

Call to Develop a Standard Acquisition Charge Model for Kidney Paired Donation

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Abbreviations: KPD (kidney paired donation), Standard Acquisition Charge (SAC), ESRD (end stage renal disease), OPO (Organ Procurement Organization), CMS (Center for Medicare and Medicaid Services), APD (Alliance for Paired Donation), HLA (human leukocyte antigen), HIPAA (Health Information Privacy and Accountability Act), STA (Southwest Transplant Alliance).

Abstract

We propose a Medicare Demonstration Project to develop a standard acquisition charge for kidney paired donation. A new payment strategy is required because Medicare and commercial insurance companies may not directly pay living donor costs intended to lead to transplantation of a beneficiary of a different insurance provider. Until the 1970s, when organ procurement organizations were empowered to serve as financial intermediaries to pay the upfront recovery expenses for deceased donor kidneys prior to knowing the identity of the recipient, there existed similar limitations in the recovery and placement of deceased donor organs. Analogous to the recovery of deceased donor kidneys, kidney paired donation requires the evaluation of living donors prior to identifying their recipient. Tissue typing, crossmatching and transportation of living donors or their kidneys represent additional financial barriers. Finally, the administrative expenses of the organizations that identify and coordinate kidney paired donation transplantation require reimbursement akin to that necessary for organ procurement organizations. To expand access to kidney paired donation for more patients, we propose a model to reimburse paired donation expenses analogous to the proven strategy used for over 30 years to pay for deceased donor solid organ transplantation in America.

In the past decade, kidney paired donation (KPD) has become the fastest growing source of transplantable kidneys by overcoming barriers faced by potential live kidney donors

who are immunologically incompatible with their intended recipients as a consequence of blood type incompatibility or the presence in the candidate of preformed anti-donor antibodies. As of 2010, over 1000 KPD transplants have been performed in the United

U.S. KPD and NDD Transplants 2000 - 2010

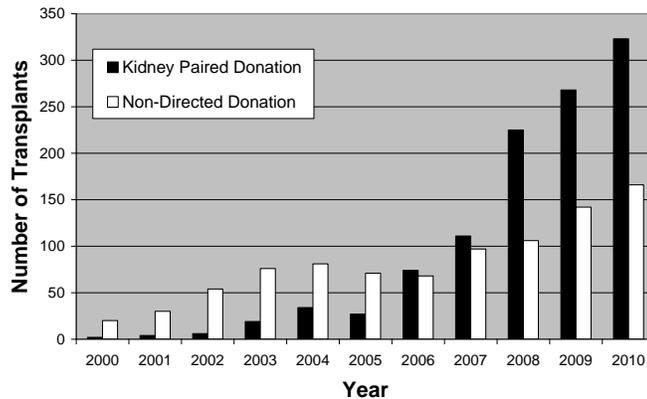


Figure 1. Kidney Paired Donation (KPD) and Non-directed Donor (NDD) transplants per year

States, most of them in the last three years (see Figure 1).(1)

Financial considerations in kidney transplantation

While adding several hundred kidney transplants per year to the national totals is a substantial accomplishment, it falls short of what might be accomplished. To put this in context, every year in America over 116,000 people are diagnosed with End Stage Renal Disease (ESRD).(2) More than half of these individuals are not practical candidates for renal transplantation, because of age or infirmity, so that in 2010 only 31,734 patients were added to the national kidney transplant waiting list that already contained 77,556 waiting patients.(1, 3) In 2010, only 15,434 of these waitlisted patients received kidney transplants; of these, 9,714 received a kidney from a deceased donor and 5,720 were given a living donor’s kidney.(1) It is estimated that about one third of patients who have a willing living donor will find that their willing donor is incompatible.(4) Thus, in 2010, it is likely that over 3,000 ESRD patients had a willing, but incompatible living donor. KPD offers the opportunity for a significant proportion of these

incompatible pairs to undergo an otherwise unattainable living donor kidney transplant.

