Living Kidney Transplantation: Ethical Approaches to Enhance and Evaluate Donations

Center for Health Care Ethics
Lakehead University

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Outline

- Background: Working Definitions and Statistics
- Ethical and Other Issues Associated with Living Kidney Donation
- Living Donor Advocacy
- The UTSW DAT Committee
- Concluding Remarks
Objectives

- Describe the role of advocacy in living kidney donation.
- Demonstrate why a team approach assures a more comprehensive consideration of the complex factors involved in live kidney donation.
- Present some of the ethical and social issues associated with living kidney donation.
The Case of Dr. Alvarez

John Alvarez, MD, is a 35-year-old separated Hispanic male nephrologist who wishes to donate one of his kidneys for one of his patients (paired donation). He has two children with his wife, Maria, but they are in the process of divorcing. His patient is a 31-year-old single female who urgently needs a kidney transplantation. He denies having any kind of special relationship with his patient, including any romantic interests. He just wants to “do the right thing” after one of his patients died because he could not find a donor.
Working Definitions

• “Living kidney donors are living persons who offer to donate, or actually donate, a kidney to a kidney recipient.”
  (UTSW University Hospital, Living Kidney Policy 1-154)

• “A living donor is a person who agrees to have a voluntary nephrectomy of a healthy kidney, which will subsequently be transplanted into another person who is experiencing renal failure.”
  (DeWolf Bosek & Sargeant, JONA’S Healthcare Law, Ethics, and Regulations, 2012)
Canadian Context – Some Stats

- An estimated 2.6 million Canadians have kidney disease, or are at risk.

- The two leading causes of kidney failure in new patients:
  - Diabetes – 35%
  - Renal Vascular Disease (including high blood pressure) – 18%

- Nearly 39,300 Canadians living with kidney failure in 2010
  - Three times more than in 1990

- Nearly 3,400 people are on a transplant waiting list.

- Nearly 40% of kidney transplants are made possible by living donors.

(Canadian Institute for Health Information; The Kidney Foundation of Canada)
Hemodialysis is the treatment used in the majority of dialysis cases. Cost: roughly $60,000 per patient per year.

Cost for a kidney transplant: approximately $23,000, plus $6,000 per year for medication necessary.

“Over a five-year period, a transplant is approximately $250,000 less expensive per patient than dialysis while improving quality of life.”

(The Kidney Foundation of Canada)
Canadian Context - Donation

- About 14 kidney donors per million people in Canada
- 26 to 28 donors per million people in USA
- More than 30 donors per million people in Spain
- Between 2000 and 2009, 10,641 kidney transplant procedures were performed in Canada.
- Ontario led the country with the most living donor transplants, followed by British Columbia.

(Chai, Postmedia News, 2011)
Canadian Context – Ethnicity

- “Australia, Canada and New Zealand research shows that indigenous patients received significantly less kidney transplants compared to white patients in these countries” (Yeates et al, 2009).
- “Among Canadians starting dialysis, patients of East Asian and Indo Asian background are less likely than whites to receive a renal allograft” (Prasad, 2007).
- “Differences in access to organ transplantation seem to be a universal problem despite different ethnic groups in each country” (Maasdam et al, 2012).
Ethnicity by Donors in Canada, 1996-2006 – Trpeski, 2007 (Canadian Organ Replacement Register [CORR])

NDD- Neurologically determined death; LRD-Living related donor; LUR-Living unrelated donor
Ontario – Trillium Gift of Life Network, 2012

- NUMBER OF PERSONS WAITING AS AT SEPTEMBER 6, 2012

WAITING FOR

- Heart 57
- Heart Lung 2
- Kidney 1089
- Kidney Pancreas 52
- Liver 214
- Lung 76
- Pancreas- Whole 27
- Small Bowel 0
- Other 6

TOTAL 1523
Ontario – Trillium Gift of Life Network, 2012

- NUMBER OF PERSONS WAITING AS AT SEPTEMBER 6, 2012

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Ontario – Trillium Gift of Life Network, 2012

