

# Barriers to implementing protocols for kidney paired donation and desensitization: survey of US transplant programs

**Context**—Special types of kidney transplant exist for patients who have willing but incompatible donors. Two types of transplants that circumvent donor-recipient incompatibility are “kidney paired donation” and “desensitization.” Lack of access to these protocols limits living donations and shortens the life span of patients with willing but incompatible donors.

**Objective**—To understand potential barriers to implementing kidney paired donation and desensitization, as well as attitudes toward nondirected donation and compatible type O donation, which would maximize the number of kidney paired donation transplants performed via chains.

**Design**—We created a 56-question Web-based survey to elicit information from US transplant program directors about 24 potential barriers to implementing these protocols.

**Participants**—Of 166 programs contacted, 96 responded, including 88 complete and 8 partial responses. After pediatric-only programs and multiple responses from the same program were removed, 84 total (78 complete) remained.

**Main Outcome Measures**—Respondents were asked to designate each barrier as “major,” “minor,” or “not a barrier.”

**Results**—Availability of dedicated nurse coordinators and the United Network for Organ Sharing’s variance request process (although kidney paired donation does not actually require a variance) were significant barriers to kidney paired donation. Most respondents (54%, 42/78) would prefer to participate in a regional rather than a national protocol for kidney paired donation. Risk of complications was the most significant barrier to desensitization. University affiliation, region, and training (nephrologist vs surgeon) had little effect on perception of barriers. Most (92%, 71/78) would evaluate nondirected donations; 53% (41/78) would encourage compatible type O donors to enter kidney paired donation. (*Progress in Transplantation*. 2010;20:357-365)

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Approximately one-third of patients with end-stage renal disease may have willing potential living donors who are blood-type or cross-match incompatible.<sup>1</sup> Live donor kidney transplant is preferable to deceased donor transplant because patients and grafts survive longer after live donor kidney transplant.<sup>2</sup> Kidney paired donation (KPD) and desensitization are complementary methods to maximize the likelihood of live donor kidney transplant. As of August 5, 2010, a total of 951 kidney paired donations and hundreds of desensitizations had been performed nationwide.<sup>3</sup> An estimated 1000 to 3000 patients per year could receive a kidney transplant from a live donor through a national KPD protocol.<sup>4,5</sup> A national KPD pilot program is expected to be fully implemented by December 2010.<sup>6</sup>

Our survey had 3 key aims. First, we addressed the barriers to implementing KPD and desensitization. The success of a national KPD protocol depends on a critical mass of transplant programs participating. This national survey is the first to explore these barriers; in a 2005 study in Ohio, Woodle et al<sup>7</sup> suggested that donor travel costs, medical-legal issues, donation to “strangers,” and lack of superiority of KPD over desensitization programs might be barriers to live donor kidney transplantation. Our approach allows us to identify statistically significant barriers, in addition to commonly held beliefs about KPD.

Second, we examined attitudes toward nondirected donation, which will be important as the United Network for Organ Sharing (UNOS) decides whether to incorporate nondirected donations into the national

KPD program. Nondirected donations can initiate chains, allowing more total transplants than could be achieved by pairs alone. There are 2 types of chains, “closed” (domino) chains and “open” (nonsimultaneous, extended, altruistic donor) chains. Open and closed chains are both initiated by a nondirected donation. Open chains end with a bridge donor and are nonsimultaneous. Closed donations end with simultaneous donation to a list recipient. Chains have already shown how KPD and desensitization are complementary.<sup>8</sup>

Third, we examined attitudes toward actively encouraging compatible type O donors to enter KPD. Compatible type O donors could initiate chains and/or improve chances of matching type O recipients, if priority is placed on matching them. Intended recipients of these type O donors could theoretically obtain better matched organs.<sup>8</sup>

## Materials and Methods

### Survey Instrument

We designed a 56-question Web-based survey to collect information about previous experience with and barriers to implementation of KPD and desensitization. The survey was approved by the institutional review board at Massachusetts General Hospital. Directors of kidney transplant programs were asked whether they considered potential barriers to be “a major barrier, a minor barrier, or not a barrier.” Respondents were also asked about their familiarity with each protocol, the number of transplants performed, and plans to continue each protocol. If a protocol had not yet been implemented, we asked whether implementation was imminent. We also asked about plans to participate in a national KPD program, reimbursement, and referral of patients for KPD or desensitization. Finally, we asked about 2 controversial issues related to KPD: the respondent’s policy regarding nondirected (“altruistic”) donors and any policy that actively encourages type O donors who are compatible with their recipients to participate in KPD. The specific questions regarding nondirected donation and type O donors were as follows:

*Question 1.* Which of the following statements reflects your center’s attitude toward nondirected donation? Nondirected donors are people who wish to offer a kidney to any random recipient (a “stranger”).