These additional transplants save lives and money. Costs related to ESRD represent the largest category of Medicare expenses, accounting for 6.7% of the entire Medicare budget in 2009—the last year for which data is available.(2) Over half a million patients are afflicted by this disease, costing Medicare \$29 Billion in 2009—\$82,285 per year for each patient treated with hemodialysis.(2) While transplantation costs more than dialysis in the first year, when averaged over the life of the transplant, kidney transplantation costs \$29,983 per patient per year, saving Medicare in excess of \$250,000 per patient over five years compared with hemodialysis.(2)

Despite this opportunity to save and improve thousands of lives while simultaneously saving millions of dollars compared with the costs of maintaining patients on dialysis, the principal stakeholders – the Center for Medicare and Medicaid Services (CMS), commercial insurance carriers, and transplant hospitals – have not to date made the investment necessary to transform KPD into a sustainable healthcare strategy achieving its full potential. Why? It is the practice of payers to reimburse hospitals and physicians for delivered healthcare services. Covered benefits and contracts do not provide payment for the *possibility* of a delivered healthcare service. Thus, while KPD has substantial potential to save lives and money, a system has not yet been developed to fund the creation of pools of evaluated incompatible pairs that are necessary for KPD systems to identify compatible matches. This same conundrum confronted deceased donor kidney transplantation in the 1970s. Why would a payer pay for the costs of evaluating and recovering organs from a deceased donor with no guarantee that the organs from that donor would be given to one of their patients?

Fortunately, CMS developed a strategy to pay organ procurement organizations (OPOs) for these “up front” expenses using the concept of a standard acquisition charge (SAC). In this approach, CMS assured OPOs that

approved costs would be reimbursed for any expenses incurred related to evaluating and recovering deceased donor kidneys.

To accomplish this, the OPOs were allowed to charge the transplant hospitals a standard acquisition charge based on their cost to recover kidneys and then to incorporate those costs as part of the cost of the transplant procedure (see Figure 2). The CMS Hospital Insurance Manual 15-1 states that the following expenses may be reimbursed through a deceased donor kidney standard acquisition charge:

- 1). Costs of kidneys acquired from other providers;
- 2). Transportation of the organs;
- 3). Surgeons' fees for excising cadaver (sic) kidneys;
- 4). Tissue typing services furnished by independent laboratories; and
- 5). Preservation and perfusion costs.(5)

Using these approved expenses, OPOs calculate a SAC retrospectively using the prior year's total cost to the OPO to recover deceased donor kidneys divided by the number of deceased donor kidneys transplanted. Medicare further reimburses the OPO for any approved costs it incurred in kidney acquisition that were not recovered through its SAC fees. These differences are then recalculated into the SAC for the next year to better reflect the true on-going cost of evaluating and recovering deceased donor kidneys. In other words, CMS indemnifies the organ procurement organizations so that their costs for recovery of deceased donor

kidneys are covered before they know the identity of the recipient of those kidneys. Likewise, transplant hospitals are willing to pay the cost of obtaining a deceased donor kidney for transplantation through this SAC fee approach because CMS guarantees reimbursement of their portion of these fees. By the time the transplant centers pay these SAC fees, the recipient for the deceased

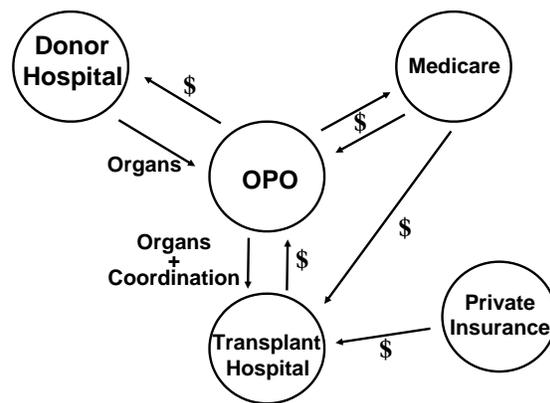


Figure 2. The flow of donor organs and money in deceased donor transplantation.

