deceased donor kidney is well documented. These standardized kidney containers should be purchased in volume (including a national maintenance contract) and seamlessly shared across all OPOs.
- **Lost or Damaged Organs:** The OPTN should provide a quarterly report on all organs lost in transit or damaged (e.g. kidney frozen in flight, kidney ended up in wrong city, etc.). A RCCAP should be completed for every lost or damaged kidney keeping in mind that each kidney has the potential to save someone's life and also save Medicare and the private insurance companies approximately \$500,000.

Enhance Donor-Recipient Matching

The current OPTN point allocation for donor-recipient matching is based on A, B, DR antigen miss-matches. This point allocation approach to donor-recipient matching is dated and should be upgraded to reflect the latest science for evaluating the quality of the donor-recipient matches (e.g. Living Donor KPI, specific antigen mismatch risk for de novo antibody, epitope matching, etc.). This is an opportunity for collaborative research to find the best approach for improving long term graft survival through better donor-recipient matching.

Conclusion

Thank you for requesting feedback from the National Kidney Registry on these important concept papers. Please let us know if you have any questions or if we can be of any additional service to the OPTN on these important matters.