- We are unlikely to evaluate nondirected donors even if they present here wishing to donate.
- We would evaluate nondirected donors only if one of the recipients on our list benefited; we would not evaluate a nondirected donor if there was a chance he/she could be matched to a recipient at another center unless we would receive a living donor for one of our patients in exchange.

- We would evaluate a nondirected donor regardless of whether or not one of our patients benefited, knowing that the donor might be matched to a recipient at another center.

*Question 2.* One common concern about kidney paired donation is that blood type O patients may be difficult to match/transplant. This is because type O donors who are ABO compatible and cross-match negative with their intended recipients have no incentive to participate in paired donation. Would your center consider implementing a policy that actively encourages type O donors who are compatible with their recipients to participate in paired donation?

- Only if the O donor’s intended recipient could obtain a better organ (ie, a younger, healthier organ) by participating in paired donation.
- No, because participating in paired donation is medically unnecessary for pairs with type O donors (barring cross-match incompatibility).
- No, because it would be unethical to ask a compatible pair to participate in a paired donation.
- Yes, because 2 recipients would obtain transplants if the O donor participates in a paired donation.

### Participants

A list of kidney transplant programs with phone numbers was obtained from UNOS. We contacted each program and searched the Internet to obtain the current e-mail addresses of each medical and/or surgical director of kidney transplantation. Of 242 total kidney transplant programs, we excluded 32 pediatric-only programs, 5 military hospitals, 3 programs that performed no living transplants, and 5 programs that were not certified by the Organ Procurement and Transplantation Network, which left 197 programs. Eight directors were directors of more than 1 program, leaving 189 directors of unique programs. We obtained 166 e-mail addresses; 23 programs did not provide names or e-mail addresses for their directors online and did not respond to multiple requests for contact information.

E-mails to program directors described the study purpose and provided a secured hyperlink to complete the online survey (SurveyMonkey). We asked respondents to provide their UNOS program code so that we could track whether multiple responses were received from a particular program. In the 6 cases where both medical and surgical director responded, only answers from the first respondent were analyzed. Responses from roles other than the program director were allowed, as long as the individual was familiar with the policies and procedures of the program. This occurred in only 2 cases; the vast majority of respondents were program directors. We contacted potential

respondents up to 6 times via e-mail and telephoned up to 3 times. Partway through the study, in order to increase response rate, the institutional review board approved monetary incentives in the form of \$50 gift cards to respondents. This additional funding enabled us to raise our response rate from 44% to 55%.

**Analysis**

Survey responses were coded and exported into SAS 9.1 (SAS Institute, Cary, North Carolina) for analysis. Bivariate analyses included  $\chi^2$  tests or Wilcoxon rank-sums for variables that were not normally distributed, and Fisher exact tests when the expected number of subjects in more than 25% of the cells was less than 5. We used 2-sided *P* values, with significance level set at a *P* of .05. For some analyses, we developed a logistic regression model in which the dichotomous dependent variable was “plan to have the protocol in the future,” as described later.

A logistic regression model was used to explore factors associated with plans to have the protocol in the future. Variables considered significant in bivariate analysis were included in exploratory regression analysis using forward, backward, and stepwise regression. Barriers that remained significant were then explored further, using the following model to predict the log odds of planning to have the protocol in the future ( $\pi$ ):

$$\text{logit}(\pi) = \log(\pi/1-\pi) = a + (\beta_1 * \text{prior experience}) + (\beta_2 * \text{university affiliation}) + (\beta_3 * \text{training}) + (\beta_4 * \text{transplant volume}) + (\beta_5 * \text{barrier})$$

In that model, we were most interested in which barriers affected plans to have the protocol (KPD or desensitization) in the future. Independent variables were previous protocol experience, university affiliation (vs private hospital), training (surgeon vs nephrologist) and transplant volume (having performed greater or less than the national median number of transplants), as well as the individual barriers. Collinearity diagnostics were performed by checking tolerance, variance inflation factor, and condition index. Model convergence was satisfied and goodness of fit was confirmed by using the global null hypothesis, deviance, and residual score statistic.

