

Ethical Considerations for Participation of Nondirected Living Donors in Kidney Exchange Programs

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Kidneys from nondirected donors (NDDs) have historically been allocated directly to the deceased donor wait list (DDWL). Recently, however, NDDs have participated in kidney exchange (KE) procedures, including KE 'chains', which have received considerable media attention. This increasing application of KE chains with NDD participation has occurred with limited ethical analysis and without ethical guidelines. This article aims to provide a rigorous ethical evaluation of NDDs and chain KEs. NDDs and bridge donors (BDs) (i.e. living donors who link KE procedures within KE chains) raise several ethical concerns including coercion, privacy, confidentiality, exploitation and commercialization. In addition, although NDD participation in KE procedures may increase transplant numbers, it may also reduce NDD kidney allocation to the DDWL, and disadvantage vulnerable populations, particularly O blood group candidates. Open KE chains (also termed 'never-ending' chains) result in a permanent diversion of NDD kidneys from the DDWL. The concept of limited KE chains is discussed as an ethically preferable means for protecting NDDs and BDs from coercion and minimizing 'backing out', whereas 'honor systems' are rejected because they are coercive and override autonomy. Recent occurrences of BDs backing out argue for adoption of ethically based protective measures for NDD participation in KE.

Key words: ABO incompatibility, cross-matching, kidney exchanges, live donor transplantation, nondirected organ donation

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Introduction

In 1997, an ethics-based evaluation of kidney exchange (KE) was published prior to clinical application (1). Ethical issues addressed in this publication (coercion, privacy, confidentiality, right to medical knowledge and commercialization) were restricted to the simplest scenario for KE, that is, between two ABO-incompatible donor/recipient pairs of blood groups A and B only. Subsequently, several additional ethical issues were addressed (also, prior to clinical implementation of KE) including incorporation of O blood group donors, racial inequities and list exchanges (2–5). This ethical and scientific framework provided the founding principles for the Paired Donation Network (6).

While KE transplants have been performed with increasing frequency, the number of KE transplants performed has remained below expectations (7). Recently, new strategies have been proposed for increasing KE transplants, including nondirected donor (NDD)-facilitated KE (hereafter referred to as 'open' or 'closed' KE chains) (8,9). NDDs are a particularly vulnerable group of living kidney donors that have generated substantial ethical consideration and discussion and development of ethically based practice guidelines (10–16). Similarly, NDD inclusion in KE procedures raises important ethical issues that have not previously been subject to rigorous consideration and debate. Although one publication considered ethical issues regarding NDD participation in KEs, the ethical scope in this article was limited to a brief discussion of models for NDD kidney allocation (9). This work did not consider two important ethical issues regarding NDD participation in KEs: (1) disadvantaging the O blood group deceased donor wait list (DDWL) and (2) permanent diversion of NDD kidneys from the DDWL. Herein, we provide a more comprehensive consideration of ethical, scientific and practical implications of NDD participation in KE procedures and KE chains.

Methods

Unfortunately, the KE field does not have a standardized nomenclature. Definitions utilized in this article were selected by the authors to facilitate ethical analysis. Descriptive terms are used when possible, but more commonly used terms were sometimes favored.

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Definitions

NDD: A person who volunteers to donate a kidney to any individual, without designation of an intended recipient.

KE procedure: An exchange of kidneys between any number of donor/recipient pairs where all donors undergo simultaneous surgery and may or may not involve an NDD.

NDD-facilitated KE: A single KE procedure initiated by a NDD kidney donation involving any number of donor/recipient pairs in which the final kidney donor donates to the DDWL.

Closed chain KE: Two or more KE procedures, in which: (1) the initial KE procedure is initiated by kidney donation by an NDD, (2) the KE procedures are linked by bridge donors (BDs, see below), (3) involves any number of donor/recipient pairs, (4) within each KE procedure, all donors undergo simultaneous surgery and (5) the final KE procedure is terminated by kidney donation to the DDWL. (Figure 1A).

Open chain KE: (Also termed 'never-ending chains'). Open chain KEs are identical to closed chain KE, with the exception that a kidney is never donated to the DDWL. In an open chain KE, the final donor in each KE procedure becomes a BD, thereby initiating a subsequent KE procedure. By definition, open KE chains continue indefinitely, and do not result in living donor kidneys being allocated to the DDWL.

