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Informed Consent of Living Kidney Donors: Pitfalls and Best Practice

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Abstract Informed consent is clearly considered the ethical bedrock fundamental to living organ donation, a procedure lacking medical benefits for its participants. Recent guidelines have focused on strengthening content components of living kidney donor informed consent, including Organ Procurement and Transplantation Network (OPTN)/United Network for Organ Sharing (UNOS) policies that prescribe key components, and integration of the Independent Living Donor Advocate (ILDA), as mandated by Centers for Medicare and Medicaid Services (CMS) and the OPTN/UNOS. The European Union member states' Working Group on Living Donation provided recommendations for care standardization in the "Toolbox Living Kidney Donation," including integration of an independent clinician advocate. However, even with these changes, studies suggest inconsistency in informed consent elements across transplant programs, and retrospective studies show that although the vast majority of living donors (LDs) reflect back positively on the experience of donation, some describe lacking complete knowledge of risks (or process) before donation. Processes to assure achievement of informed consent remain in the purview of individual transplant centers to implement and measure. Herein, methods to assess prospective LD intentionality, voluntariness, and understanding of risks/benefits are described, with promising techniques highlighted and recommendations for best practice outlined. Specific clinical challenges are addressed, including ambivalence, risk of secondary gain, and difficulty integrating understanding of risks. Finally, additional content elements are proposed to improve validity of informed consent in specific clinical circumstances.

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Introduction: Basics of Informed Consent in Living Donation

Informed consent occurs when a competent person makes an autonomous choice about whether or not to access medical treatment, armed with adequate information and understanding regarding risks, benefits, and expected outcomes [1]. The process is often described as reciprocal, in which clinician and patient share information disclosure, processing, and decision making. The patient's ultimate intention to proceed, understanding of process and benefits, and free will to decide are fundamental. That said, in any clinical practice setting, these factors present along a continuum between clarity and confusion [2].

Informed consent within the context of living organ donation has added necessary components, most notably the strong establishment of the donor's autonomous desire to proceed, given that s/he gains no medical benefits from donation. In addition, in the shared transaction of living donor (LD) transplantation (LDT), the prospective donor must gain an understanding of the procedure's expected outcomes for donor and recipient [3, 4••]. These tenets have been present since the beginning of LDT. Prior to the first LD transplant case, surgeon Joseph Murray assembled a separate team to care for the prospective donor and to facilitate thorough and unbiased risk assessment and education [5, 6]. Gordon summarized components beautifully, as follows:

> "The principle of respect for persons requires that potential living donors (LDs) be competent and informed, and comprehend the risks to themselves of undergoing

the procedure, as well as the risks, benefits and alternatives available to the recipient. Further, potential LDs must be willing to donate and be free from undue pressure to consent to the procedure. …Moreover, respect for autonomy means that LDs have the right to determine how much risk they are willing to accept, and conversely, that LDs (and the recipients) have the right to refuse the donation." [4••]

Regulatory Guidance

Specific elements of informed consent for LDs have gained focus over time in consensus conferences outlining best practice, and have eventually been integrated into regulatory guidelines to promote strengthened processes, and for standardized elements of disclosure and education. The 2000 *Consensus Statement on the Live Organ Donor*, as well as the *Declaration of Istanbul*, identified LD voluntary status as essential to informed consent, and affirmed that a living kidney donor should understand treatment options for the recipient [7–9]. A 2011 Joint Societies consensus conference on LD long-term follow-up reinforced that donors must understand personal medical risks (short- and long-term) associated with the procedure [10].

In 2007, LD consent guidelines were regulated via the Centers for Medicare and Medicaid Services (CMS) Conditions for Transplant Center Participation and reinforced in Organ Procurement and Transplantation Network (OPTN) care requirements [11, 12, 13••]. These policies also mandated the implementation of an Independent Living Donor Advocate (ILDA), or an ILDA team (IDAT), defining their function as a professional independent of recipient care and therefore positioned to assess LD readiness with reduced risk (or appearance) of conflict of interest, with OPTN subsequently requiring center-specific protocols. Later, OPTN/United Network for Organ Sharing (UNOS) LD informed consent policies, released in 2013 and revised in 2014, further outlined content elements, if not processes or assessment methods, for LD consent [13••, 14]. The 2013 OPTN/UNOS policy also outlined that potential LDs must consent to donor evaluation separately from the consent to the procedure itself [13••].