donor kidney has been identified, so there is no ambiguity for the payer about who is benefiting from payment of the deceased donor evaluation and recovery expenses. Through this strategy, deceased donor transplantation has become widely available throughout the United States. Without this mechanism to pay the costs of deceased donor evaluation and kidney recovery—*before knowing the identity of the recipient of the organ*—deceased donor kidney transplantation would have been limited to the few organs that transplant hospitals were able to identify and recover for their patients alone.

Financing kidney paired donation is more analogous to paying for deceased donor kidney transplantation than it is to paying for routine living donor kidney transplantation. In routine living donor kidney transplantation, the living donor “allocates” their kidney to a specific known recipient and thus the payer for these expenses can be identified prospectively. When the living donor participates in paired donation, it is not known prospectively who will receive their kidney. What is clear is that the traditional payer for living donor evaluation expenses—the intended, incompatible recipient’s insurance company—often has not been willing to directly pay the expenses related to the incompatible donor’s evaluation if that donor’s kidney will not be transplanted into a recipient insured by that insurance company. The recent participation of compatible living donor/recipient pairs in paired donation as a means of creating additional transplants raises questions about how to pay for these donor evaluations as well.(6, 7)

Imagine if transplant centers had to negotiate with insurance providers every time a potential deceased donor became available. Transplant hospitals would have to negotiate to find a payer for the cost of obtaining organs from the deceased donor—with no guarantee that a recipient whose insurance was provided by the payer would receive one of the recovered organs. If this were the case, deceased donor transplantation in America would come to a standstill. Essentially, this is the quandary of kidney paired donation in the United States today. It is possible that development of a funding strategy for KPD analogous to that employed to fund deceased donation could also facilitate the creation of a

single large pool of incompatible pairs that could incorporate the separate pools currently managed by multiple competing KPD programs. Studies have shown that larger pools foster transplantation of more difficult to match patients and a higher percentage of patients overall.(4, 8)

The problem with the current KPD payment system

Ten years of experience managing multi-center KPD consortia have now made clear four critical components of a paired donation program that are not currently reimbursed through a coherent payment strategy. If KPD is to reach its full potential, the current payment structure will need to be redesigned to accommodate the following obstacles:

1. Transplant centers, Medicare and commercial insurance companies are reluctant to pay for incompatible living kidney donor or non-directed donor evaluations if there is no guarantee that the donor will donate a kidney to one of their covered recipients.
2. While payment for the shipment of deceased donor kidneys is a routine component of the deceased donor kidney transplantation system, the costs for living donors to travel to a recipient's center as part of a kidney paired exchange is not currently an allowable expense on a Medicare cost report. Likewise, the shipment of a living donor kidney between centers involved in a kidney paired exchange is not currently an allowable expense on a Medicare cost report. Payment of expenses incurred performing living donor nephrectomies at one center with subsequent shipping of the kidney to another center for transplantation presents challenges at many levels.(9)
3. The administrative cost of running a kidney paired exchange program is not an allowable expense on a Medicare cost report. These expenses include such items as staff salaries (directors, coordinators, HLA

laboratory technicians, software developers, and secretarial and administrative support), software development, maintenance of a HIPAA compliant web-based data entry and matching system, insurance, educational programs, fundraising, and business costs such as office space, supplies, and teleconferencing. In the absence of a national strategy for paying for kidney paired donation (similar to the mechanism for paying for deceased donor transplants described above), \$1.5 million of philanthropy has been required to date to cover the costs of facilitating paired donation matches through one such KPD matching program (the Alliance for Paired Donation - APD), alone.

4. The costs associated with tissue typing to perform the crossmatches necessary to evaluate the many competing possible matches identified by KPD matching software are not an allowable expense on a hospital's cost report if those crossmatches are being performed for a patient at another hospital.