**Results**

**Survey Responses**

Directors of 166 transplant programs were contacted, and 96 (58%) responded (88 complete, 8 partial). In analysis, we excluded respondents from 6 programs that were “multiples” (programs from which more than 1 director responded) and 5 programs that performed pediatric-only transplants, leaving 84 responses (78 of which were complete). After excluding ineligible respondents, the response rate was 55% (according to the standard definitions of the American

Table Respondent characteristics

| Variable   | No. (% of 78 total) <sup>a</sup> |
|--|----------------------------------|
| Respondent training                              |                                  |
| Nephrologist                                     | 34 (44)                          |
| Surgeon  | 42 (54)                          |
| Other (ie, transplant coordinator)               | 2 (3)                            |
| Type of program                                  |                                  |
| University-affiliated                            | 43 (55)                          |
| Private hospital, affiliated with university     | 17 (22)                          |
| Private hospital, not affiliated with university | 18 (23)                          |

<sup>a</sup> Percentages may not total 100 because of rounding.

Association for Public Opinion Research for response rate).<sup>9</sup> Only 2 of the respondents were not program directors (nurse coordinator or other designee of program director). The only difference between the respondents before the incentive and the incentivized respondents was that smaller programs tended to be more likely to respond after the incentive was offered, but this difference was not statistically significant (*P*= .09).

**Program Characteristics**

The Table contains demographic data for the respondents. Using publicly available data (www.unos.org), we compared patient volume between responding programs and nonresponding programs. Responders were similar to nonresponders, except that responders performed significantly more total transplants (*P* < .01). The percentage of nephrologists and surgeons was relatively equal (44% vs 54%).

**Barriers to Implementing KPD Protocols**

The most frequently cited barriers to implementing KPD were unequal quality of kidneys, logistics of donor travel, and logistics of working with other centers (Figure 1). The barrier “unequal quality of kidneys” was worded as follows: “In some cases, inequities might arise in the quality of the 2 kidneys used in a paired donation.”

Notably, however, barriers that actually had an impact on plans to have the protocol in the future were not necessarily the most oft-cited barriers. After previous experience with the protocol and transplant volume were controlled for, respondents who expressed concern about availability of nurse coordinators (*P*= .03) and the UNOS variance request process (*P*= .02) were less likely to plan to have KPD in the future. In other words, having a nurse coordinator and navigating the UNOS variance request process (although KPD does not actually require a variance) were seen as the most important, not just the most frequent, barriers. As our results indicate, simply identifying a potential barrier does not by itself prove that the barrier will affect plans to use the protocol, but these concerns

