Meeting Report

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Dynamic Challenges Inhibiting Optimal Adoption of Kidney Paired Donation: Findings of a Consensus Conference

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While kidney paired donation (KPD) enables the utilization of living donor kidneys from healthy and willing donors incompatible with their intended recipients, the strategy poses complex challenges that have limited its adoption in United States and Canada. A

consensus conference was convened March 29–30, 2012 to address the dynamic challenges and complexities of KPD that inhibit optimal implementation. Stakeholders considered donor evaluation and care, histocompatibility testing, allocation algorithms, financing, geographic challenges and implementation strategies with the goal to safely maximize KPD at every transplant center. Best practices, knowledge gaps and research goals were identified and summarized in this document.

Key words: Allocation, donor evaluation, finances, histocompatibility testing, kidney paired donation, nondirected donors, paired kidney exchange, transport

Abbreviations: CMS, Centers for Medicare & Medicaid Services; EPC, Executive Planning Committee; HLA, human leukocyte antigen; KPD, kidney paired donation; NDD, nondirected donor; SAC, standardized acquisition charge; UNOS, United Network for Organ Sharing.

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Introduction

KPD, otherwise known as paired-kidney-exchange (1), has emerged as a strategy to utilize grafts from healthy and willing donors incompatible with their intended recipients (2). KPD registries match incompatible donor/recipient pairs to facilitate transplants that would otherwise have been impossible or high risk. KPD represents the fastest growing source of transplantable kidneys in the last decade (3). In addition to single center registries (4), there are seven active multicenter KPD registries in the United States (Alliance for Paired Donation, Johns Hopkins, National Kidney Registry, North American Paired Donation Network, North Central Donor Exchange Cooperative, United Network for Organ Sharing (UNOS), Washington Regional Transplant Community). Each registry has unique and innovative strategies to address the challenges of KPD (3,5-9). Notwithstanding these complexities the safety of the donors and recipients remained paramount in our considerations.

To identify and address the dynamic challenges and complexities that hinder the full realization of KPD potential,

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a consensus conference was organized and held on March 29–30, 2012. Surgeons, nephrologists, immunogeneticists, clinical and financial coordinators, psychologists, social workers, living donors, transplant recipients, insurance industry and government agency representatives convened with the aim "to achieve consensus and disseminate best practices, to identify barriers to optimal participation, and to collect and analyze data through scientific research that will maximize kidney paired donation at every transplant center in the United States and worldwide." Workgroups addressed donor evaluation and care, histocompatibility testing, allocation, financing, geographic considerations and implementation strategies. Here, we summarize the Workgroups' key recommendations and research goals.

Methods

The Kidney Pancreas Advisory Council for the American Society of Transplantation identified the need and created a proposal for a consensus conference on contemporary issues facing KPD that was accepted by the Executive Board. The American Society of Transplant Surgeons leadership agreed to cosponsorship and other key professional stakeholder societies were approached for participation and support. An Executive Planning Committee (EPC) was formed that delineated six topic areas corresponding to Workgroups and selected Workgroup Leaders (2 per workgroup) and Facilitators (1 per workgroup) (Appendix). Workgroup Leadership, guided by the EPC, then selected workgroup members with careful attention to diversity of constituency, expertise, and geography

Workgroups prepared for the conference by identifying challenges, reviewing data and exchanging ideas and expertise. The EPC, Workgroup Leaders and Facilitators teleconferenced monthly. The Consensus Conference on Kidney Paired Donation, held on March 29–30, 2012 in Herndon, VA, convened 73 physicians, histocompatibility experts, allied health professionals, transplant administrators, representatives from current KPD programs, commercial insurers and patients (donors and recipients). Workgroup recommendations were presented in a public plenary session. The conference report was written by Workgroup Leaders and Facilitators who reviewed the relevant sections with their respective Workgroup Members. The first and last authors assembled and edited the final manuscript. KPD terms are defined in Table 1.

KPD Donor Evaluation and Care

The health and safety of the living kidney donor is the foremost responsibility of transplant centers. Informed consent to donate a kidney for KPD must include an explanation of the challenges imposed by the involvement of geographically distant transplant centers and the extra precautions necessary to ensure donor safety and privacy. The summarized recommendations (Table 2) address these unique considerations to optimize KPD and thereby reassure potential donors and their recipients.