Limited KE chain: A closed KE chain in which the chain is terminated after any number of KE procedures (linked by BDs) by a kidney donation to a DDWL recipient. Optimally, limits are defined prior to the initiation of the first KE procedure in a KE chain. Limits may include: (1) the number of KE procedures or transplants, (2) elapsed time (from the original NDD kidney donation) or (3) personal decision of a BD at any time. Once the limit is reached, the BD is informed that he/she has the option to donate to the DDWL, or to wait for a KE to be identified.

Bridge donor (BD): Prior to a KE procedure, the final kidney donor from the KE procedure agrees not to donate his/her kidney at the same time as their loved one receives a kidney transplant (i.e. within the same KE procedure), but rather at a later date, whereby he or she donates a kidney to initiate a second KE procedure. As such, the BD therefore 'bridges' or 'links' two distinct KE procedures (that occur on differing dates) within a KE chain.

Honor system: An 'understanding' intended to prevent backing out by BDs. Backing out occurs when a BD decides not to donate a kidney after the BD's original intended recipient has received a kidney transplant within a KE chain. The 'understanding' is created by education of the BD about the possible effects of backing out on subsequent recipients within a KE chain, and/or the DDWL.

Results

NDDs—historical considerations

NDD kidney transplants were initially reported by Sadler in 1971 (13), but the practice was abandoned for over two decades because of poor results with HLA-mismatched living donor kidney transplants. In 2000, Matas reported a series of NDD transplants with excellent results (14), which led to widespread application. Later reports by Matas (15) and from a national consensus conference (12) provided ethical standards for NDDs. Many of these ethical considerations are also applicable to BDs (see definition in

Methods) and provide a basis for NDD participation in KE programs.

Bridge donors: BDs represent an ethically important entity in KE chains, but their unique ethical issues have not been addressed. These issues include: donor education, informed consent, coercion, exploitation and commercialization, privacy and confidentiality. Because the ethical issues for NDDs and BDs are quite similar, they are generally considered together.

NDDs—practical considerations

Initial screening of NDDs: Originally described by Matas (14), initial screening of potential NDDs is conducted via an interview (telephone or in person, or both) by an experienced transplant professional. If NDDs are being considered for KE, the person conducting the interview should be knowledgeable about NDD participation in KEs. Interviews should provide educational information about donation (evaluation, surgery, postoperative recovery, complications and costs) and the risks and benefits of KE. The initial interview should obtain pertinent medical and psychosocial history, including the individual's motivation for donation. The initial screening interview should include previously published screening questions for NDD (Table 1 in Reference 13).

Education and informed consent: KE programs that allow NDD participation should have educational materials available that provide information regarding kidney donation, NDD kidney donation and KE. These educational materials should be provided following a successful initial screening procedure, as previously suggested (14). A list of basic information for education regarding living kidney donation, NDD kidney donation and KE participation is presented in Table 1.

Center selection and travel considerations for NDDs and BDs:

NDDs and BDs should be informed of possible travel requirements for KE participation, and that travel can be minimized by referral to geographically proximate transplant centers. To facilitate this, NDDs and BDs should be provided a list of transplant centers that allow NDD participation in KE. NDDs and BDs should be informed that it is preferable for donation to occur at the recipient's transplant center. NDDs and BDs should be aware that the travel requirement may not be absolute, as some transplant centers may allow transportation of the donated kidney. NDDs and BDs should also be provided information regarding risks and benefits transporting kidneys.

KE Timing: NDDs and BDs should be aware that the exact date for kidney donation may not be immediately known and that delays, rescheduling or cancellations may occur. NDDs and BDs should be informed that they have a right to express their preference for the transplant date and the transplant center for their donation procedure.