Proposal to develop a KPD SAC

Therefore, we propose the funding of a demonstration project to ascertain reasonable costs for these KPD functions and to provide a mechanism to aggregate these costs under a KPD SAC. We believe the best mechanism for paying for the development of a kidney paired donation SAC is through a Medicare Demonstration Project. A Medicare Demonstration Project would save money, and could be initiated either directly by CMS or by a legislative mandate from the U.S. Congress. Thus, broad support will be necessary from the transplantation community and its professional associations such as the American Society of Transplantation, the American Society of Transplant Surgeons, the Association of Organ Procurement Organizations, the American Society for Histocompatibility and Immunogenetics, and the National Association of Transplant Coordinators. Support from commercial insurance companies will also be essential.

As KPD and its financing remain in their infancy, the costs of initiating a new program—like any initial start-up—will likely have a higher cost per unit in the initial phase that will mature to a more acceptable cost per unit as the volume grows. Thus, one advantage of creating a demonstration project is that it could help to defray the initial start-up expenses while simultaneously allowing stakeholders to evaluate the cost effectiveness of the proposal using real data as opposed to speculation. Assume at the outset of the demonstration project that 1 in 4 enrolled pairs are transplanted, and that as the project creates a larger pool size, 1 in 3 pairs are able to be transplanted. As the number of KPD transplants increases, fixed administrative costs would be divided over a larger number of transplants and the overall cost per transplant would be expected to decrease.

We therefore propose a demonstration project with three aims: 1) Collect actual financial data from a clinically active kidney paired donation program that will allow the calculation of the real-life cost per KPD transplant so that a realistic KPD SAC can be designed to reflect accurate historical data; 2) Pay for the additional expenses associated with the average KPD transplant that are not allowable under current reimbursement mechanisms; 3) Expecting the cost per KPD transplant will decrease significantly over the course of the demonstration project, the demonstration program funds will pay for the high start-up costs of establishing an accurate, affordable KPD SAC and thereby increase the likelihood that the stakeholders will adopt the redesigned payment strategy to create a sustainable model for the future.

At the end of the demonstration project, it will be clear how much these additional components of a KPD cost, the impact that paying for them has on transplant center participation, the impact appropriate funding has on the efficiency of a KPD program in terms of the percent of the pool that can be transplanted, and the return on investment that can be expected when adequate funding mechanisms are in place. This data will be critical to determine whether such a system is feasible and to establish a sustainable SAC fee for KPD that accounts for all of the necessary components to operate a KPD program. The information will allow the stakeholders—transplant centers, Medicare and

commercial insurance companies—to anticipate the costs involved, the return on investment, and most importantly, establish a new approach in which these expenses can be paid retrospectively based on real data instead of projections.

At the conclusion of this demonstration project, it will be possible to construct a SAC fee that is based on historical data and that can be assessed after the recipient has been transplanted, so that the stakeholder is guaranteed benefit from their payment. With acceptance from Medicare, transplant centers will be able to place these SAC fees on their cost report—just as they currently place SAC fees for deceased donor kidneys on their cost report—and a sustainable mechanism of payment will assure that the entity that pays the KPD costs will be appropriately compensated so that they will be willing to continue paying these pre-transplant expenses. With acceptance by the transplant centers and Medicare, and a well-defined SAC that is billable to a single patient, commercial insurance companies will be able to build these fees into contracts with participating transplant centers. Additionally, since the cost per KPD transplant is expected to decrease significantly over the course of the demonstration project, the demonstration program funds will pay for the high start-up costs of establishing an accurate, affordable KPD SAC and thereby increase the likelihood that the stakeholders will adopt the more affordable, redesigned payment strategy to create a sustainable model for the future.