All potential living donors should be informed about KPD early in the educational process, prior to compatibility testing. This allows sufficient time for the potential donor to

consider donation preferences, discuss options with their family and the donor evaluation team, and attenuate feelings of pressure or coercion if KPD is presented after incompatibility is determined.

A centralized information resource for nondirected donors (NDDs), describing the benefits and risks of donation options, should be developed by the transplant community. Because of their potential to trigger multiple transplants, all NDDs should be informed about KPD. NDDs should undergo psychosocial assessment prior to medical evaluation to ensure that they are making an informed and noncoerced choice. The National Living Donor Assistance Center should provide travel and lodging expenses to NDDs.

General living kidney donor consent and evaluation quidelines, such as those being developed by the AST/ASTS/NATCO/UNOS Joint Societies Work Group should be integrated with local center protocols and utilized for KPD donor evaluation (10). However, unique aspects of multicenter KPD warrant additional guidelines. KPD donor consent must include discussion of other donation options, the risks of kidney transport, the possibility of last minute cancellations, and the potential for an unexpected redirection of the kidney. In addition, the consent should specify the donor information that will be disclosed to the actual recipient. Only information that is necessary to assess kidney quality and potential for disease transmission should be included. Anecdotal reports have shown that disclosing unfavorable recipient outcomes such as primary nonfunction or recipient death can have adverse psychological consequences for the donor. Therefore, the Workgroup recommended that centers inform donors of the psychological risks of receiving recipient information and disclose only what the recipient has authorized.

Donor follow-up should abide by the recommendations of the Joint Societies Work Group consensus document (10). In the KPD setting, we recommend that the center performing the donor surgery bear responsibility for donor follow-up care, including the management of donation-related complications and completion of regulatory documents.

Histocompatibility Recommendations for KPD

Recognizing the importance of histocompatibility testing and laboratory-to-laboratory variation in test methods and transplant center-to-center variation in KPD acceptance criteria, a standardized approach was sought for both testing and information. Our Workgroup recommendations are based on two premises: (1) that histocompatibility laboratories validate and correlate their test methods with their centers' clinical protocols; and (2) that histocompatibility experts are essential participants in the evaluation of potential KPD. Suggested "best practices" include

Table 1: Glossary

Batch matching: Identifies best matches among currently available participants

Bridge donor: A donor whose intended recipient has already received a kidney from another incompatible paired donor and waits to donate to a suitable recipient at a later date

Chain of custody principle in KPD: Precise and detailed documentation of the kidney's location and the responsible parties (name and contact information) for the donor kidney from its recovery until its delivery

Closed chain: A KPD chain that ends in the transplant of patient on the waitlist

Dynamic optimization: Identifies best matches among currently available participants but with consideration of and accommodation for (near) future match opportunities

Hierarchical matching: A matching strategy that orders potential match solutions based on based on a specific order of operations such as the most number of sensitized patients, the longest chains, etc.

Interactive matching: A matching strategy that generates multiple potential match solutions, and incorporates human judgment to choose among them

Kidney paired donation (KPD): Process in which two or more candidates with willing and healthy, but incompatible donors can exchange donor grafts such that two or more compatible transplants can occur simultaneously or in sequence. Also known as kidney paired exchanges

KPD champion: A person at a transplant center who advocates for KPD as a transplant option and identifies patients that may benefit from KPD

Lifeguard status: "A term attached to an airliner's radio call sign when the aircraft is transporting time sensitive medical materials" (38) **Nondirected Donor (NDD):** An individual who donates a kidney to a recipient with whom they have no emotional or genetic relationship. Also known as an altruistic or a Good Samaritan donor.

Nonsimultaneous extended altruistic donor (NEAD) chain: Clusters of chain transplantations, in which the donor at the end of each cluster served as a "bridge donor," thus extending the interrupted chain at a later time

Open chain: A KPD chain that continues to be extended by donating to a recipient who offers an additional donor

Optimization matching algorithms: A matching strategy that identifies the solution with the largest number or best selection of transplants in the weighting system chosen, for example, priority points reflecting relative values for donor and recipient characteristics