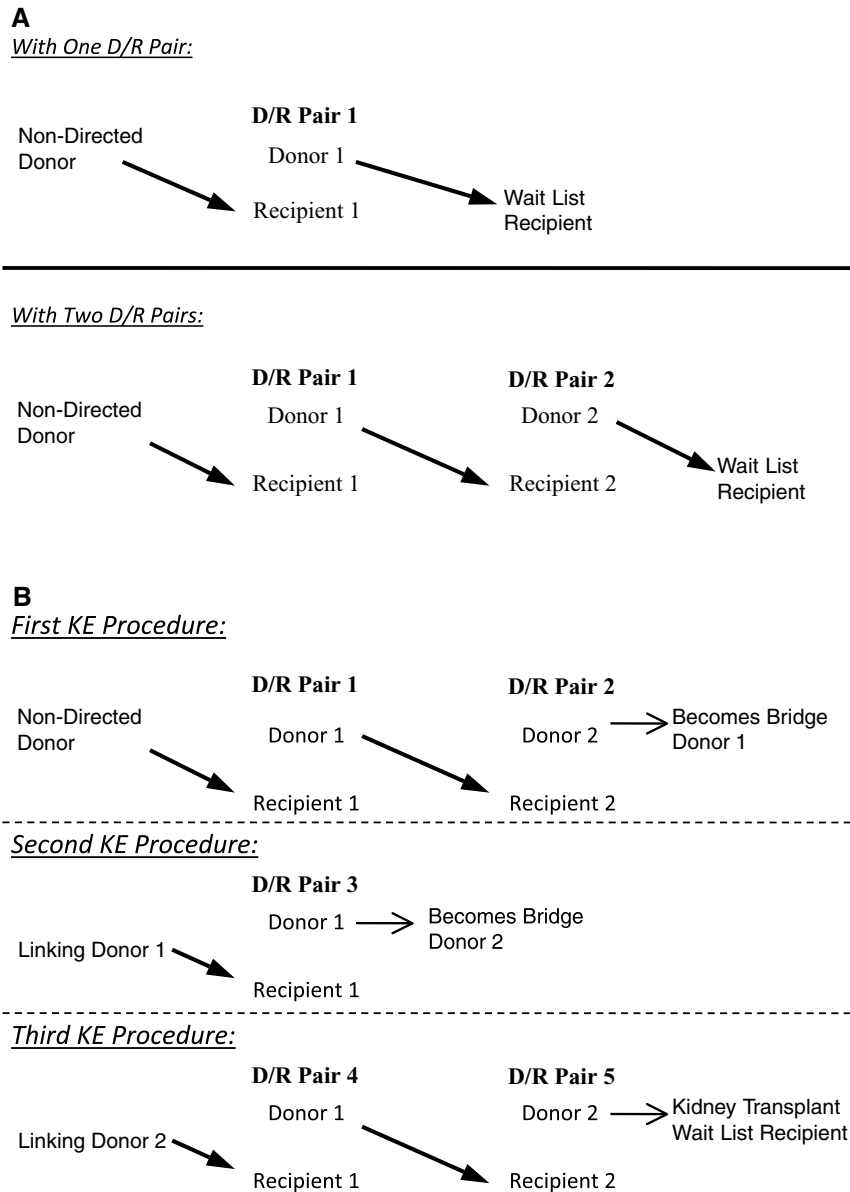


Figure 1: (A) A closed chain kidney exchange procedure may involve 1, 2 or more incompatible donor/recipient pairs. The final donor kidney in the cascade of kidney donations is donated to the deceased donor wait list (DDWL). (B) Limited kidney exchange (KE) ‘chains’ consist of two or more KE procedures, each of which is carried out on a different date. The initial KE procedure in a KE chain is initiated by a nondirected donor (NDD). Individual KE procedures are joined by a ‘bridge’ donor (BD). Limited KE chains are ended by donation of a kidney by a BD to a recipient from the DDWL. (C) Open chain KEs chains consist of two or more KE procedures each of which is carried out on a different date. The first KE procedure in a KE chain is initiated by donation from an NDD and individual KE procedures are joined by ‘bridge’ living donors. In open chain KEs, BD kidneys are always donated to initiate a subsequent KE procedure, and are never allocated to the DDWL. (D) ABO blood group considerations for NDD participation in KE programs. The figure demonstrates how an O blood group NDD kidney can be donated, but a non-O blood group kidney distributed to the DDWL. Absence of protective mechanisms and monitoring for blood group distributions to the DDWL may result in the O blood group wait list being disadvantaged, particularly because O blood group kidneys are in great demand in KE programs.