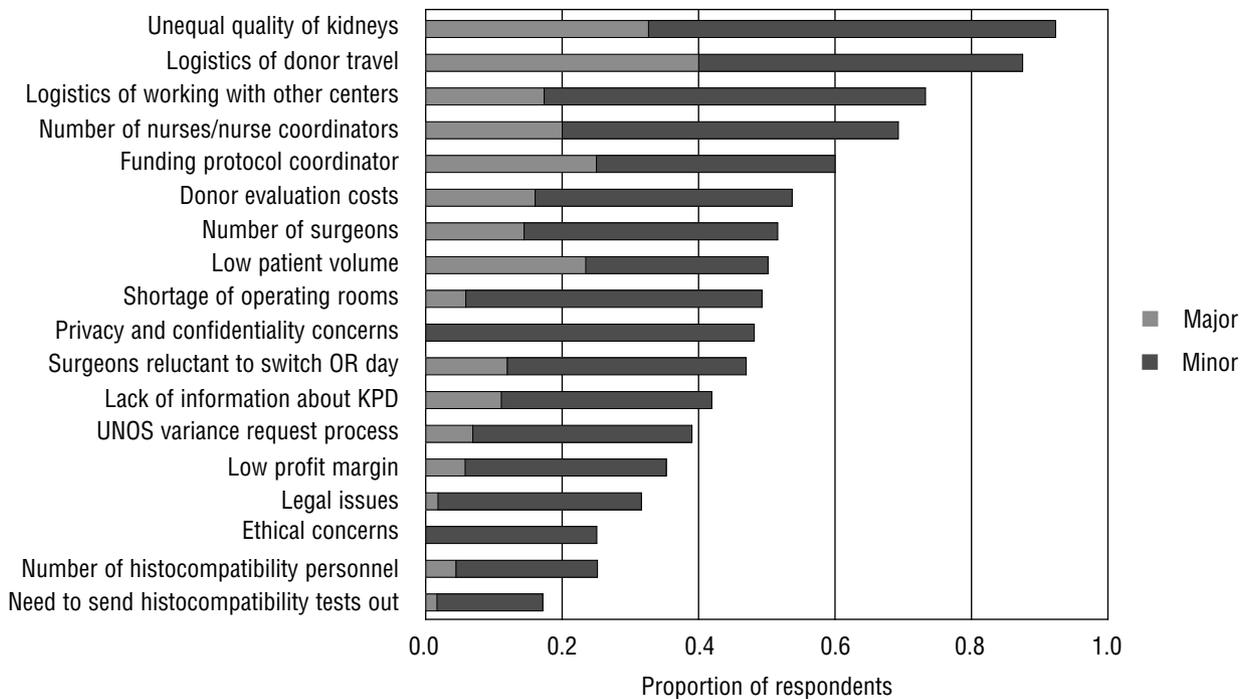


Figure 1 Most frequently cited major and minor barriers to implementing kidney paired donation.

Abbreviations: KPD, kidney paired donation; OR, operating room; UNOS, United Network for Organ Sharing.

may still color public and expert opinion on innovative kidney transplant options.

Variables that did not remain significant in the logistic regression were university affiliation (vs private hospital) and training (nephrologist vs surgeon). Because they were not significant, university affiliation and training are not discussed further.

### Participation in a National KPD Protocol

Among programs that have already instituted a KPD protocol, 65% (33/51) would join a national KPD protocol, if offered the opportunity. Another 27% (14/51) said they “probably” would participate in a national protocol. It should be noted, however, that among all programs (including those that have not yet implemented KPD), when asked whether they would prefer to participate in a national, regional, single-center, or no KPD protocol, only 37% (29/78) of programs would prefer to participate in a national protocol (Figure 2). A majority (54%, 42/78) would prefer a regional protocol. Current participation in a multicenter (versus single-center) KPD protocol increased the odds of planning to participate in a national KPD protocol (odds ratio = 10.39, 95% CI = 2.12-50.8,  $P = .004$ ).

### Barriers to Implementing Desensitization Protocols

The most frequently cited barriers to implementing desensitization protocols were high pharmaceutical costs, plasmapheresis costs, and risk of complications

(Figure 3). Logistic regression showed 2 barriers that affected plans to implement desensitization: concern about risk of complications ( $P = .003$ ) and self-identification as a small (low-volume) program ( $P = .009$ ) made respondents less likely to plan to have

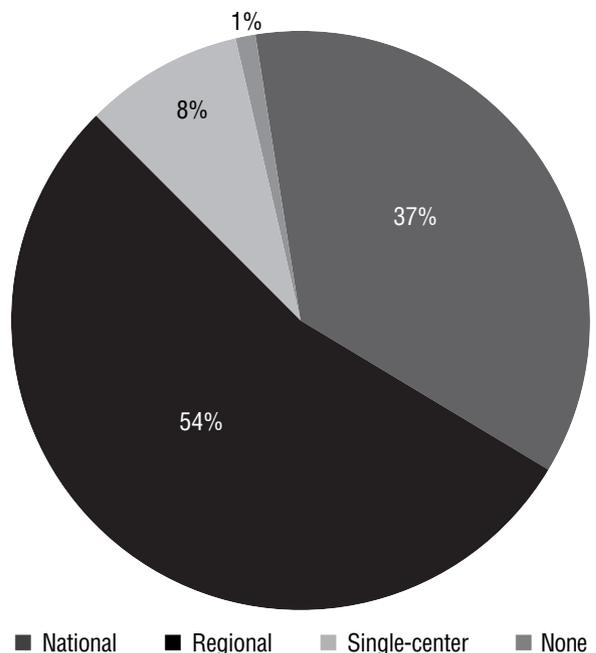


Figure 2 Most respondents prefer a regional program for kidney paired donation to a national program.