Table 2: Consensus recommendations for KPD donor evaluation and care

- All potential NDDs should be informed about KPD as an option prior to initiating evaluation
- The medical and psychosocial evaluation of an NDD should be guided by the "Evaluation of the Living Kidney Donor—a Consensus Document from the AST/ASTS/NATCO/UNOS Joint Societies Work Group" recommendations (10)
- NDDs should undergo preliminary (i.e. screening) assessment by a mental health professional before the medical evaluation is initiated
- The National Living Donor's Assistance Center should provide travel and lodging expenses to the NDDs
- In addition to the standard informed consent donor nephrectomy, KPD donor informed consent should include these additional elements: risks and benefits of non-KPD donation options, kidney transport, possible kidney redirection due to unforeseen circumstances, and the inability to provide information about the actual recipient
- Donor privacy should be strictly protected. Specific consent should be obtained from the donor if their name is released to the press
- The donor center evaluation processes and procedures at which the donor nephrectomy takes place should be followed
- All evaluative studies (including anatomic imaging) should be completed before registering a donor in KPD and repeated after 12 months. Anatomical imaging, however, does not need to be routinely repeated

recommendations that deal with the extent of human leukocyte antigen (HLA) typing; the timing and nature of antibody characterizations; the definition and listing of unacceptable antigens; the reporting of histocompatibility data; and the performance of prospective and final crossmatches (Table 3).

HLA typing should be done by molecular methods and include all major loci and common null alleles. The definition of sensitization is difficult given the high sensitivity of the solid phase immunoassays which can vary depending on test type, manufacturer kit design, assay protocol, lot variations of reagents and possible interference from IgM antibodies, immune complexes and/or the presence of therapeutic monoclonal antibodies (11–14). Setting uniform criteria for cutoff values for positive antibody levels is problematic given that levels corresponding to positive crossmatch tests also vary for different antibody

specificities (14). Further, there are conflicting reports on transplant outcomes across low levels of donor-specific HLA (15–19).

Given these challenges, it is imperative that transplant centers work closely with their laboratory to define "centerspecific risk criteria" for listing unacceptable antigens. Recommendations to accomplish this task include correlating antibody tests with actual crossmatch results; establishing ranges of positive reactions for different antigen specificities; and considering risk conferred by repeat mismatches and historic sensitization. Antibody analysis should be done by at least two methods and specificities should be confirmed using an HLA single antigen assay. To permit comparative evaluations among centers, laboratories should report both the types of assays used for antibody evaluations and the ranges of reactivity considered positive. Histocompatibility testing for desensitization coupled with

Table 3: Recommended guidelines for KPD histocompatibility testing

- HLA typing: Should be DNA based for HLA-A,-B, -C, -DRB1, -DRB3-5, -DQA1, -DQB1, -DPB1 loci and inclusive of certain specific alleles and common null alleles, as needed. Extended donor typing may be required depending upon antibody specificities
- Antibody testing: Two methods should be used, at least one being a solid phase immunoassay. Antibody specificity should be confirmed by a single antigen assay. Assay limitations should be recognized and considered in interpretation. Antibody testing should be performed at least quarterly and after any proinflammatory/sensitizing event
- Unacceptable antigens: Unacceptable antigens should be assigned based on the transplant center's crossmatch acceptance criteria and should be updated whenever antibody tests indicate a change. There should be two levels of unacceptable antigens, high and low risk; possible listing of antigen combinations to address multiple, weak antibodies. Definition of sensitization should be based on the calculated panel reactive antibody
- Virtual crossmatching: Correlation of antibody assays with transplant center risk criteria is essential. Labs should achieve 95% accuracy in crossmatch prediction. Labs should try to identify combinations of multiple, weak antibodies that could yield a positive crossmatch when a donor has all of the corresponding antigens
- **Crossmatching:** Flow cytometric crossmatches are recommended for sensitized patients. Unexpected positive results should be resolved and unacceptable antigens updated. Patients should be inactive until reasons for failed crossmatches have been resolved and unacceptable antigens are updated. Cryopreserved donor cells should be available for preacceptance, "exploratory" crossmatches.
- Exchange of specimens and data: There should be standardized practices for test requisitions, labeling, and shipment of shared samples. Data entry should be verified by two person audit, at least one of whom should have histocompatibility expertise
- **Communication:** Histocompatibility Laboratory Directors should participate in the evaluation of proposed paired donation matches and be available to provide consultation. KPD programs should have a *Histocompatibility Advisory Committee* comprised of physicians, surgeons, coordinators and histocompatibility experts provide quality assurance review and facilitate logistical planning for testing

KPD should include additional testing needed to monitor desensitization efficacy.

