Creating a Medical, Ethical, and Legal Framework for Complex Living Kidney Donors

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The ever-increasing waiting times for deceased-donor kidneys have focused attention on living donation as a useful way to increase the supply of organs for transplant candidates (1). Many renal transplant centers now routinely accept donors with risk factors for developing future kidney disease, a group of patients that we term "complex living donors" (2,3). A lack of consensus about what constitutes an important risk factor and insufficient data about long-term outcomes for complex living donors have generated heated debate among transplant professionals over the ethics of allowing donation to proceed (4–6).

A medical, ethical, and legal framework for protecting complex living donors therefore is important given the diverse, sometimes conflicting pressures that transplant centers are under to accept living donors. The devastating cardiovascular mortality of chronic kidney disease (CKD) has contributed to the sense that long waiting times for deceased donor kidneys represent a "crisis" in which transplant candidates may die before receiving an organ (7–10). Potential recipients and their families, referring nephrologists, or donors themselves may encourage transplant centers to accept complex donors (1). In addition, transplant centers often generate income, prestige, or media attention for hospitals, accelerating the expansion of transplant programs.

In the United States, patients can readily access information about which hospitals have the most active centers (11). Volume counts in attracting transplant candidates. Hospital administrators may encourage or provide incentives to transplant groups to increase the number of transplants, including those that involve complex living donors (4).

Nomenclature and Categorization of Risk

Complicating the debate about living donors with risk factors is nomenclature. Our discussion focuses on potential long-term medical risks to donor health. In his discussion of donors with hypertension, Matas (10) used the term "marginal living donors." We have eschewed this term because of potential confusion with the concept of the deceased "marginal donor," in which case the focus of concern is kidney quality and recipient outcome rather than potential harm to the donor (12). We also have avoided Steiner's (13) term "donors with isolated medical abnormalities," because multiple risk factors for future kidney disease may coincide in the same patient and because risk factors such as BP present as a continuous variable, which may not be strictly normal or abnormal. We favor "complex living donors," a term that lacks stigma and that emphasizes that the problem is one of decision making in the absence of sound medical data or consensus guidelines.

A shared definition of the concept of a complex living donor is necessary for studying donor outcomes, measuring variations between centers in accepting such donors, and ultimately developing professional guidelines to protect donor interests and safety. Given the morbidity that accompanies CKD, transplant professionals must be concerned about donor medical issues that increase the risk for CKD, not just ESRD. In Table 1, we propose a categorization of the diverse factors that may increase medical risk for complex donors. The list is not exhaustive, and combinations of risk factors may lead to interaction.

Sparse Data about Long-Term Risk for Complex Donors

The transplant professional who is faced with counseling a complex donor is confronted with sparse and unsatisfying data about the magnitude of long-term risks. Numerous studies have suggested that donors without important medical abnormalities face risks for ESRD no higher than those of age-matched peers (14–21), but this evidence cannot be applied convincingly to complex donors. An exhaustive review of the medical literature on all factors that impinge on the health of complex donors is beyond the scope of this article. However, an examination of the quality of evidence for donors with three common conditions—hypertension, nephrolithiasis, and obesity—illuminates the challenge of deciding whether it is reasonable to subject complex donors to nephrectomy.

Hypertensive living donors have been studied as extensively as any other group of complex living donors (21). The largest study by Textor *et al.* (22) reported 12 mo of follow-up of GFR, proteinuria, and BP in 24 hypertensive and 125 nonhyperten-

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Table 1. Categories of living-donor risk factors[a]

Type of Risk Factor	Example
Evidence of current renal disease	Hematuria, proteinuria, nephrolithiasis
Direct risk for CKD	Hypertension, obesity
Reduced nephron mass	Age >65 yr
Genetic risk factor	Family history of ESRD in first-degree relative
Risk factor for a risk factor for CKD	Diabetes in a first-degree relative, impaired fasting glucose
Cardiovascular risk factor	Smoking, hyperlipidemia, hypertension
Other	Black race, sickle trait
Combination of previous risk factors	Hypertensive black patient