- NUMBER OF PERSONS WAITING AS AT SEPTEMBER 6, 2012

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<td>Heart Lung</td>
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<td>Kidney</td>
<td>450</td>
<td>639</td>
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<td>Kidney Pancreas</td>
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<td>33</td>
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<td>Liver</td>
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<tr>
<td>Lung</td>
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<td>32</td>
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<tr>
<td>Pancreas (Whole)</td>
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<td>17</td>
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<tr>
<td>Small Bowel</td>
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<td>0</td>
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<tr>
<td>Other</td>
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<td><strong>TOTAL</strong></td>
<td><strong>612</strong></td>
<td><strong>911</strong></td>
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Statistics about Kidney Donation

- 26 million American adults have Chronic Kidney Disease (CKD) and more than 485,000 Americans are treated for end stage renal disease (ESRD).
- In 2005, 85,790 patients died as a result of kidney disease.
- Two main options to treat effectively ESRD: dialysis and transplantation.
  - Transplantation is the preferred option since it replaces normal kidney function between 40-80% whereas dialysis replaces less than 10%.

(National Kidney Foundation; Keown, 2004)
Statistics about Kidney Donation

- 92,021 patients await for a kidney transplant as of April 25, 2012.
- The number of living donors decreased from 2004 (7,004) to 2006 (6,732) while the prevalence of chronic renal failure has increased.
- 5,769 living kidney donor transplantations performed in 2011.
- In 2011, 4,903 kidney patients died while waiting for transplantation.

(National Kidney Foundation; Keown, 2004)
Statistics on U.S. Living Kidney Donors

The State of U.S. Living Kidney Donors

Connie L. Davis* and Mathew Cooper†
*Department of Medicine, University of Washington, Seattle, Washington; and †Department of Surgery, University of Maryland, Baltimore, Maryland

Background and objectives: Increasing living kidney donation mandates ongoing assessment of living donors for future health risks and revision of national health policy.

Design, setting, participants, & measurements: Living kidney donors as reported to the Organ Procurement and Transplant Network database from January 1988 through December 2008 were reviewed for minor medical abnormalities, presence of donor health care coverage, and occurrence of surgical complications and death.

Results: At donation in 2008, 19.5% were obese, 2.0% had a history of hypertension, and 3.5% had proteinuria. The median estimated GFR of living donors was 92.2 mL/min. Additionally, 12.2% of donors were reported not to have health insurance at the time of donation. By racial background, 14.9% of black and 17.0% of Hispanic donors did not have insurance at donation. Perioperative complications included blood transfusion (0.4%), reoperation (0.5%), and vascular complications (0.2%). Death occurred within 30 days of donation in 0.03% donating between October 1999 and December 2008. During those same years, overall donor death was 2.8%.

Conclusions: Almost one quarter of living donors have medical conditions that may be associated with future health risk. Close follow-up and a registry of these donors are necessary. Only then will we be able to inform prospective living donors most accurately of the real risk of donation on their health and survival. Additionally, these data speak to the need for a national discussion on the provision of health insurance for living donors.

Age Group of Living Kidney Donors

*Table 1.* Percent in each age range of living donors over time (5)

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<td>46.3</td>
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<td>36.7</td>
<td>32.7</td>
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<td>35 to 49</td>
<td>39.4</td>
<td>43.5</td>
<td>46.3</td>
<td>47.7</td>
<td>47.2</td>
<td>43.4</td>
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<td>50 to 64</td>
<td>12.1</td>
<td>12.6</td>
<td>15.4</td>
<td>18</td>
<td>20.3</td>
<td>24.1</td>
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<td>0.8</td>
<td>1.1</td>
<td>0.9</td>
<td>0.9</td>
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Ethnicity of Living Kidney Donors

Table 2. Ethnicity of living kidney donors over time as percentage of the living donor population (5)

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<td>African American</td>
<td>11.6</td>
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<td>12.9</td>
<td>12.9</td>
<td>13.3</td>
<td>11.9</td>
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<tr>
<td>Caucasian</td>
<td>76.1</td>
<td>73.8</td>
<td>72.6</td>
<td>70.3</td>
<td>69.1</td>
<td>69.1</td>
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<tr>
<td>Hispanic</td>
<td>9.1</td>
<td>10.5</td>
<td>10.6</td>
<td>11.9</td>
<td>12.9</td>
<td>13.8</td>
</tr>
<tr>
<td>Asian</td>
<td>0.3</td>
<td>0.5</td>
<td>1.9</td>
<td>3.3</td>
<td>3.4</td>
<td>3.8</td>
</tr>
<tr>
<td>Other</td>
<td>2.9</td>
<td>3</td>
<td>2</td>
<td>1.6</td>
<td>1.3</td>
<td>1.4</td>
</tr>
</tbody>
</table>
Figure 1. The number of waitlisted transplant candidates and living donor and deceased donor transplant recipients by year (1).
Living Donors’ Relationship to their Recipient (A=1988; B=2008)
Ethical Issues