Laboratories should strive to achieve 95% accuracy in KPD crossmatch predictions and define two levels of unacceptable antigens: (1) absolute contraindications (antibodies with high likelihood of causing a positive crossmatch); and (2) relative contraindications (antibodies that might yield positive crossmatches when antigens are present in certain combinations). Ideally, KPD matching algorithms KPD should accommodate such designations. It is vital that antibody analyses and unacceptable antigens be updated, with retesting of unacceptable antigens at least quarterly, after any potentially sensitizing event, and after any unexpected crossmatch result. To permit meaningful evaluations of antibody data, laboratories should report assay type and ranges of reactivity that correlate with expected crossmatch results.

Lastly, effective communication among KPD registry members is essential to optimal KPD matching. Laboratory directors and staff should be available on a full time basis to consult on KPD matches. There should be a written agreement with respect to testing KPD recipients and donors. An advisory committee comprised of physicians, surgeons, coordinators and histocompatibility experts should not only evaluate prospective matches, but assist in logistical planning for collection of test samples and ongoing quality assurance review of unexpected positive crossmatches. Similar committees should also be established within individual transplant centers.

KPD Allocation Policies and Algorithms

Usually, computerized matching algorithms are used to identify the "most desirable" combination of donor and re-

cipient pair matches. However, as yet, there is no consensus regarding the "best" KPD matching strategy. Existing KPD allocation protocols can be separated into two broad categories, employing either mathematical optimization or hierarchical matching rules.

Optimization systems assign priority points for donor and recipient characteristics, administrative concerns, and transplant center preferences. Point designations reflect the clinical and operational values of the allocation system. Point values should not be arbitrarily assigned but reflect true biological effects: e.g. additional consideration for highly sensitized, pediatric, or medically urgent candidates, ESRD time, preservation of blood type O donors for blood type O recipients, rarity of donor tissue type and zero HLA mismatches (2). Priorities for reducing distance between centers and prioritizing same center matches could be incorporated but should be deemphasized as they represent logistical rather than biological considerations. Optimization selects the combination of matches that yields the highest number of points (2).

In contrast, rules-based hierarchical systems match pairs based upon a specific order of operations. For example, a hierarchical system might identify the matches that would transplant the greatest number of sensitized patients, but exclude solutions where blood type O donors donate to nonblood type O candidates. Interactive systems employ prespecified algorithms or human judgments to compare multiple solutions and "choose" the solution that best meets the priorities of the system. Advocates within the Workgroup who favor optimization strategies point out that for any given weighting system, optimization always achieves the largest number or best selection of transplants in contrast to hierarchical strategies that might obscure the most preferred solution (20). On the other hand, advocates of hierarchical and interactive systems favor the

flexibility of generating and comparing multiple solutions for the same match-run.

Batch matching refers to deferring match runs until an adequate pool of candidates has accrued. However, batching identifies the best matches among only the participants listed (21–23), excluding future opportunities that might yield greater benefit. Too frequent matching reduces the total number of matches that might be made. When pairs are listed in multiple registries, registries that match too frequently can preempt effective matching in other registries. Dynamic optimization has been proposed as an alternative to batch matching. Dynamic optimization would defer some matches available today to accommodate match opportunities that may be available in the future (24).

Nonsimultaneous extended altruistic donor (NEAD) KPD chains are initiated by a NDD and end with an unmatched donor (6). In "open" NEAD chains the end-of-chain donor is a "bridge donor", facilitating future KPD chains when compatible candidates are identified. In "closed" chains the end-of-chain donor donates to the deceased donor waiting list. Chains simplify matching as the initiating-donor's compatibility with the KPD pool is not constrained by the need to find a compatible donor for his/her associated candidate. The Workgroup recommended allowance of both open and closed chains (25), with chains ending when bridge donors are difficult to match or prefer not to wait longer (26). Shorter chain segments and exchanges are less likely to be scuttled than longer segments (27). However, longer chains may allow transplantation of more highly sensitized patients, although strategies for rapid correction of broken chains are essential. Finally, practices that maximize benefit for all candidates, such as combining KPD with desensitization, inclusion of NDDs, and use of compatible pairs should be encouraged (25,28-30).

