Informed consent for living organ donation

Timothy Pruett, MD
Charles O. Strickler Transplant Center, University of Virginia
Informed consent-therapy

- Obtained thousands of times every day in US hospitals.
- Legal definition of content required for “adequate” informed consent varies by state. Physicians have to love Virginia.
- The premise has been adopted is that the person being treated should be told in an understandable manner the possible benefit of proposed therapy, risks involved with the therapy and alternatives that are available. The individual can refuse the offered therapy and it will be respected.
Living donation Informed Consent: no therapeutic benefit to the donor

- Analogous to deriving consent to do clinical research; except there is an expected, predictable benefit to the a person needing the organ.
- Traditional practice has stressed altruistic donor motives.
- Although the practice of living donation of organs has expanded to include individuals unrelated to the recipient, little information has been generated to assess the needs for informed consent.
Informed consent-research

• WWII Nazi prisoner research, “Doctor’s trial” that led to the Nuremberg Code, 1947
  – 20/23 defendants accused of murder and torture in the conduct of medical experiments on concentration camp inmates.
  – Statesville (Illinois) Penitentiary experiments in which prisoners were given malaria used in the defense of the Nazi physicians.
• “Principles of Ethics concerning Experimentation with Human Beings” AMA 1946. 1. Consent must be obtained…in the absence of coercion. Subjects …informed of hazards.
• “The voluntary consent of the human subject is absolutely essential.” The first point of the Nuremberg Code.
• Tuskegee syphilis experiment (1932-1972, USPHS) embarrassment. We don’t always modify behavior to meet existing principles.
Doctor-patient relationship: therapeutic vs. research

- Therapy: Hippocratic oath is about treatment: the physician vows to act in the interest of the patient, or at least no harm the individual.
- Research: physician’s primary goal is test a hypothesis about a disease or therapeutic process. It is a separate goal from therapeutic intent.
  - Nuremburg Code combines the Hippocratic values (best interest of the subject, 2-8 and 10) with proclamation that subjects can actively protect themselves (principles 1 and 9).
- Organ donation is different, but incorporates elements from both therapy and research.
When a perfectly healthy person dies, it is a tragedy

Mt. Sinai experience, Jan 2002. Brother of a liver recipient died after a right hepatectomy.
What standard that should be applied for informed consent of the living organ/liver donor?

• ACOT in response to the death of the living donor in NY. We live in an era of heightened awareness.
immunodeficiency virus and other infectious diseases if the disease cannot be detected in an infected donor; and (8) the right to refuse transplantation.

OPOs make every effort to obtain a social/behavioral history for each potential donor from the next-of-kin or other knowledgeable individual. If a potential donor has engaged in a behavior that would have put him or her at high risk of contracting an infectious disease, such as HIV or hepatitis (for example, injecting illegal drugs), donation generally is ruled out, unless the risk to the recipient of not performing a transplant is greater than the risk of contracting an infectious disease. In such case, informed consent regarding the possibility of transmission of infectious disease must be obtained from the transplant recipient.

In 2002, there was a case in Oregon in which hepatitis C was transmitted to transplant recipients that received organs from an individual who tested “negative” for hepatitis C at the time of donation. After further investigation, it was determined that the recipients became infected with hepatitis C.

the Secretary’s request. ACOT has agreed upon a set of “Ethical Principles of Consent to Being a Live Organ Donor.” The principles state that the person who gives consent to becoming a live organ donor must be:

- Competent (possessing decision making capacity),
- Willing to donate,
- Free from coercion,
- Medically and psychosocially 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.

ACOT also endorsed two other ethical principles:

- Equipoise; that is, the benefits to both the donor and the recipient must outweigh the risks associated with the donation and transplantation of the live donor organ; and
- A clear statement that the potential donor’s participation must be completely voluntary, and may be withdrawn at any time.

ACOT further recommends that the

- The fact that the potential donor’s participation is voluntary, and may be withdrawn at any time,
- The fact that the potential donor may derive a medical benefit by having a previously undetected health problem diagnosed as a result of the evaluation process,
- The fact that the potential donor undertakes risk and derives no medical benefit from the operative procedure of donation,
- The fact that unforeseen future risks or medical uncertainties may not be identifiable at the time of donation,
- The fact that the potential donor may be reimbursed for the personal expenses of travel, housing, and lost wages related to donation,
- The prohibition against the donor otherwise receiving any valuable consideration (including monetary or material gain) for agreeing to be a donor,
- The fact that the donor’s existing health and disability insurance may not cover the potential long-term costs and medical and psychological consequences of donation,
Adult-to-adult living liver transplant consortium (A2ALL): Informed consent

- Meet the legal standards of informed consent of the various states. ACOT guidelines.
- Meet the physician-patient standard of trust.
  - What type of information is best suited to address the needs of a potential donor and does the person understand and process the information that is given?
  - Will the information given to the potential donor during the informed consent process affect the acceptance of postoperative events?
Questions raised—what does the potential organ donor need to hear in order to make an informed decision?