Alternative Approaches and Implementation

An alternative method to pay for the costs associated with a KPD program would be for individual transplant centers to develop center-specific SACs that could be charged to other transplant centers when exchanges involved recipients at other centers. These expenses would include the cost of evaluating incompatible donors at that specific center, the administrative cost of operating the KPD program at that center, tissue typing laboratory expenses related to KPD, and, when shipping a kidney, costs associated with a donor nephrectomy. The total expenses associated with running a KPD program at a center would be divided by the total number of KPD donors who actually donated. As the number

of KPD transplants performed at each center may be highly variable, such an approach may lead to large variability in center-specific KPD SAC charges and payment of widely disparate costs between transplant centers could be a disincentive to centers participating in such exchanges.

Furthermore, center-specific KPD SACs would not provide for the administrative costs of running a national KPD program. These expenses could be accounted for by an additional KPD SAC that was incremental to the center-level costs. Alternatively, a transparent registration fee could be developed that divided the costs of running a KPD program by the total number of incompatible pairs registered in the program.

Alternatively, centralization of administrative costs could be achieved by augmenting the responsibilities delegated to OPOs to include authority to manage KPD administrative costs, or by the creation of new entities analogous to OPOs through which central KPD administrative services and financing could be managed. The regulatory and legislative pathway to change the mandate of OPOs or to create new KPD OPO equivalents is likely to be complicated and lengthy. Creation of a KPD SAC would be an important and informative first step in this process. Whatever solution, adoption of a KPD SAC or registration fees will require CMS approval and oversight so that such expenses can be allowable on individual transplant center cost reports.

The current strategies in place to pay for the administrative costs of the four major national KPD programs are not sustainable. Funding strategies range from programs that operate without charging participating centers and are supported by philanthropy to strategies that involve registration/transplant fees that are not directly calculated from costs, are not transparent, and are not allowable expenses on a transplant center's cost report. To achieve a robust national KPD program, America needs to improve the mechanisms by which KPD is financed.

Financial Impact

The proposed demonstration project will not only allow for more patients to be transplanted through KPD, but will quickly pay for itself by creating substantial savings for America's healthcare system. Schnitzler, et al. determined the value of deceased donor kidney transplants, demonstrating that each recipient's life is extended by an average of 7.2 years.(10) Accounting for the cost of the extra years of life, Matas et al. showed that a living unrelated kidney donor transplant reduces the lifetime medical costs of the recipient by an average of \$94,579.(11) Thus, even though a kidney transplant extends the life of the recipient, total lifetime medical costs are reduced. From a cost effectiveness perspective, in which society would be willing to pay for the survival and quality of life benefits provided by a kidney, it is estimated that living unrelated donor kidney transplants are worth at least \$269,000 to society and may be worth as much as \$500,000.(11) There is no expectation that standard acquisition costs associated with KPD will exceed even a small portion of these figures. There are few treatments where the best treatment is also the least expensive, so it is clear that there is considerable financial justification to society for investing in efforts to expand the organ supply with living unrelated donor kidney transplants.

While kidney transplantation is the least expensive and most effective form of therapy for ESRD, use of this treatment is limited by the number of available kidney donors. Patients transplanted with deceased donor kidneys live 7-10 years longer than patients treated with dialysis, but those fortunate to have a compatible living donor kidney transplant live nearly twice as long as those who receive a kidney from a deceased donor.(10, 12, 13) However, most patients either have no willing donors or their willing donors are incompatible. Thus, most of the 90,000+ patients currently on the waiting list in America will wait at least 3 or more years for a deceased donor's kidney and 4,600 patients per year die while wait-listed.(14, 15).

Development of a KPD SAC to overcome the financial barriers that prevent many of these patients from attaining a living donor transplant is an investment that benefits society as a whole. We believe the proposed demonstration project will create a sustainable funding mechanism for KPD that

will allow for a national KPD system to be established that has the potential to create at least 1,000 additional living donor kidney transplants per year and generate an annual value of \$200 - \$500 million dollars for America's healthcare system.(4)

Disclosures:

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