While Canada has adopted a single, national KPD registry, the United States has multiple multicenter and several single center KPD registries. Centers performing in-center exchanges may withhold easy-to-match pairs, referring only difficult to-match-pairs (e.g. highly sensitized candidates, or blood type O candidate with a blood type AB donor) to collaborative KPD registries. Notably, pairs enrolled in more than one KPD registry can be disruptive when the same KPD pair simultaneously matches in more than one program. While separate KPD programs persist, the Workgroup strongly recommends rapid review of match offers and immediate inactivation of multiply listed candidates in all registries whenever a prospective match is accepted.

Although advantages of multiple KPD registries include the innovation and competition to drive KPD forward, dividing participants into separate, smaller pools ultimately decreases matching opportunities, particularly for sensitized candidates (2,21,30). The Workgroup believes that the greatest benefit for candidates will eventually be achieved

in a single well-functioning registry that encompasses the successful aspects of currently operating programs.

Overcoming Geographic Barriers to KPD

Increasing the size of KPD pools by including pairs from distant geographic areas facilitates higher transplant rates (2) and, indeed, many KPD transplants have occurred over substantial distances (9,31). However, balance is required between achieving higher transplant rates and limiting the complexities and costs inherent to geographical expansion (Table 4).

Exchanges between distant centers require kidney transport or donor travel. Both options should be available to KPD participants. Donor travel is advantageous in that it foregoes the logistical complexities of organ transport, minimizes cold ischemia time and reduces financial complexities related to donor costs. However, for the donor, travel is costly, subjects him/her to an unfamiliar surgical team and hospital, and often separates him/her from support networks and his/her recipient. Follow-up care, particularly if complications ensue, can be challenging. If the donor does travel, inconvenience and expense should be minimized. The recipient center should complete evaluation and donation during the same visit if possible. Payers should cover donor travel and lodging costs given that, by donating and traveling, the donor is enabling not only the recipient's transplant, but also those of other recipients.

All KPD centers should be willing to send and receive kidneys. This practice has been safe, reliable (32–35) and is now the most prominent strategy to cross geographic barriers (9). Donors are able stay at their local center with familiar providers and an intact support network. Of the first 272 transplants in the National Kidney Registry, 63% of the grafts were transported to another institution (9). Clearly, kidney transport results in longer cold ischemia time, poses additional logistical and billing complexities, risks unexpected transportation challenges including flight delays, and requires nephrectomies and/or transplantations during off hours. In addition, a kidney recovered by an unfamiliar donor team engenders anxiety over anatomical and technical issues, particularly if there is poor communication prior to and immediately after the donor nephrectomy.

Despite these concerns, evidence from both retrospective registry data and prospective clinical studies (9,32–35) led to a Workgroup consensus that living donor kidneys can be safely transported and that kidney transport maximizes KPD participation and volume. To minimize risk and optimize transplant function, protocols should specify (1) standardization of packaging and labeling, consulting OPO expertise if necessary; (2) establishment of chain-of-custody during shipment with full and detailed documentation of the kidney's location and the parties (name and contact

Table 4: Recommended policies to overcoming geographic barriers to KPD

- Donors should have the option to travel to the recipient center and to choose to where they are willing to travel. Donors should never be required to travel
- KPD centers should be willing to transport kidneys, both to and from the center
- A standard format for sharing patient information and medical records should be defined
- Payers should cover donor travel and lodging costs when a donor travels for KPD.
- Packaging, labeling and transportation may benefit from OPO support or guidance
- Direct surgeon-to-surgeon communication is recommended prior to and immediately after KPD donor nephrectomy
- All kidney transport should follow chain-of-custody principles
- When traveling by commercial plane, all flights should be designated lifeguard. Kidneys on nonstop routes should be accompanied by a tracking device. Kidneys on routes involving any layovers should be accompanied by a courier

information) responsible for the donor kidney from its recovery until delivery; (3) use of "lifeguard status" for all commercial flights to include a request to waive the standard lockout for tendering, to expedite loading and unloading of the kidney to and from the plane, and to secure priority takeoff and landing; (4) use of tracking devices for nonstop travel; (5) provision for escorts for layover routes who can facilitate alternative transportation in the event of delays and missed connections.

KPD Financial Challenges

Multicenter KPD incurs unique financial costs that are challenging to recover under current standard transplant centers practices (3,8). Strategies to pay for the following costs were discussed: (1) evaluation of potential KPD donors, (2) evaluation of NDDs, (3) immunogenetics and histocompatibility testing, (4) KPD administration including staff salaries, (5) KPD registry administration, (6) donor travel or kidney transport, (7) donor nephrectomy facility and professional fees and (8) donor complications/follow-up (3,8). Three payment models were evaluated: departmental charges, center-specific living donor standard acquisition charge (SAC) and a national KPD SAC.