Range of Practices

In practice to date, LD informed consent processes have been shown to vary widely across transplant programs in the USA and worldwide, with discrepancies noted in standards, consistency, and implementation [4••, 15–20]. In separate pieces, both Gordon and Rodrigue et al. identified significant 'variability and deficiencies' in the consent process across the spectrum of LD care [4••, 15]. Though these studies reviewed care practices prior to implementation of OPTN LD consent policy requirements, concerns raised about variability in quality of informed consent process continue to be valid. In a 2013 survey of US transplant program consent processes, Thiessen et al. found that although nearly all centers obtain written consent for evaluation from LDs, most forms lack elements required by CMS or OPTN. Specifically, elements regarding disclosure of recipient health or transplant waitlist status were often missing; other items (payment for follow-up care; risk of donor medical or psychosocial complications) were often ambiguous at best [19]. As the practice surveys by Steel et al. show, implementation of the ILDA role has varied widely as well, with ambiguity about use of the role in provision of informed consent, and in the degree to which the ILDA assessment is a component of donor candidacy [20, 21]. OPTN policy was intentionally not proscriptive about ILDA qualifications and training, pending (needed) data informing best practice. Meantime, the American Society for Transplantation Living Donor Community of Practice, in an ILDA guidance document currently in press, offered recommendations for skill sets and training [22]. In the 2014 "Toolbox Living Kidney Donation," the European Union member states' Working Group on Living Donation included recommendations for continuity in donor consent elements across member states, including provision for an independent clinician advocate in donor care [23].

Methods of Assessing Voluntary Status—Intentionality

Clearly, all living organ donors must be willing volunteers. Lacking desire to proceed is a straightforward contraindication to living organ donation [17]. However, sustained ambivalence and experience of 'pressure' (internal and external) around organ donation decision making is not uncommon [17, 24, 25]. For the purposes of LD candidacy, 'not deciding' about donation must be the same as 'deciding not to' proceed, a crucial standard to communicate to the profoundly ambivalent potential donor, who has not decided to proceed, but who also has not elected to close out the donation process.

In best practice, transplant programs employ various strategies to assist prospective donors struggling with ambivalence, including a 'cooling off period' [25, 16, 17], a 'scaling system' of readiness, referral for counseling/support, and, most recently by Dew et al., use of motivational interviewing approaches [24, 25]. Of note, literature suggests that donors who describe ambivalence at the time of donation are at higher risk for a poor psychosocial outcome [24–26]. Best practice explores the prospective donor's readiness, or stage of decision making, as a process: the psychosocial provider (and/or the ILDA) conducts repeat assessment of the prospective donor's desire to proceed after s/he has completed medical

evaluation, and been educated about individualized risk profile and LDT expected outcomes [25].

Pressured Decision Making

Contemplation of living donation is commonly affected by feelings of pressure and obligation, felt internally and/or imposed externally. Valapour et al. found that 40 % of surveyed donors felt decision-making pressure [2, 17]. These feelings may be identified positively, as in chosen role or aspirational identity; they may also be felt internally as a duty, associated with seeing a loved one suffer [28]. Influences affecting voluntary status, in Valapour et al.'s work, ran along a continuum ranging from persuasion to coercion [2, 17]. Studies have repeatedly shown that LDs with the highest degree of (presumably, external) pressure around decision-making also had the highest rate of regret, or at least 'unsureness' about whether they would choose to donate again [26–28].

Psychosocial providers and the ILDA evaluate whether a potential LD can choose to donate (or not) without inducement or fear of reprisal. Interviews elicit distinctions between internalized pressure and external pressure (coercion) that affects donor autonomy and safety. It is conceivable for a potential LD to disclose others' efforts at inducement, and his/her own ability to make an autonomous decision about donation despite this pressure. If the prospective donor's experience of external pressure (or coercion) is affecting decision-making, however, transplant teams must assist with various options for stopping the donation process, with a variability in logistics noted in national surveys of practice. At the least, Thiessen et al. recommended that all prospective donors be offered a general statement regarding an 'unsuitability to donate' at any time [29••].

Direct Payment

As the organ shortage grows, concerns about organ sales, and exploitation, have climbed [9]. As outlined in the OPTN/UNOS living donor informed consent policy requirements, informed consent must include disclosure that "it is a federal crime for any person to knowingly acquire, obtain or otherwise transfer any human organ for valuable consideration (i.e., for anything of value such as cash, property, vacations)" [13••]. Prospective donors must agree to abide by these provisions. That said, risk of secondary gain as a driver for prospective LDs is notoriously difficult to assess accurately.

At first glance, it would appear that the challenge of assessing underlying motivation increases as more potential donors present to transplant centers without an emotional connection to their intended recipients (with motivation less likely to be centered around concern for a suffering loved one). The proportion of first-degree relatives as LDs continues to decline [30]. Whereas in 1989 only 8 % of transplant programs would consider a non-directed donor (NDD), by 2007, 61 % of responding programs evaluated NDDs [15]. However, and my own clinical practice seconds this, a Joint Societies consensus conference recommended that evaluation processes and structure fundamentally be the same for potential donors, regardless of relationship (or lack thereof) between donor and recipient [31]. In all cases, understanding of expectations between donor and recipient (including a lack of a financial relationship) should be agreed upon prior to proceeding. If areas of risk are identified, transplant teams may require the prospective donor to demonstrate sustained interest and coping with a prescribed 'cooling off' period, or seek consistency in the prospective donor's narrative history about motivation and expectations or between his/her desire to donate and other behavior (e.g., volunteer work).