## Barriers to implementing protocols for kidney paired donation and desensitization

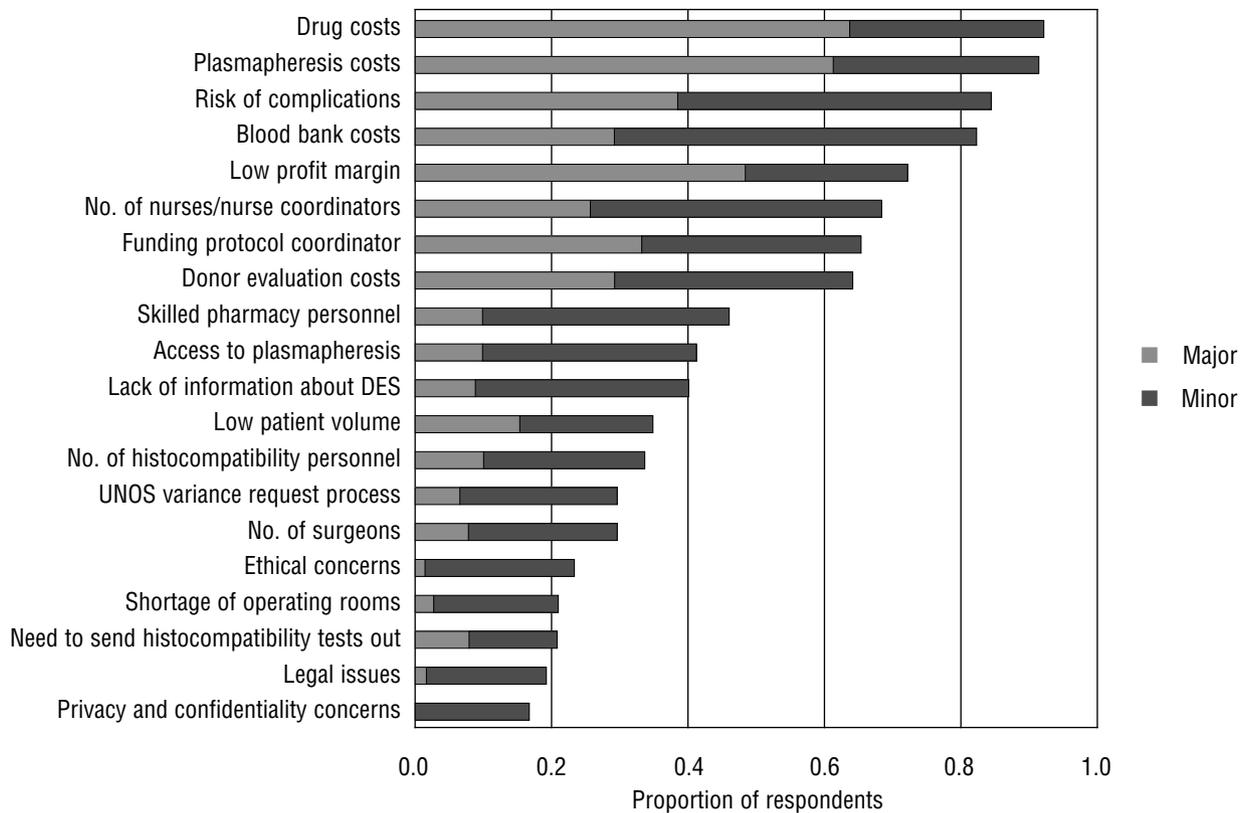


Figure 3 Most frequently cited major and minor barriers to implementing desensitization.

Abbreviations: DES, desensitization; UNOS, United Network for Organ Sharing.

desensitization in the future. Thus, although “cost of desensitization” was a major concern cited frequently by many respondents, it was trumped by “risk of complications” in terms of statistical significance.

### Evaluation of Nondirected Donors

We asked whether each transplant program would evaluate nondirected donations, regardless of whether a patient on that program’s transplant waiting list benefited. Figure 4 shows that the vast majority (92%, 71/78) of respondents would evaluate nondirected donations. Sixty-eight percent (68%, 53/78) would evaluate nondirected donations regardless of whether a patient on their own list benefited.

### Encouraging Type O Donors to Participate in KPD

Only 32% (Figure 5) would encourage type O donors to participate without reservation (a few programs stated in comments that they already do so). Another 21% would encourage type O donors to enter KPD protocols only if the intended recipient could obtain a “better” organ, for a total of 53% who would encourage compatible type O donors to enter KPD. The remaining 47% would not do so because it would be either unethical (10%) or medically unnecessary (37%).

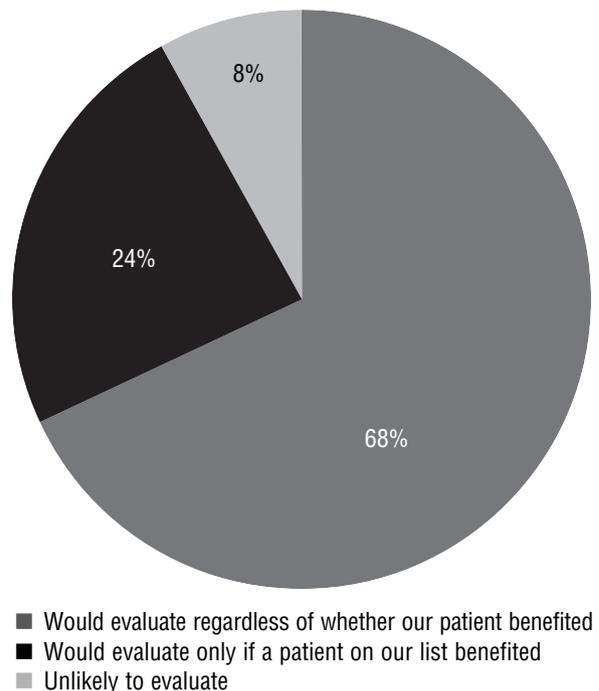


Figure 4 Evaluation of nondirected donors: most transplant centers would evaluate nondirected donors regardless of whether their own patient benefited.