The following criteria were used to evaluate each model: (1) donor expenses must be ultimately paid for by the recipient center; (2) predictability; minimizing center-to-center variations in donor costs charged to recipient centers; (3) portability; minimizing barriers to professional reimbursement for donor nephrectomy posed by recipient payer contracts; (4) full recovery of donor evaluation, surgery, follow-up care, and complication treatment costs by donor centers; (5) compliance with Centers for Medicare & Medicaid Services (CMS) rules; and (6) administrative ease (eliminating individual negotiations for every transplant). There was a consensus that a national KPD SAC would best achieve these criteria (Table 5).

In a national KPD SAC, all costs associated with evaluating potential KPD donors would be aggregated by a single administrative institution. To account for geographical and other cost-of-care differences between hospitals this institution would differentially reimburse donor evaluation expenses at a predetermined rate acceptable to CMS,

commercial payers and providers. The aggregated national costs would then be used to derive a KPD SAC charged to recipient centers at the time of transplant. The SAC represents the average cost of a realized donor (donor who actually donated) and would be calculated annually. Each recipient center would pay the same SAC, regardless of the donor center, eliminating individual negotiations. NDDs could be evaluated without financial risk (or ownership) by the evaluating center. The availability of an outside entity to pay for donor evaluation costs prior to an actual match would reduce upfront financial risks inherent in KPD. The elimination of financial risk could, however, increase the cost of KPD.

Currently, CMS dictates that all professional services during a living donor's donation hospitalization are Part B expenses and thus cannot be recorded to the cost report. The Workgroup proposed that, similar to deceased donor donation, the national KPD SAC should encompass donorrelated professional fees thereby eliminating the need for individual agreements with out-of-network payers. A national KPD SAC would be a single, consistent and predictable cost. This predictability is valued by both recipient and donor centers for contract negotiations and by payers for underwriting their transplant risk portfolio. Notably, a national KPD SAC is the model favored by several prominent transplant commercial insurance payers (36).

Financial responsibility for donor complications remains an unresolved challenge. CMS provides for the reimbursement of both professional and facility fees for donor complication costs by billing through the recipient's Medicare number. The mechanism for reimbursement from commercial payers is less clear cut. The situation becomes increasingly opaque as time from donation increases. Therefore, provisions for time-limited, comprehensive insurance for donors' complications should be developed.

KPD Implementation Strategies

The difficulties of implementing KPD protocols and polices at individual centers are amplified in multicenter exchanges when successful transplantation of multiple patients are interdependent and as the number of match offers and transplants within registries increases (9). A match offer that

Table 5: The advantages and unique challenge of a National Standard Acquisition Charge for KPD

Advantages

- Accounts for all donor evaluation, surgery and follow-up costs as well as KPD administrative costs
- Mitigates upfront financial risks of donor evaluations; reduces financial disincentives associated with the evaluation of multiple donors
- Evenly distributes cost to beneficiaries, those centers that perform KPD transplants
- Addresses financial challenges introduced by geographic disparities
- Overcomes financial challenges related to out of network donors for commercially insured patients and out of state donors for Medicaid patients

Challenges

• Infrastructure does not yet exist

falls through late in the process disrupts multiple potential transplants and incurs additional, potentially avoidable, costs. Therefore, the following recommendations were made to facilitate greater participation in KPD, reduce latestage match failures, enhance transparency and communication, and ensure quality control.

To establish and operate a KPD program, a center should identify a KPD champion to advocate for KPD and lead a KPD team inclusive of an HLA expert and dedicated coordinator. Mentors, identified by KPD registries, should be available to guide physicians and coordinators to optimize performance and efficiency and minimize process delays and mistakes that adversely impact multiple patients and centers. Programs should be encouraged to enter NDDs into KPD registries to maximize the benefit for the greatest number of patients.