NDDs and BDs who donate directly to a DDWL recipient will usually be able to have their surgery promptly arranged, as only one recipient is involved and the logistics are relatively simple. In contrast, when NDDs or BDs donate in

a KE procedure, several donors and recipients may be involved and the waiting period for surgery may be substantially longer (several weeks or more). The length of the waiting period depends on several processes including: one or

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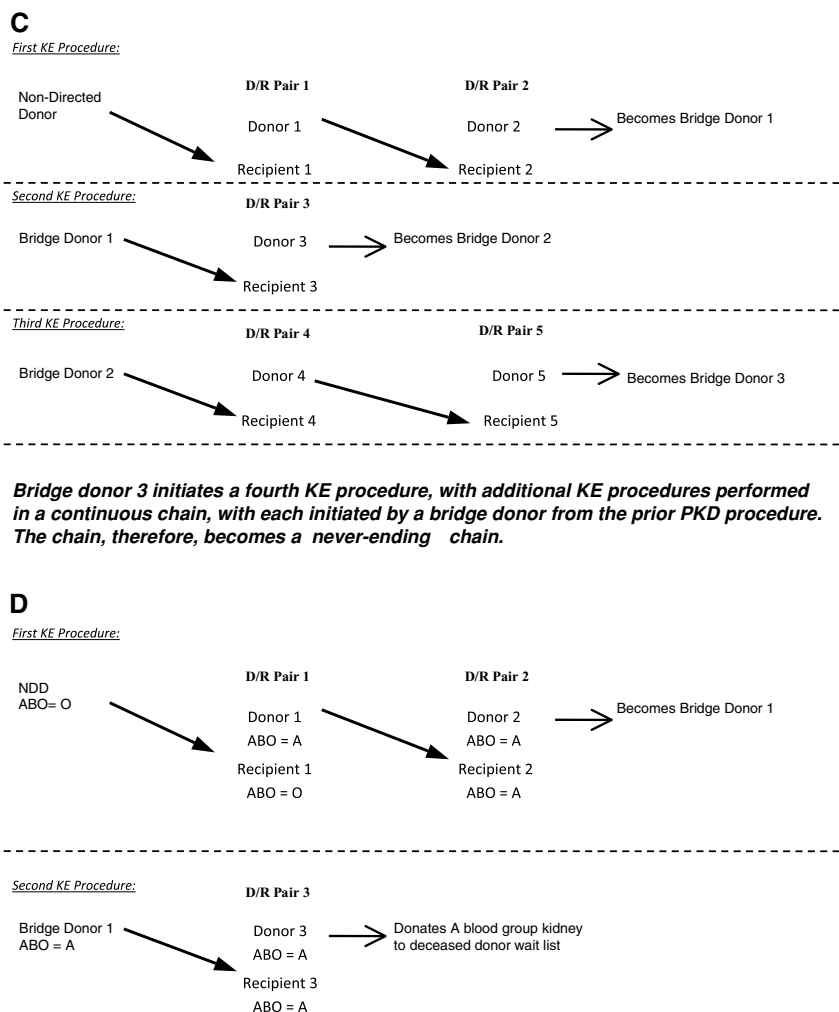


Figure 1: Continued.

more computer-generated match runs, medical review of potential matches, final cross-matching of all transplants, final medical testing, acceptance of proposed transplants by transplant teams, coordination of transplant dates and pretransplant meetings of donors and recipients.

NDDs—ethical considerations

NDD-driven KE procedures: Allocation of kidneys to the DDWL: Despite the absence of an Organ Procurement and Transplantation Network (OPTN) policy governing for deceased donor kidney allocation NDD allocation, NDD kidneys are often allocated by OPTN criteria (12,14–16). NDD participation in KEs raises the probability that NDD O blood group kidneys will be preferentially allocated to KE recipients, with non-O blood group kidneys predominantly allocated to DDWL recipients. This probability occurs because O blood group kidneys are in high demand in KE programs. As a result, O blood group waiting times may be adversely affected (Figure 1D). Monitoring for these effects on the O

blood group DDWL should be performed in KE programs that allow NDD participation. Monitoring should include: (1) number and blood type of NDD kidneys donated in KEs and (2) allocation of O blood group kidneys in NDD-driven KEs. To our knowledge, modeling of potential negative effects on the DDWL incurred by allowing NDD participation in KE has not been published.