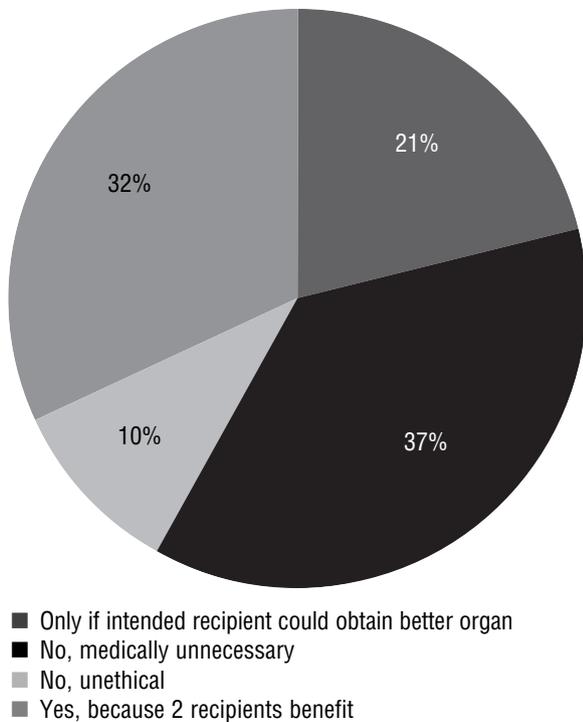


Figure 5 A lack of consensus exists regarding whether we should actively encourage type O donors to participate in kidney paired donation.

**Reimbursement**

We asked about third-party reimbursement for each protocol. Reimbursement for KPD was much better than for desensitization (Figure 6). A history of “always” or “sometimes” being reimbursed for KPD did not significantly affect the likelihood of continuing, but reimbursement for desensitization was closer to having a significant effect ( $P = .08$ ).

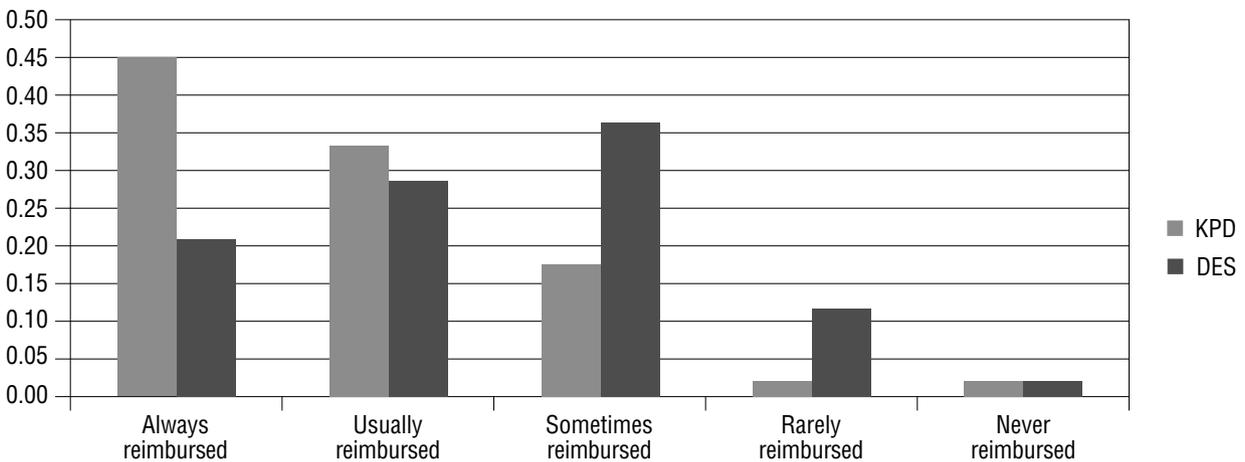


Figure 6 Insurance reimbursement for each protocol: reimbursement for kidney paired donation (KPD) is more consistent than reimbursement for desensitization (DES).