[a]CKD, chronic kidney disease.

sive donors at the Mayo clinic. The center used three methods of BP assessment: Automated BP, manual checks by specially trained nurses, and 24-h ambulatory BP measurements. Twenty-one hypertensive donors were excluded from donation for various medical reasons; the Mayo authors report having a "structured program" regarding hypertensive donors in place at the center, but the patients were not enrolled in a research protocol. At nephrectomy and 1 yr later, the hypertensive donors had a slightly lower GFR and slightly more proteinuria than nonhypertensive donors. Notably, many of these donors were started on angiotensin receptor blocker therapy, which may have reduced proteinuria (22).

Some transplant professionals have been reluctant to accept results of Textor *et al.* as evidence of the long-term safety of accepting hypertensive patients as donors (6). The relative risk of hypertension for development of kidney disease over 12 mo is likely to be low; therefore, Textor's results may not be surprising. The risk for CKD for a small group of hypertensive white patients at a single center also may not be generalizable to other groups of hypertensive donors. Notably, hypertension continues to be listed as a contraindication to living kidney donation on the United Network for Organ Sharing patient web site (23).

There are fewer data addressing donors with nephrolithiasis. Nephrolithiasis may be discovered *via* history or incidentally with imaging. Variables that may relate to recurrence risk include previous number of episodes, stone composition and size, presence of underlying systemic disorders that affect mineral metabolism, and results of urine studies (24). Two published case series addressed nephrolithiasis recurrence rates in patients after nondonor nephrectomy. In a series of 50 patients who underwent nephrectomy for complications related to a previous stone, Lee *et al.* (25) reported a recurrence rate for kidney stones of 30% in the contralateral kidney over a mean follow-up time of >5 yr. Two patients experienced anuric, acute renal failure from recurrent stones, and another patient developed proteinuria with ESRD. Worcester *et al.* (26) compared stone recurrence in 115 patients who underwent nephrectomy for various reasons (30% related to stones, 25% because of infection, 30% because of obstruction) *versus* 3151 patients with two kidneys. Recurrence was 14% in the patients who underwent nephrectomy, with a mean follow-up of 6 to 8 yr. Worcester *et al*. noted that stone recurrence in two-kidney patients was higher than in single-kidney patients but did not report the analogous recurrence rate for two-kidney patients during the same follow-up period. These patient populations likely have a higher risk for recurrent stones than would kidney donors with nephrolithiasis. Nonetheless, the lack of data on living donors with nephrolithiasis complicates extrapolation of these data to long-term donor risks.

Obese donors and their physicians likewise have few data to guide decision making. Many interested donors are obese, and given rapidly changing demographics of Western and developing nations, a substantial number of nonobese donors may become obese later in life. Long-term studies of obese living donors are not available (3,21,27).

Increased body mass index (BMI) has been associated with risk for proteinuria and FSGS, and kidney function for obese donors also can be harmed indirectly through increased rates of diabetes, hypertension, and the metabolic syndrome (28). Heimbach *et al.* (29) compared obese and nonobese living donors at the Mayo clinic. Of 553 donors reviewed, 58% had 1-yr follow-up data, at which point obese donors had similar levels of urinary microalbumin and GFR as other donors and no change in BMI. A cross-sectional study by Praga *et al.* (30) reported rates of proteinuria and CKD among patients who underwent nondonor nephrectomy at a single center in Spain. Nephrectomy had been performed for reasons such as nephrolithiasis, unilateral hydronephrosis or masses, and complications of pyelonephritis. Exclusion criteria for the study were subsequent development of systemic diseases such as diabetes since nephrectomy. Of 115 patients initially considered, 73 were included, 20 of whom developed proteinuria. The proteinuric patients were more likely to be obese than nonproteinuric patients. Prespecified hypotheses of the study, however, were unclear, and the pathologic indications for nephrectomy may limit the generalizability of Praga's results to living kidney donors.