A critical ethical question regarding NDD participation in KEs involves the number of additional transplants that an NDD-facilitated KE should generate to justify diversion of O blood group kidneys from the DDWL. Obviously, unrestricted diversion of O blood group kidneys is ethically problematic. However, if modeling studies indicate that substantially more transplants can be generated, some moderate level of O blood group kidney diversion could be ethically acceptable. However, to date, modeling studies have indicated that NDDs resulted in an extra 0.99 transplants in closed chains and an extra 0.90 transplants

Table 1: Requisite information for education and informed consent for living kidney donation, nondirected kidney donation, paired kidney donation and nondirected donor participation in paired kidney donation

Living kidney donation

- Requirement for medical testing prior to donation
- Requirement for adoption of healthy lifestyle
- Requirement for regular follow-up after donation
- Donor risks

Major complications (bleeding requiring transfusion, open conversion, postoperative hernia requiring surgical repair, postoperative chronic pain, deep venous thrombosis, pulmonary embolism)

Death risk 1/3000

Recipient risks (kidney loss to rejection, technical complications or other reasons; transmission of disease [CMV, EBV, etc])

Nondirected kidney donation

- Participation in recipient selection not allowed
- May inquire expenses for travel and lost wages and medical care
- Federal assistance with travel and lodging costs is available
- Help at home following surgery will be required

Nondirected donor participation in kidney exchange

A list of transplant centers offering nondirected kidney donation will be provided to assist in selection of a center for evaluation, and possible later kidney donation

May or may not be able to meet recipients who have benefited from the kidney donation

Knowledge of the number of people helped will not be available until after the surgery

Layman's explanation of ABO incompatibility and cross-match incompatibility

Advantages and disadvantages of KE versus desensitization

Histocompatibility testing for potential matches

Frequency of match runs

Likelihood of receiving a transplant

Logistics of the KE procedures, including donor travel

Unique financial aspects of KE

Donor/recipient matching policies

Timing of kidney donation will have a degree of uncertainty, and a waiting period of up to several weeks to establish after medical evaluation is complete

Waiting period is necessary because computer matching must be performed, and evaluation of matches usually takes a few to several weeks

Duration of waiting period may be several weeks or longer, and may be limited if the donor chooses to do so

Explanation of 'prelimited' KE chain concept, time limits and right to choose a time limit

Travel requirement may be minimized by NDD selection of geographically proximate transplant centers

in open chains (17). The fewer extra transplants observed in open chains were due to backing out by BDs, which was assumed to occur at a rate of 5% per month. The authors (ESW, RS, JD) are aware of two BDs who have terminated chains by backing out. BD backing out is not expected to occur in a single KE procedure, as all donors would donate simultaneously. Data regarding rates of BD backing out are needed to support additional modeling studies to evaluate the potential negative effect on the O blood group wait list induced by NDD participation in KEs. The O blood group DDWL problem could be solved by addition of a requirement that, for every NDD kidney donated to initiate a KE chain, a kidney of the same blood type must be donated to the DDWL at the end of the KE chain.

Transplant center autonomy, NDD kidney allocation, transplant center relationships to KE programs:

In a multicenter collaborative KE program, it is important to assure fairness in allocation when NDDs are involved. If kidney allocation is perceived by a transplant center as inequitable, NDD referral from this center may decrease. When NDDs self-refer to individual transplant programs (outside of a KE) the donated kidney is usually allocated

to a DDWL recipient from the same program. Therefore, it is imperative that allocation policies be developed that specify how living donor kidneys from NDD-initiated KE procedures and chains are to be allocated to DDWL recipients. Transplant centers will have considerable interest in being assured that referral of NDDs from their center ultimately benefits their DDWL recipients. A potential solution is for KE programs and member transplant centers to adopt policies for NDD kidney allocation.

NDDs may self-refer directly to coordinating offices of KE programs. These NDDs should be provided a list of transplant centers that allow NDD participation in KEs. NDDs, after being adequately informed, should have the right to decide between donation directly to the deceased donor waiting list and KE participation. NDDs that self-refer directly to large, multimember KE programs should also be able to select a transplant center for their evaluation, donation and follow-up care.

A potential allocation algorithm for living donor kidneys from KE procedures where the NDD is self-referred to the coordinating office of a KE program would include

a rotational system whereby kidneys are allocated equitably to the donor service areas (DSAs) that represent KE member programs. Within each DSA, KE-derived living donor kidneys would be allocated according to criteria similar to current OPTN policies for deceased donor kidney allocation.