**Referral**

Twice as many programs ( $n = 48/78$ , 62%) have referred a patient to another program for desensitization as for KPD ( $n = 24/78$ , 31%). Small programs were more likely to refer patients for KPD than larger programs, but this difference was not quite significant ( $P = .05$ ).

**Plans to Implement Each Protocol**

Future implementation plans are shown in Figure 7. Interest in KPD is growing rapidly. In 2007, a survey (conducted by J.R.R.) showed that 49% of transplant programs offered KPD<sup>10</sup>; in our study, 59% of respondents offer KPD, and most who lack KPD plan to implement it in the next 5 years. Interest in desensitization is also growing, but more slowly.

**Plans to Continue Each Protocol**

All programs (100%) that have already implemented KPD plan to continue. In contrast, only 87% (45/52) of programs that perform desensitization intend to continue.

**Discussion**

We have shown that barriers to implementation of KPD and desensitization are not necessarily the most commonly cited concerns. Second, we have shown that most transplant centers (68%) would evaluate nondirected donors regardless of whether one of their own patients benefited. Third, our study suggests a lack of consensus regarding evaluation of type O donors for “altruistic” paired exchange.

The most frequently cited barriers to KPD (unequal quality of kidneys, donor travel) were not the ones that significantly affected plans to have KPD in the future. Instead, the significant barriers to KPD

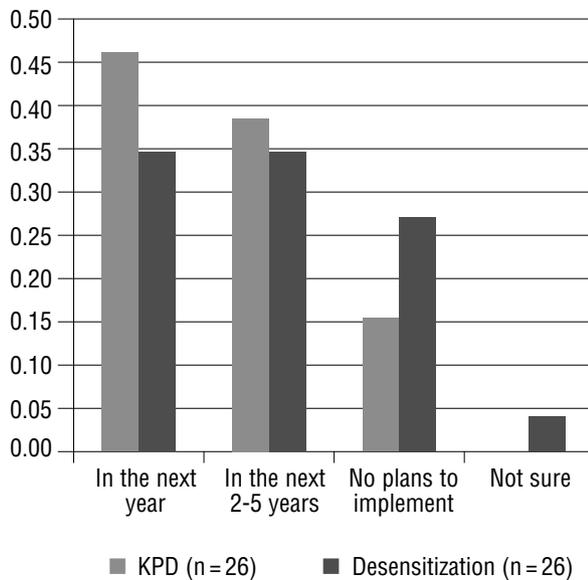


Figure 7 Plans to implement a new protocol for kidney paired donation (KPD) among transplant programs that lack the protocol.

were availability of nurse coordinators and the UNOS variance request process. As noted earlier, KPD does not actually require a variance from UNOS for participation. Therefore, some education may be warranted, to make sure everyone understands that a variance is unnecessary. But transplant centers will be required to apply to participate in the national program, and this requirement may be a deterrent for some centers. Hiring and paying for a dedicated staff member/nurse coordinator appears to be the biggest true barrier. The proposal to include nondirected donations and chains in a national KPD program states,

Centers must designate one representative who can be the single point of contact for KPD and who is willing to participate in regular conference calls to discuss the operations of the KPD system. The KPD Financial Subcommittee will continue to meet to address financial barriers to participation in the KPD system.<sup>11</sup>

Indeed, a full-time dedicated staff member may be required to manage complex KPD protocols. The KPD Financial Subcommittee, then, should address this point and leverage experience of existing coordinators to smooth the transition.

We found that most transplant programs (68%) would evaluate nondirected donations regardless of whether their own patients benefited. The current proposal to include nondirected donations in KPD would allow transplant programs to stipulate whether they are willing to participate in open or closed chains; in

closed chains, a recipient on their own waiting list would “benefit.”<sup>11</sup>

On August 11, 2009, the UNOS/Organ Procurement and Transplantation Network Ethics Committee reviewed a proposal regarding the inclusion of nondirected donations and chains in KPD; several ethical questions were raised by the Ethics Committee, including the “unequal quality of kidneys” argument addressed in this article.<sup>12</sup> In KPD, transplant program directors may be concerned about “inequalities” in age or function of the 2 donor kidneys. For example, they may have doubts about transplanting a 60-year-old donor kidney into a young adult whose intended donor was 30 years old, even if the kidney is a good match based upon HLA and ABO compatibility. Implementation of a national KPD program may reduce the relevance of this barrier because the pool of available organs will be larger, making matching on desirable characteristics easier. Algorithms may be used to allow patients to set preferences such as a preferred range of donor ages. It seems that a great deal of discussion remains before the appropriate use of nondirected donations and chains in the national KPD program is conclusively decided. Simulations have shown that open and closed chains would most likely yield similar numbers of transplants; closed chains are favored when donor renegeing surpasses 5%.<sup>13</sup>