• What is the goal of informed consent?
  – Allow for a “good” decision, based on relevant information. Requires an understanding by the requestor of the donor motivations and disclosure of events that, once disclosed may affect the decision (pro or con) to donate.
  – Minimize negative perception of donation process and psychological acceptance of untoward complications, when they occur.
Donors’ Motives & Decisions to Donate

1. The range of observed motives

Typical typology of motives

\(N = 343\) unrelated bone marrow donors

Switzer, Dew, Butterworth et al., 1997
Kidney Donors’ Motives & Decisions to Donate

• Immediate/minimal deliberation: 62%
• Period of deliberation/conscious choice: 25%
• Postponement (musical chair analogy): 5%
• Unreliable/not enough information to code motives 8%

Simmons et al., 1987
## Donors’ Motives & Decisions to Donate

Among biological or emotionally related potential donors, who volunteers to donate?

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<tr>
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<th>205 families facing kidney txp</th>
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<tr>
<td></td>
<td>Donors</td>
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<td>Greater emotional closeness</td>
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<td>Greater perceived costs of donation</td>
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<td>Greater perceived benefits of donation</td>
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<td>Greater willingness to donate</td>
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<td>Greater obligation to donate</td>
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<td>Perceived decision to cause conflict</td>
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<td>with immediate family</td>
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<td>Opposition from spouse</td>
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(Simmons et al., 1987)
The Consequences of Donation

Perceived health shortly post-donation

SF-36 physical health subscales 1-4 mos. post-donation

N=48 kidney (Smith et al.), 472 marrow, 285 PBSC (Switzer, Dew et al.)
The Consequences of Donation

2. Psychological costs vs. benefits to the donor

Costs: Prevalence of psychiatric disorder during first year post-donation
The Consequences of Donation

Psychological Costs: Prevalence shortly post-donation

- Felt depressed
- Health worries
- Unhappy about donation
- Given up part of me for nothing in return
- Would not donate again
- Relationship with recipient more difficult
- Financial hardship

- Kidney, n=167 (Schover)
- Kidney, n=118 (Simmons)
- Kidney, n=536 (Smith)
- Bone Marrow, n=472 (Switzer)
- PBSC, n=285 (Switzer)
- Liver, n=26 (Sterneck)
The Consequences of Donation

Examples of improvements in self-esteem and happiness from pre- to 1-year post-donation

*Simmons et al., 1987*

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<tr>
<th>Change in self-esteem</th>
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<th>Change in happiness</th>
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<tr>
<td>Improved (53%)</td>
<td>Improved (44%)</td>
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<tr>
<td>Worse (26%)</td>
<td>Worse (24%)</td>
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<tr>
<td>No change (21%)</td>
<td>No change (32%)</td>
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The Consequences of Donation

Example of the role of ambivalence

Pre-donation ambivalence → Physical difficulty with donation → Negative feelings shortly post-donation → Negative feelings 1 year post-donation

251 bone marrow donors; Switzer, Simmons & Dew, 1996
A2ALL Approach

- A consent form incorporating the ACOT guidelines was made into an audiovisual presentation and distributed to the centers.
- Information presentation is linked with quality of life assessments (at a variety of time points) and motivation assessment.
- To assess ability of the potential donor to make an informed consent with the provided material, the MacArthur Competency Assessment Tool for clinical research (MCAT-CR) is used to assess the capacity the potential donor’s capacity for informed consent.
Disclosure/discussion of things that can happen after living organ donation

• Pain to some degree will be experienced in all cases.
• Death (always discussed and reported to be 1/500) occurs very infrequently
• The things in between can go on and on
  – All adverse events that have been reported to occur with a frequency of >1:100.
  – The really serious adverse outcomes occur with a much lower frequency were also mentioned (risk of HIV and HCV through transfusion), but some/many were omitted. Admittedly, a bit capricious.
6½ pages, single spaced

- Document designed to meet the needs of the “deliberative” potential organ donor (and conform to ACOT guidelines). We don’t know what the “intuitive” donor needs to hear in order to make an informed decision to donate.

- Does not come close to comprehensive disclosure of possible adverse outcomes.

- The document is too long as it exists to be significantly retained.
The donor advocate

- Part of the ACOT recommendation is that the potential donor will be assigned someone not associated with the transplant team to be their advocate. Definition of qualifications and function of the donor advocate is not clear.
  - UVa: Contracted with Family Practice (MD, psych and social work) to perform our donor evals. Practice in other centers is variable, social worker or physician with variable relationship with the txp program. Until we get more information, this good idea is just a good idea.
Concerns

• The psychological outcomes for the unrelated donor will mirror those of the “deliberative” donor (increased rate of negative outcomes).
  – What rate of negative outcomes becomes unacceptable?
• The highly emotional donor (parent) will not make a “competent” decision to donate.
• The information that is given during the informed consent process is irrelevant to the ultimate satisfaction/acceptance of the individual for living organ donor.