- **Nonmaleficence**
  - Physical harm
    - Risks associated with surgery
  - Psychological/spiritual harm
    - Emotional burden of donation; inability to “let go” the organ
    - Potential spiritual consequence of donation
  - Social harm
    - Social and family relationships
    - Potential impact on life insurance/health insurance eligibility

(DeWolf Bosek & Sargeant, *JONA’S Healthcare Law, Ethics, and Regulations*, 2012)
Ethical Issues

● Autonomy
  - Coercion and manipulation from family members or friends ("A good sister would donate", "The only hope is to find an unrelated donor…", etc.).
  - Informed consent (understanding risks and benefits; understanding other options; etc.).

(DeWolf Bosek & Sargeant, JONA’S Healthcare Law, Ethics, and Regulations, 2012)
Ethical Issues

- **Altruism**
  - Assessing motivations for donation (guilt, family or public attention, etc.).
  - Absence of financial/emotional compensation as a result of donation.

(DeWolf Bosek & Sargeant, *JONA'S Healthcare Law, Ethics, and Regulations*, 2012)
Ethical Issues

- Respect for Persons
  - Protection of the donor’s rights and values
  - Protection of the donor’s health information (lifestyle, health status, etc.)

(DeWolf Bosek & Sargeant, JONA’S Healthcare Law, Ethics, and Regulations, 2012)
Long-Term Consequences of Kidney Donation

Hassan N. Ibrahim, M.D., Robert Foley, M.B., B.S., LiPing Tan, M.D., Tyson Rogers, M.S., Robert F. Bailey, L.P.N., Hongfei Guo, Ph.D., Cynthia R. Gross, Ph.D., and Arthur J. Matas, M.D.

(2009)
Other Issues – Long Term Outcome of Kidney Donation

- Study looking at vital status and lifetime risk of end-stage renal disease (ESRD) in living kidney donors and non-donors.
- 3698 kidney donors from 1963 – 2007 matched for age, gender, and race/ethnic group with controls.
- Conclusions: Survival and risk of ESRD appear to be comparable to those in the general population.
Figure 1. Survival of Kidney Donors and Controls from the General Population. I bars at 5-year intervals indicate 95% confidence intervals for the probability of survival among kidney donors.
Other Issues – Racial Variation in Medical Outcomes

Racial Variation in Medical Outcomes among Living Kidney Donors

Krista L. Lentine, M.D., Mark A. Schnitzler, Ph.D., Huiling Xiao, M.S., Georges Saab, M.D., Paolo R. Salvalaggio, M.D., Ph.D., David Axelrod, M.D., Connie L. Davis, M.D., Kevin C. Abbott, M.D., M.P.H., and Daniel C. Brennan, M.D.

(2010)
Other Issues – Racial Variation in Medical Outcomes


- Findings: After kidney donation, black and Hispanic donors, as compared to white donors, had an increased risk of hypertension, diabetes requiring therapy, and chronic kidney disease.
Other Issues – Foreign National Donors

- Some challenges:
  - Provide an equivalent US medical and psychosocial evaluation in English from country of origin (or from another US transplant center).
  - Provide documentation of adequate medical insurance or personal financial means (medical procedures for transplantation process, relevant post-surgery care and health maintenance.
  - Limited insurance coverage post-surgery (recipient’s insurance, one year at UTSW).

(UTSW University Hospital, Living Kidney Policy 1-154)
Consensus on Live Organ Donation

- Members of the Live Organ Donor Consensus Group, and Affiliations
  - “The person who gives consent to be a live organ donor should be competent, willing to donate, free of coercion, medically and psychologically suitable, fully informed of the risks and benefits as a donor, and fully informed of the risks, benefits, and alternative treatment available to the recipient.”