We found a lack of consensus about encouraging type O donors who are compatible with their intended recipients to participate in KPD. Slightly more than half (53%) would encourage type O donors to “altruistically” participate, whereas 47% would not because it would be unethical (10%) or medically unnecessary (37%). Compatible type O donors have little incentive to “altruistically” participate in KPD because they can donate directly to their loved one. Because type O donors have little incentive to participate, type O recipients are difficult to match in KPD. However, type O-compatible donors might be interested in helping their intended recipients obtain even “better” (ie, younger, better HLA match) organs through KPD. If type O-compatible donors could start chains, they could be restricted to closed chains so that their intended recipient would simultaneously receive a kidney.

One surprising result of our survey was that most respondents preferred not to participate in a national KPD program. We cannot conclusively derive their reasons for not wanting to participate in a national program. We can only look at their reasons as stated in open-ended comments, and most respondents who did not want to participate in a national program at the time of our survey were concerned about donor travel. Donor travel was frequently cited as a concern and has been part of the discussion for some time, not only because travel is expensive, but because family support systems are stretched when donor and recipient

undergo surgery in different locations. However, donor travel is less of a problem than historically thought. Some of our respondents may not have been aware that the KPD proposal approved by the UNOS board of directors in June 2008 allowed points to be assigned for geographic proximity<sup>14</sup> or that shipment of donor kidneys could potentially be an option, especially if cold ischemia time is less than 8 hours.<sup>15</sup> In addition, if open (nonsimultaneous, extended, altruistic donor) chains as described by Rees et al<sup>8</sup> and in a recent proposal to UNOS<sup>11</sup> are approved, then the implied constraints on donor travel could be different; open chains give donors the flexibility to see their loved one through surgery and, after some recovery time, proceed with travel to donate to the next recipient in the chain.

Transplant program volume or “size” was associated with plans to have KPD and desensitization in the future. Small programs may believe that they do not have the financial resources or capacity to manage KPD or desensitization. Small programs were significantly more likely to refer patients for KPD but not desensitization, so it is possible that candidates for KPD will filter up into larger programs. However, there is a financial incentive for transplant programs to keep patients and perform deceased donor transplants rather than referring the patient for KPD. Incentives could be developed to encourage referral of appropriate candidates for KPD, to help optimize matches on a national scale.

For desensitization, risk of complications mattered most in the decision to stop (or never to implement) desensitization, even though costs were the most commonly cited concern. This finding suggests that transplant centers may be willing to take financial risk to provide patients a survival advantage. Desensitization protocols require the purchase of expensive drugs, including biologics, the costs of which can be high and unpredictable. Plasmapheresis costs were the second most oft-cited barrier. Although only 20% of programs reported that they are “always” reimbursed for desensitization, reimbursement did not quite have a statistically significant association with plans to continue the protocol. Risk of complications was cited as a major concern that significantly influenced the likelihood of having desensitization in the future, perhaps reflecting the increased risk of antibody-mediated rejection with ABO-incompatible desensitization. It should be noted that complications such as antibody-mediated rejection are associated with increased costs.<sup>16</sup>

Limitations of our study should be addressed. Larger programs were more likely to respond, possibly leading to response bias. However, larger programs were not necessarily more likely to have already implemented each protocol. Larger programs were neither more nor less likely to have KPD ( $P = .18$ ), but

they were more likely to have desensitization ( $P = .02$ ). Larger programs were not significantly more likely to have performed more than the median number of KPDs or desensitizations. We could not evaluate the impact of region because our sample size was too small to analyze responses for differences among the 11 UNOS regions.

Our study is the largest study to date on barriers to implementation of KPD and desensitization. Future research is needed to better understand the impact of region on participation in KPD and desensitization. Education is needed on several fronts, to train dedicated staff, to explain that a variance is not actually necessary to perform KPD, and to help new programs navigate the complexities of paired donation and desensitization. A national living donation collaborative, using a format comparable to the Breakthrough Collaboratives, may be the optimal way in which programs can learn from one another about effective KPD and desensitization implementation strategies. Further exploration of concerns about unequal quality of kidneys could help policymakers identify ethical constraints for algorithms that allow patients or transplant programs to select preferences. As the launch date for a national KPD protocol approaches, efforts should be directed at delivering information and support to maximize informed participation.

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