The shortcomings of the published evidence of long-term risks to living kidney donors with hypertension, nephrolithiasis, and obesity are evident; the data for donors with other risk factors likewise are sparse. Changing demographics, increasing life expectancy, and better therapies for CKD make quantifying the long-term risk of living kidney donation for complex donors even more problematic. As a result, the decision as to

whether a complex potential donor should be accepted should be placed within a well-informed ethical and legal framework that acknowledges limits on data and provides for independent sources of opinion for prospective donors.

Ethics of Accepting Complex Living Kidney Donors

The three major ethical principles that should guide transplant professionals' consideration of complex donors are beneficence to the recipient, nonmaleficence regarding the donor, and the donor's right to autonomy. Beneficence implies an active attempt to advocate strongly for the best medical treatment for patients with ESRD, which for many means transplantation. Although frank solicitation of organs is considered problematic, transplant professionals should use all reasonable means to procure an organ for their patients (31). After repeated documentation of racial inequalities in organ transplantation, for instance, advocates for minority groups have argued that the health care system must be willing to make substantial organizational changes to ensure equal access to organs (32–35); such a demand rests on recognition of beneficence as an active principle in transplantation. Therefore, consideration of living donors, including those with potential risk factors for future renal disease, remains a basic ethical responsibility for transplant professionals.

Complicating this duty, however, is the principle of nonmaleficence—the notion that medical professionals have a duty to "do no harm"—which is threatened by a scenario in which living donors must undergo a surgical procedure with a range of substantial risks, including death (31). In addition, living donors subject themselves to harm voluntarily, typically desiring to answer the need of another person, rather than gaining direct physical or financial benefit from their action (36,37).

Having beneficence and nonmaleficence in direct opposition is an unusual ethical scenario. One may conceptualize the "opposing" demands placed by beneficence and nonmaleficence as weights balancing like a seesaw on a fulcrum of autonomy. In practice, donor autonomy can be respected only by strict adherence to informed consent. Without ensuring valid informed consent on the part of prospective donors, the ethical tension between the responsibility to help transplant candidates and the well-founded concern about harming donors cannot be resolved by appealing to donor autonomy.

Informed consent usually requires a competent patient, comprehension of the circumstances, lack of coercion, and objective presentation of quality information about risks and benefits (38). In the scenario of complex living donors, the first three factors must be achieved and documented; the problem with information quality is more challenging.

The judgment of the potential donor is not simple; donors often have complex motivations, beliefs, and perceived obligations that may not be apparent and that may influence risk tolerance. For instance, a mother may be willing to tolerate a high level of personal risk because of her powerful desire to help her child. Some prospective donors are motivated by duty, love, or religious conviction and are indifferent to risk. Must attention to risk and benefit be forced on them?

The adequacy of informed consent should be examined systematically for every donor, and methods to protect the consent process may vary between centers (39). Donors should receive information about the evaluation process, the nephrectomy procedure and potential complications, likely postoperative timeline to full activity and work, and uncertain long-term risks to renal function. Donors should be cognizant of possible future medical expenses and possible difficulty in obtaining life insurance related to donation. Center-specific outcomes for donors and recipients should be presented. Printed information should be written at a sixth-grade level (38).

Evaluation of donor and recipient by different nephrologists seems to be common practice. The donor's nephrologist should advocate only for the donor's interests, and care should be taken to avoid external influences on this relationship. For example, if the donor's nephrologist works within with the transplant center, then he or she also could be subject to the center's general interest in increasing organ transplantation.

Donors also should be provided with multiple opportunities to rescind their decision to donate during the course of their workup (38). Some transplant professionals and ethicists have argued that potential donors who opt out of donation for personal reasons should be allowed to represent their decision as having happened for an undisclosed "medical" reason, to protect the potential donor's relationships with the recipient and others (39).