  (Abecassis et al. *JAMA*, 2000)
The Big Picture

- Living organ donors should
  - Be competent – informed consent
  - Willing to donate – donation free of coercion
  - Medically and psychologically suitable
  - Fully informed of the risks and benefits as a donor
  - Fully informed of the risks, benefits, and alternative treatment available to the recipient
Canadian Federal Regulations

- Health Canada
  - Safety of Human Cells, Tissues and Organs for Transplantation Regulations (SOR/2007-118)
    - Section on Donor Suitability Assessment
    - No mention of advocacy
Kidney Foundation of Canada

- Advocacy:
  - Section “Who can advocate?”
    - Individual advocacy:

  “…Most renal programs have nephrology social workers as part of the renal team. Part of their role is to advocate on behalf of patients to ensure they have access to services for which they are eligible.”
US - Federal Requirement

“The transplant center that performs living donor transplantation must identify either an independent living donor advocate or an independent living donor advocate team to ensure protection of the rights of living donors and prospective living donors.”

(42 CFR 482.98 - Condition of Participation: Human Resources)
With recommendations from the Advisory Committee on Organ Transplantation (ACOT) HHS recommends the participation of independent donor advocates to represent the interests of the living donors throughout the process of donation.
CMS and UNOS

- Donor advocacy has been endorsed by centers for Medicare and Medicaid Services.
  - Since 2007 transplant centers are required to designate an independent donor advocate or to establish an independent donor advocate team.

- The United Network for Organ Sharing (UNOS) includes the recommendation to have a designated advocate into their regulatory bylaws.
Definition of Donor Advocate

“The Donor Advocate is an individual separate from the transplant team whose roles in the transplantation process include: (1) conducting an independent psychosocial-ethical evaluation of living donor candidates for the purposes of assessing the voluntariness of, and the adequacy of informed consent for, the potential donor; and (2) assist in providing support and referral for living donors at any stage of the transplant process.”

(UTSW University Hospital, Living Kidney Policy 1-154)
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(UTSW University Hospital, Living Kidney Policy 1-154)
The Donor Advocacy Team consists of a group of medical professionals and laypersons who: (1) review and contribute to the evaluation of the suitability and voluntariness of any living donor candidate; (2) provide counsel, support, and referral for living donors at any stage of the transplant process; and (3) assist in developing living donor policy and evaluating the overall outcomes of the living donor program.

(UTSW University Hospital, Living Kidney Policy 1-154)
Donor Advocacy Team (DAT)

The Donor Advocacy Team consists of a group of medical professionals and laypersons who: (1) review and contribute to the evaluation of the suitability and voluntariness of any living donor candidate; (2) provide counsel, support, and referral for living donors at any stage of the transplant process; and (3) assist in developing living donor policy and evaluating the overall outcomes of the living donor program.

(UTSW University Hospital, Living Kidney Policy 1-154)
Donors’ Expectations

- Study New York Presbyterian Hospital (2006)
  - During routine follow-up (3 months after donation) donors were asked what they expected from an advocate:
    - “Look out for my best interest”
    - “Make sure I am healthy enough to donate”
    - Just let me do this”
    - Educate me about the risks, carefully evaluate me, and then tell me I am going to be OK”
    - “Don’t treat me like a cadaver”
    - “Give me my own health care team”

(Rudow, Progress in Transplantation, 2009)
The UTSW DAT Committee

- The DAT committee had its first meeting December 2007 (meeting once a month).
- The DAT committee operates as a type of quality assurance approval body for the selection of potential living kidney donors.
- Fourfold function:
  - Education
  - Research
  - Policy Development
  - Consultation
Tasks of the DAT Committee

- Identify and evaluate potential psycho-social risks
- Ensure donors understand risks, benefits and potential outcome of donation (donor and recipient)
- Assess donors’ decision making capacity and ability to cope with surgery
- Assess donors’ motives and degree of absence of coercion, guilt, undue pressure, etc.
- Review life circumstances (family relationships, employment, etc.)
- Review support system for recovery period
- Evaluate factors demanding further educational and therapeutic interventions pre-surgery
- Make recommendations (counseling, access to medical care post-surgery, etc.)
Advantages of a Team Approach