Methods of Assessing Understanding

As is outlined in OPTN policies for living donor care, the LD must understand the evaluation process, the medical, surgical and psychosocial risks of living donation, and treatment options and expected outcomes of LDT for the recipient [13••]. Effective assessment of comprehension is crucial, given literature suggesting past LDs lacked adequate knowledge and understanding of risks [4••, 16, 17, 19]. Although CMS and OPTN requirements prescribe content elements, methods of education provision, and assessment of understanding, are not defined, and it is here there is room for growth in best practice standards.

Extant literature has focused on optimum ways to encourage people to consider living donation, and to learn basic facts about risk and process. Effective approaches include culturally competent education, home visits, web-based portals, and family-centered approaches [32–36]. However, few data support specific methods to communicate, and assess, a medically cleared potential LD's understanding of his/her risk profile and expected outcomes. Structured interview techniques help potential donors focus and reflect understanding back, a method that has been clearly supported in other fields of practice [35, 37]. Some transplant programs have integrated knowledge testing prior to donation, though data about the impact and merit of this does not yet exist, and a validated tool has not yet been built—let alone one that can accommodate learning barriers and differences.

With or without a comprehension 'exam,' if the prospective donor has gaps in understanding, s/he should receive additional assessment, education, and intervention. Gaps in understanding may be attributed to cognitive deficits that preclude provision of informed consent; inadequate integration or

understanding of risks/benefits; or evidence of significantly unrealistic expectations associated with donation. In many cases, an initial lack of understanding may not be a permanent contraindication to living donation, but can instead trigger additional consults, e.g., neurology or psychiatry, and/or tailored teaching to accommodate learning barriers (most often at our center, literacy limitations) [38].

It is also not uncommon for prospective living donors to voice that risks are of "no concern," that they want to donate "no matter what." Simmons and others, dating back to the 1970s and 1980s, found that LD decision making centers on moral, rather than deliberative, reasoning [39]. As such, part of the informed consent process is to assess whether prospective living donors have actually integrated risk information, and to help them slow down enough to process data, risks, and options.

In addition, psychosocial risk profile affects patients' ability to integrate understanding of risks. Some potential donors lack the maturity to identify themselves as vulnerable to risk (often associated with life stage) [40]; others demonstrate 'magical thinking' about what living donation will do for the intended recipient [41]. Each of these factors could be described as a relative contraindication or risk factor, warranting assessment and review.

Specific Content Elements

With several recent studies exploring the long-term impact of LD (and debate in the literature about implications of these data), content elements of informed consent should be expanded to include the evolving understanding of the risk of end-stage renal disease in LDs compared with healthy non-donors [42–46]. The prospective LD should learn about factors influencing donor medical and psychosocial risk variability (e.g., hypertension, body mass index, depression), and discuss implications for his/her specific risk profile [42–47]. The informed consent process should also include content about the potential impact of LD on future pregnancy [48, 49], factors influencing expected outcomes of the LDT [50, 51], as well as potential risks/benefits to not proceeding with donation, particularly in regard to the emotional impact of witnessing recipient health outcomes [52].

OPTN/UNOS policy mandates a separate informed consent process for the risks of the living donor evaluation itself. Although content elements are not prescribed, they should at least include description of the evaluation and donor candidacy process, the risk of identification of a health condition that precludes donation, and the risk that this diagnosis may affect insurability (rates and issuance). Additional content elements might include description of the transplant center's procedures in the event of discovery of misattributed paternity, a topic that has long been controversial in the transplant community, so clarification of policy would be helpful to communicate up front [53].

Content Elements for Informed Consent Within Specific Living Donor Transactions

Aspects of care for the non-directed LD and for the LD in paired donation warrant additional informed consent content elements. A 2013 Joint Societies Consensus Conference on Paired Kidney Donation outlined that, in these systems, donors should consent to risks specific to paired donation (e.g., a broken chain, or a kidney lost in transit) [54]. These donors (and especially bridge donors) should also consent to process differences (e.g., timing unpredictability; potential for additional testing) [55]. NDDs and LDs for paired exchange should be advised of confidentiality guidelines limiting information exchange about 'actual' recipient outcomes, particularly as this information has been linked to donor satisfaction [24, 54–57].

Conclusions

It is to be noted that the vast majority of living kidney donors, in the short- and long-term after donation, are glad they donated. Most prior donors describe the act of donation as profound, gratifying, and defining [24]. That said, predictors of struggle following LD include ambivalence, unexpected medical or financial consequences, and poor recipient health outcome. Each of these factors might be mitigated with robust decision-making aides and educational processes, and further research into best practice is warranted. Specifically, processes to support donor integration of risks should be validated (including the pros and cons of donor testing). Methods to help reluctant prospective donors stop the donation process (including the pros and cons of the so-called 'medical-out') should be explored, along with identifying the least traumatic ways to decline an enthusiastic prospective donor's candidacy [54]. And, perhaps ironically, standardized consent components should describe the variability in LD risk (especially when looking at the long-term consequences of living donation), and multidisciplinary teams at transplant centers should focus on helping prospective donors understand their specific risk profile.

Compliance with Ethics Guidelines

Conflict of Interest R.E. Hays declares that she has no conflict of interest.

Human and Animal Rights and Informed Consent This article does not contain any studies with human or animal subjects performed by any of the authors.

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