The fundamental ethical problem with accepting complex living donors is limited medical information about the magnitude of potential risk. If data about donor risk are misrepresented, then donor autonomy is undermined. This ethical problem remains challenging even with current attempts to maximize the independence and the integrity of the informed consent process. If a member of the transplant team senses that the informed consent process is not protecting a complex donor adequately, then the center should refuse the donor. One might ask whether the center then is permitting paternalism to supersede a donor's right to autonomy, but transplant professionals, as a team, must feel ethically comfortable with the decision to accept or refuse each donor. The conscience of each member of the transplant team merits protection, even if a decision to reject a kidney donor seems paternalistic. Physicians have the right to impose their own sense of acceptable risk in offering procedures to their patients.

Legal Context for Accepting Complex Living Donors

In addition to medical evidence and principles of ethics, the legal system can influence transplant professionals' management of complex donors. The Uniform Anatomical Gift Act, enacted with slight variations in all 50 states and the District of Columbia, provides the framework for allowing mentally competent adults to donate organs. Although some basic standards may be attached to the process of obtaining informed consent—for example, requiring presence of a witness—the content of the required disclosure largely is unregulated. As a result, the standard of care for the transplantation procedure and the informed consent process have been determined by judge-

Table 2. Proposed changes in approach to complex living kidney donors

Type of Safeguard	Example	Purpose
Ethical	Integration of donor advocate	Maximize independence of donor evaluation
	Potential donors contact previous donors with similar risk factors or demographics	Improve informed consent process
Legal	Practitioners understand state laws regarding informed consent	Educate transplant practitioners about legal environment
	Informed consent documented serially over workup	Protect patients from harm
Medical	Long-term outcome studies for complex donors	Identify which risk factors are clinically important
	Ensure plan for follow-up primary care after nephrectomy	Maximize likelihood that medical complications are identified and treated

made common law through lawsuits alleging negligence such as lack of informed consent or medical malpractice. Generally, courts have required organ donor consent to be informed by the disclosure of pertinent risks and benefits of the procedure (40). However, some courts have considered requiring a more rigorous standard of voluntariness in the informed consent process (41) and have extended the disclosure requirements to include risks for future harm. In one case, a man donated a kidney to his sister who had developed ESRD from hemolytic-uremic syndrome (HUS). The donor then developed HUS that led to ESRD 6 mo after donation. He charged that the transplant physicians had not informed him adequately about the possibility of a familial form of HUS that potentially could place him at future risk. Even though the defendant's medical expert argued that there was no "conclusive medical evidence linking the activation of hemolytic-uremic syndrome to surgery," the jury found that the informed consent process should have involved disclosure of this risk (42).

A charge of medical malpractice requires a causal connection between the injury and the transplantation procedure, which, as indicated in the previous paragraph, can be hard to establish for complex living donors who subsequently develop CKD. In searching legal databases, we were able to identify very few such cases against transplant professionals, but there may be more that were settled privately. In addition, recognizing the difficulty of establishing causation between an act and development of a bad outcome many years later, many states have enacted firm statutes of limitations for medical malpractice lawsuits. Most states' limits range from 2 to 4 yr (but can be extended if a patient remains under continuing care of the physician or the physician attempts to conceal the injury from the patient). In one Iowa case, a 23-yr-old man donated a kidney to his brother but developed ESRD himself 10 yr later (41). He charged that the original hospital and physicians were "negligent in not responding to his unwillingness to donate" and engaged in "psychologic manipulation," but the court found the case barred by Iowa's firm 6-yr statute of limitations (43). Not all states have enacted similar statutes of limitations; some, such as Pennsylvania, follow a "discovery rule" and permit malpractice cases to be brought up to 2 yr after discovery of the alleged injury, no matter when discovery occurs (44).

Transplant physicians should be aware of individual states' interpretations of disclosure and of voluntariness requirements for informed consent. Although few records of malpractice cases relating to the care of complex living donors exist, it is not hard to imagine that more cases will arise as a result of changing medical standards for donation.