KE chains and the DDWL: KE chains raise unique and important ethical issues related to the DDWL and NDDs. When first applied, KE chains were all closed, that is, they concluded with donation of a living donor kidney to the DDWL. Subsequently, the alternative strategy of open KE chains (also termed 'never ending') (18) resulted in living donor kidneys being permanently diverted from the DDWL, as they were perpetually used to initiate subsequent KE procedures (Figure 1C). Open chain KE procedures are becoming increasingly common (19–22).

Chain KEs raise ethical issues because they may disadvantage DDWL candidates. DDWL candidates who do not have a living donor are not eligible to participate in KE, and therefore are disadvantaged by open chain KEs. In fact, open chain KEs deprive a disadvantaged population (those on the DDWL) from their only opportunity to receive a living donor kidney transplant. Similarly, both open and closed chain KEs disadvantage some individual blood group populations on the DDWL. The degree of disadvantage for each blood group is a function of ABO blood group distribution in the NDD population (which theoretically should approximate that of the US population, adjusted for racial mix) and the demand for individual blood group populations of KE wait list recipients. As an example, O blood group kidneys are in great demand among KE wait list recipients, and are likely to be rapidly transplanted in KE chains, thereby reducing the number of O blood group kidneys that get distributed to the DDWL recipients.

Proponents of open chain KEs argue that the theoretical increase in living donor transplants justifies the negative effects on the DDWL, in part because additional patients will be transplanted who would otherwise go on the DDWL and increase waiting times. However, the issue of permanent diversion of living donor kidneys by open chain KEs away from the DDWL removes the only opportunity for many DDWL recipients to receive a living donor kidney transplant. The fundamental question becomes: how great an increase in the number of living donor kidney transplants is enough to justify permanent diversion of a kidney from the DDWL in open chain KEs? As a corollary, should a greater increase be required for an O kidney than for an A kidney that is lost to the DDWL?

Some modeling data exist that quantify the effect of open chain KEs on transplant volume (17), however, the effect of varying rates of BD backing out is not known. Second, modeling studies have suggested that BDs do not drive subsequent KE procedures within a KE chain as efficiently

as the original NDD (17). As described below, BDs may result in progressively lower match efficiency with subsequent KE procedures within a chain. This phenomenon may therefore render open chain KEs self-limiting (23). As an example, if a blood group O NDD kidney initiates a chain, it is likely that the O kidney will be used preferentially within the first few recipients. As KE chains proceed through a series of KE procedures, BDs of less common blood types will eventually be encountered, and therefore become a rate-limiting factor. For example, once a BD of AB blood group is encountered, the chain will be effectively terminated, as the only viable option will be DDWL donation, as AB recipients are rarely found in KE programs. Transplantation of A₂ kidneys into O blood group recipients provides an additional means for mitigating the O blood group donor shortage in KE programs, as it has similarly done for the DDWL. Finally, the issue of participation of compatible donor/recipient pairs as a potential solution for relieving the O blood group shortage in KEs is not addressed in this communication, as it is currently an intensely debated issue, and as such, is beyond the scope of this article.

The problems of 'backing out' by bridge donors in KE chains and 'honor systems': Some KE programs have not required simultaneous anesthesia induction within open or closed KE chains. The substantial waiting periods that BDs will face may increase the likelihood of backing out of the donation and/or their perceived coercion. Although the number of open chain KEs initiated to date remains relatively small, two BDs are known to have backed out (ESW, RS, JD, personal observations). Moreover, there is neither a requirement nor mechanism for reporting of backing out by BDs. Recent work by Waterman et al. has highlighted the magnitude of the problems that long waiting periods exert on willingness of BDs and NDDs to donate in KE procedures (24). This work demonstrated that the willingness of NDDs to donate in KE programs wanes over time. These problems can be effectively addressed by the institution of time limits.

'Honor systems' (defined in Methods) have been developed and applied in open KE chains as a means for minimizing backing out by BDs (20). Honor systems are ethically problematic because they are inherently coercive. It is concerning that transplant professionals have been quoted as perceiving 'no fundamental ethical dispute' with such honor systems (20). Approaches for addressing the backing out problem that are preferable to honor systems include: (1) BD education, (2) prompt identification and conduct of KE procedures involving BDs and (3) institution of predefined limits (time limits or transplant number limits as described above).