Multiple strategies were identified to reduce preventable late-stage match failures that disrupt multiple compatible transplants in large exchanges. The donor workup should be completed prior to KPD listing, updated annually (excluding anatomical testing), and reported in a standardized format. Ideally, recipient centers should preselect acceptable donors to increase the percentage of viable match offers. User-friendly database interfaces for data entry with automated histocompatibility data transfer capacity should be employed. In the future, central banking of cryopreserved donor lymphocytes would enable prematch offer crossmatching of multiple highly sensitized patients to increase the likelihood that actual match offers will have negative final crossmatches.

The KPD process is highly complex, requiring extensive coordination between multiple coordinators, nurses and physicians at multiple programs. As a result, standardization of the content and timing of communication is paramount to maximize the confidence of all involved parties. Prompt responses to match offers should be required. Once a KPD match offer has been accepted, the entire donor evaluation record including imaging, selection committee minutes, consent documents and United Network for Organ Sharing (UNOS) ID/TIEDI source documents should be sent to the recipient center for review. Prior to a planned transplant, a "logistics call" should confirm the date, operating room time, and the details of kidney transportation. The donor surgeon should communicate

directly with the recipient surgeon 24 hours prior to donor incision to verify recipient status and immediately after the nephrectomy to report anatomy and intraoperative events. Coordinators should communicate within 24 hours to exchange donor and recipient status updates. Finally, any diagnosis of potentially transmissible disease in the donor within two years postdonation should be reported to the recipient center, the KPD registry and UNOS. KPD registries and centers should collect outcomes data and follow established processes for reporting of adverse events.

Discussion

Currently in the United States, multiple multicenter KPD registries exist in parallel with single center programs. Although more than 300 KPD transplants were performed in 2010, there was strong consensus that many more *could have been* done (3). The Consensus Conference recommendations are intended to maximize the potential of KPD at the center and national levels.

KPD is an elegant but complex solution to the increasingly common challenge of incompatible donor-recipient pairs and the most promising avenue to substantially increase kidney transplantation. Until now, its implementation has been fragmented and incomplete, driven by individual and isolated rather than collaborative and coordinated efforts. The emergence and evolution of multiple registries has engendered significant value through innovation and competition. However, general consensus was that, eventually, a single national registry with the largest possible pool of pairs would maximize the transplants and should therefore be an overarching goal.

Acquiring the special expertise, commitment and resources necessary to run a KPD program obstructs entry for transplant centers that are currently unengaged and hinders productivity for those that are already participating (37). As KPD registries grow, efficient management of large and dynamic databases, thousands of match offers and thousands of transplants will become more challenging and thus more important. There was consensus that objective matching algorithms based on appropriately weighted biological considerations and reasonable valuation of future opportunities relative to immediate benefits must be rigorously developed. Research is necessary to

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Table 6: Suggested research

- Identify factors influencing donor and recipient willingness and preferences for entering KPD as compatible pairs
- Examine the relationship between recipient outcomes and donor outcomes in KPD setting
- Identify the perceived barriers to KPD participation among potential donors and recipients, and evaluate strategies for removing these barriers
- Determine whether the psychological and quality of life outcomes of KPD donors differ from those of traditional donors
- Conduct simulations of alternative allocation priorities and algorithms to assess competing claims of matching superiority among alternative KPD systems
- Research and testing of the various alternative approaches to dynamic optimization
- Share data from registries on incompatible pairs and other paired donation participants, on the results of match runs, and on whether or why not identified matches proceeded to transplantation
- Study the long-term effects of cold ischemia time on outcomes of live donor transplants
- Investigate the times, costs and resources required for transport of kidneys between centers (based on commercial air, car travel and other possible modalities)
- Examine the effect prioritization of geographic proximity has on disparities in access to KPD
- Development and assessment of a National KPD SAC demonstration project
- Evaluate whether a peer mentorship program can increase KPD participation among transplant centers

better understand how to implement these algorithms, especially as databases grow and become increasingly complex. The development of a unified and consistent financial model remains an obstacle to a single national system. Therefore, research efforts (Table 6) should continue to address these challenges, and CMS should play a vigorous role in exploring new financial models as a national KPD SAC will necessitate a revision of current regulations.

KPD demands and creates an intimately interdependent network of patients, physicians and transplant centers. The establishment, operation and success of the future national program critically depend on collaboration, communication and trust engendered through education and transparency and motivated by a common mission of realizing every transplantation opportunity for every patient.

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Mast and David Serur are uncompensated members of the NKR Medical Board.

Additional Meeting Participants

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Executive Planning Committee.

Workgroup leaders and facilitators.