Potential Strategies for Innovation and Research

Potential strategies to protect complex donors as well as the public's trust in living donor transplantation include maximizing the independence of donor evaluation, instituting a higher standard of informed consent, and establishing minimum guidelines for donor evaluation in all centers. Funding studies of outcomes for complex donors also will be vital to helping potential donors make informed decisions. Last, providing long-term health care benefits to complex donors would better ensure their ability to treat medical complications if they arise in the future (Table 2).

Integration of a "donor advocate" into a transplant center may offer an opportunity to have a nonpartisan professional represent the donor's interests independently. Ideally, a donor advocate would have a sophisticated medical understanding of kidney donation, would not answer to the transplant staff, and would not be subject to incentives that promote acceptance of complex donors (31), but issues related to recruiting, training, and paying such advocates could present substantial barriers; no clear model for such a donor advocacy program currently is available.

Other methods could buttress the viability of informed consent, including enhanced education or testing of donors. For instance, centers could offer potential complex donors the opportunity to discuss their decision confidentially with previous donors. Some potential donors may wish to discuss their decision with previous donors with similar demographic characteristics, such as race or gender. Testing donor knowledge is another potential strategy. Steiner (4) and others have proposed evaluating donor comprehension of risks using standardized tests before proceeding with surgery. This approach, applied to donors at the University of California at San Diego, has not

been widely adopted at other transplant centers. Technology also may be used to enhance patient education or decision making. At least one corporation has developed software that provides patients with standardized, animated information about surgical procedures, expected recovery, and risk. Justification for investing in such technology has included improving patient satisfaction and minimizing exposure to liability (45). To our knowledge, such innovations have not been applied to living kidney donation.

Considerable variation may exist as to how transplant centers present risk, perform psychosocial evaluations, and decide whether to accept complex donors. Center approaches to donor education and evaluation should be examined using well-defined end points that might have a medical, ethical, or educational focus. An example of a study that addresses a medical end point is durability of weight loss among obese donors who are counseled to lose weight before nephrectomy. An ethical end point that merits study is documentation of a psychosocial evaluation for donors that includes assessment for coercion or payment. An educational end point that merits study is quality of written materials on risk for patients with limited literacy. Such studies could provide an important foundation for setting minimum standards for the workup of complex donors.

Multicenter, long-term studies of health outcomes for complex donors also will be essential to understanding which factors impart risk in a clinically important way. Donors with risk factors that represent preexisting kidney dysfunction (*e.g.*, hematuria) or impart direct risk to future renal function (*e.g.*, hypertension) arguably should be subjected to nephrectomy only with institutional review board oversight. Ensuring that long-term health care is provided for complex donors may yield a dual benefit of meeting an obligation to donors who have made an altruistic sacrifice as well as facilitate information collection. Transplant professionals have a responsibility to advocate for the establishment and funding of these studies through professional societies and the United Network for Organ Sharing. In the absence of provision of health care benefits to donors, transplant centers should emphasize to donors the importance of primary care for the future.

Conclusions

The decision to accept a medically complex living donor rests on an uncertain medical, ethical, and legal foundation, so transplant centers ultimately must tailor their decisions to the particular circumstances of each donor. Since its inception, transplant medicine has innovated in the absence of robust data about donor and recipient outcomes. In the current scenario of complex donors, the transplant community has an obligation to be forthright when uncertainties about risk and a lack of professional consensus exist. Donors also should have a voice in the development of programs and research that are aimed at improving care.

Given evidence of increasing media and public interest in the medical and ethical basis of living donation, transplant professionals would be well advised to make internal debates about complex donors more transparent. In the past several years, stories expressing concern about living donors have appeared in diverse media outlets (46–48). If public trust in transplant professionals were jeopardized, with an attendant decline in living donation, then the harm to potential recipients would be devastating.

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