- Multidisciplinary and team approach
- Utilization of the Independent Donor Ethical Evaluation Assessment (IDEEA) to provide a uniform approach to donor candidacy evaluation.
- Comprehensive evaluation
Independent Donor Advocacy Team

- Multidisciplinary and team approach
- Utilization of the Independent Donor Ethical Evaluation Assessment (IDEEA) to provide a uniform approach to donor candidacy evaluation.
- Comprehensive evaluation
UTSW Donor Advocacy Team Committee (DAT)

- Members:
  - Psychologist
  - Chaplain
  - Lawyer
  - Community Representative
  - Two Nephrologists (not part of the transplant team)
  - Donor
  - Recipient
  - Surgeon (not part of the transplant team)
  - Medical Anthropologist
  - Psychiatrist
  - Medical Ethicist

- Each member provides a particular perspective based on his/her expertise and experience.
Independent Donor Advocacy Team

- Multidisciplinary and team approach
- Utilization of the Independent Donor Ethical Evaluation Assessment (IDEEA) to provide a uniform approach to donor candidacy evaluation.
- Comprehensive evaluation
Independent Donor Ethical Evaluation Assessment (IDEEA) Algorithm
Four Evaluation Categories

- Strong (Good)
  - No issues
  - Approved (no reservations)
Four Evaluation Categories

- Adequate (Acceptable)
  - Good Case; expressed concerns on certain issues
    - Significant past psychiatric symptoms or disorders
    - History of substance abuse
  - Approval w/recommendations
Four Evaluation Categories

- Marginal (Deferred)
  - Strong concerns about several issues
    - Limited financial capacity to manage donation
    - Lack of family support
    - Lack of insurance
    - Marked ambivalence about donating
    - Motives reflecting desire for recognition or to develop personal relationship
    - Demonstration of limited awareness of short or long term risks of donation

  - Deferred with recommendations and/or stipulations
Four Evaluation Categories

- Poor (Denial)
  - Too many issues
    - Significant ongoing psychiatric symptoms or disorders
    - Clear evidence of coercion to donate
    - Clear evidence of expectation of inappropriate secondary gain
    - Inappropriate relation to recipient (e.g. donor/patient)
    - Candidate incapable of informed consent
  - Denial by DAT Committee only
Independent Donor Advocacy Team

- Multidisciplinary and team approach
- Utilization of the Independent Donor Ethical Evaluation Assessment (IDEEA) to provide a uniform approach to donor candidacy evaluation.
- Comprehensive evaluation
Three Phase Evaluation

- Clinical Evaluation
- Psycho-social Evaluation
- Ethical Evaluation
Clinical Evaluation

- This important step is carried out by the Transplant Team.

- It concerns the collection of medical data and other relevant information concerning the medical suitability of the potential candidate to donate.

- The DAT committee does not intervene in the clinical work-up to avoid any conflict of interest.
Psycho-social Evaluation

- Purpose: gather information to present to the DAT Committee to facilitate their decision whether or not it is ethical for that candidate to donate.

- This evaluation provides the basis for determining that candidates are capable of informed consent.

- The required information is gathered through a clinical interview, the Mini Mental Status Exam, the Beck Depression Inventory II (BDI-II), and the Minnesota Multiphasic Personality Inventory-2 (MMPI-2).
Ethical Evaluation

- Based on the psycho-social evaluations of the psychologist, each case is presented to the DAT committee which assesses whether the candidate is an adequate donor from an ethical standpoint.

  - Key issues:
    - Is the donor fully informed of the risks and benefits?
    - Is the recipient fully informed of the risks, benefits and alternative treatments?
    - Is there any monetary compensation involved?
    - What is the financial situation of the donor? Does he/she have health insurance for post-surgery care?
    - Does the donor feel pressure to donate due to a clinically hopeless situation?
    - Was there a request for compensation of the organ?
Concluding Remarks

- Organ donation includes medical, psychosocial, and ethical considerations essential to the consenting process.
- To provide a more comprehensive assessment, a team approach is better suited.
- Current study comparing psychosocial evaluations (psychologist) vs. outcome team recommendations.
"...And seven years ago I donated one of my kidneys to him. I want it back."
Thank You!
Questions? Comments?