Limiting open chain KEs—a potential solution: A potential solution for problems involves setting limits on open chain KEs. Limits may be placed on the number of transplants or the number of KE procedures within a KE chain. Once a limit is reached, the current BD would donate to

the DDWL. Time limits may be set on waiting periods for BDs, where BDs would decide (prior to initiation of the KE procedure) on a predefined waiting period, after which they would be provided the option of DDWL donation or to continue to wait to donate in a future KE procedure. In addition, if an NDD or BD decides to wait, they should be offered the option to donate to the DDWL at regular, defined intervals. The process of setting time limits should be initiated at the time of pretransplant education of NDDs and BDs. Prelimited chains must include education of the initiating NDD and all BDs regarding the existence of the limit and a plan for DDWL donation.

Privacy, confidentiality and coercion: Privacy and confidentiality should be assured for NDDs and BDs in KE procedures. In addition, adequate information regarding donors and recipients must be disclosed in order to achieve appropriate informed consent. NDDs and BDs have a right to knowledge about the intended recipient and assurance that their donated kidney will be used in a medically reasonable manner.

Open and closed KE and KE chains create a more complex environment for privacy and confidentiality issues than a simple two-pair KE procedures as NDD- and BD-driven KE procedures are not mutually reciprocal. It is not unreasonable that if one or more participants in a KE procedure do not wish to meet, the other agreeable participants may still be able to meet.

Traditional approaches toward NDDs meeting their potential recipients have held that meetings prior to transplant are unacceptable because of the possibility that the meeting could have negative effects on the donor's decision to donate (14–16). Therefore, pretransplant meetings between NDDs or BDs and recipients in KE procedures should not be allowed.

NDDs and BDs should be educated that once a KE procedure is set, they will not be made aware of the number of individuals involved prior to the procedure, as this may subject them to an increased degree of perceived coercion if they become cognizant that several individuals are dependent on their kidney donation. In conclusion, issues of overt and perceived coercion, confidentiality and patient rights are complex and warrant ongoing observation and consideration.

Commercialization, exploitation and the mass media: Recommendations for NDDs have included a requirement that the interest in donating be initiated by the NDD and solicitation be avoided (14–16). However, KE websites currently exist that provide mechanisms for NDD self-referral to KE programs (www.paireddonation.org), and contain examples of televised/published mass media stories that illustrate how NDDs in KE programs may benefit large numbers of patients. Simultaneous web-based presentation of: (1) benefits of NDD participation in KE programs, (2) exam-

ples of mass media coverage of NDD kidney donation for KE and (3) opportunities for self-referral of NDDs have been seen as an attempt to recruit individuals as NDDs. The gain generated from media attention creates ethical concerns, as some NDDs may be enticed by the prospect of garnering personal exposure in the mass media. This is particularly concerning as transplant centers may also drive the media process, given that KE chains have attracted considerable publicity for hospital-based transplant programs. Therefore, protective measures for NDDs should be in place to avoid increased coercion and exploitation. One needed protective measure is for KE programs to avoid overt linkage of NDD self-referral and NDD KE participation within individual websites and other mass media exposures. When media exposure occurs, anonymity of KE participants should be maintained. Finally, it is incumbent on each transplant program performing KE transplants to screen their participants responsibly to assure that the donation procedure is free of financial remuneration, valued consideration and coercive and exploitative elements.

Conclusions: Utility versus Justice

Proponents of NDD participation in KE programs argue that the increased number of kidney transplants provides adequate justification. However, implementation of a strategy based solely on volume considerations raises significant ethical and moral concerns. A reasonable approach, therefore, for resolution of these competing interests is to compromise. Some degree of increased numbers of transplants is reasonable, but should be justified by simultaneously limiting negative effects on the DDWL, particularly for O blood group recipients. Diversion of large numbers of NDD-derived kidneys from the DDWL is not likely to be ethically acceptable. Protective measures may allow increased numbers of transplants while simultaneously protecting those vulnerable populations (the DDWL, O blood group DDWL recipients, NDD donors and BDs). One approach may be to require that KE procedures involving NDDs assure that a minimum number of transplants be performed, and that the required increase in transplants be higher when O blood group kidneys are diverted from the DDWL. Because controversy and a lack of data exists regarding the effects of: (1) NDD participation in KEs, (2) open KE chains and (3) BD backing out on the DDWL, prospectively collected data should be generated and additional modeling studies performed to fully examine the degree of potential harm to the DDWL. Certainly, a large spectrum of scenarios, and extensive modeling and clinical experience with NDDs and KE programs should be available prior to initiation of a national KE program.

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