Optimal Testing of the Live Donor to Prevent Transmission of Infectious Diseases: Consent Issues

Work Group

Emily Blumberg, MD	Transplant ID	University of Pennsylvania
Lee Bolton, MSN, ACNP	Live Donor Committee Liaison	OPTN/UNOS
Clint Burns, RN	Transplant Recipient	Johns Hopkins
Carrie Commellas, RN, CPTC, CCTC	Transplant Senior Specialist	Stony Brook University Medical Center
Matthew Cooper, MD	Transplant Surgery	University of Maryland
Benjamin Hippen, MD	Transplant Nephrology	Carolinas Medical Center
Amy Kordek, RN	Transplant Donor	Johns Hopkins
Raelene Skerda, RPh, BPharm	HRSA representative	HRSA, US Public Health Service

Background

- Consent integral part of the live donation process with an emphasis on donor safety
  - Described in multiple documents from ACOT, UNOS, NATCO, International sources (TTS, UK, Australia)
  - Donor rights including donor advocate, separation of evaluation and donation consents, risks (including of new discoveries in addition to procedural and other health risks), treatment options for recipients, freedom of choice (absence of coercion)
  - Recipient rights include treatment options
  - Do not speak specifically about identifying risks for transmission of diseases to recipient

Goal of Work Group

- To develop a guideline for consenting donors and recipients with regard to transmissible disease risks in keeping with current CMS and OPTN/UNOS requirements

Methodology

- Literature review
  - No significant data to incorporate
- Regulations
  - CMS
  - OPTN/UNOS
  - Guidelines from other countries, societies

Basic Principles of Consent: 1

- Purpose: Information/Education of risks and benefits to allow for informed decision making
  - Education of both donor and recipient with all options explained
  - Demonstrate comprehension of risks both to evaluation and procedure
- Donor: Risks of evaluation and of donation – short and long term, physical and psychological, understanding of recipient treatment options and impact on recipient of donor choices
  - Must have independent donor advocate
- Recipient: Therapeutic options including transplant
  - Risks and benefits including disease transmission

Basic Principles of Consent: 2

All consent must

- Conform to OPTN/UNOS and CMS regulations
- Be administered by appropriately knowledgeable staff
- Be documented with documentation available to all involved centers
- Given free of coercion
- Recipient and donor consent processes must be kept separate

Goal is to suggest a model for best practice considering the potential for altruistic donors, paired exchange, donor chains

Survey Results: When is Risk Assessed?

Timing	Percent of responders*
Initial Evaluation	32.8%
Initial Eval + 2 Wks Prior to Donation	23.9%
Initial Eval + 1 Wk Prior to Donation	35.8%
Initial Eval + 2 Wks Prior to Donation for High Risk	3%
Initial Eval + 1 Wk Prior to Donation for High Risk	4.5%

* Answers based on 67 responses; 88 skipped question

Donor Consent: A Multi-Step Process

- Step 1: Consent for evaluation
  - Review the evaluation process, including explanation of nature of the information that will be collected as well as specifics about testing both for the donor and the recipient
  - Information will be kept confidential, unless permission provided
  - Potential implications of information provided and test results will be discussed
    - Includes public health authority notification, insurance issues, inadvertent disclosure
    - Issues of false positive and negative tests will be reviewed
  - Donors will be asked to share detailed risk information with person obtaining consent; failure to do so may constitute contraindication to proceeding with transplant
    - Personnel obtaining consent must be knowledgeable regarding risk and comfortable discussing this topic
  - Donors will be asked about willingness to share information with recipient
  - Donors may opt out at any time ("medical excuse")

Donor Consent: Step 2 – A Time Out

- Prior to obtaining surgical/anesthesia consent, another formal discussion should be had with the donor who is eligible based on the evaluation process
  - Discussion of individual risk behaviors tailored to donor but with sufficient general information to serve as a reminder
  - Clearly counseled about risk avoidance
  - Reminder of testing to be repeated and implications of testing
  - Reminder of impact of behaviors on disease transmission
  - Reminder that recipient may be informed of general risk behavior issues
  - Opportunity to opt out with medical excuse

Donor Consent: Final Consent

- Consent for surgical procedure and risks associated
- To occur no earlier than 2 weeks prior to donation
- Review of responsibilities of donation, risk behaviors, information disclosure
- Opportunity to opt out with medical excuse

Recipient Consent

- Multi-stage process
- Should include balancing all treatment options with risks and benefits
- Should include notification that donor is undergoing extensive evaluation but that not all potential donor transmissible conditions will be knowable/anticipatable

Recipient Consent for Evaluation

- Should include education (by knowledgeable personnel) about behavioral risk for infectious diseases and testing that will occur for these diseases, including specific tests with limitations of testing (false positives, negatives)
  - Notification that identification of certain conditions may further affect their insurability as well as require notification of public health authorities

Recipient Consent for Transplantation

- In addition to surgical/anesthesia/general transplant risks, discussion of disease transmission
  - Include estimation of risks with common vs uncommon, acceptable vs unacceptable, tailored by donor information
    - Risk calculations in comprehensible terms
    - Understanding of risk as ***continuum*** of risk– not absolute
  - Reminder of donor evaluation and limitations of donor evaluation

What Recipient is Entitled to Know About the Donor

- General information that may affect their decision making *similar* to that available on deceased donors
- Cannot disclose specifics as per HIPAA regulations

Ultimate Goals: 3

- Attempts to standardize consent process across centers will be key for improving the safety of donor chains/paired exchanges
  - Minimum standard for consent which may be refined by individual centers
  - Development of skeleton documents that include updated risk assessments for "live donor" to allow for uniformity among centers
    - Of note, risk may vary with geography, which may require consideration in chains
- Center obligations will be defined and limited
  - All centers will be responsible for guaranteeing accuracy of shared information
  - Decision to pursue work up for newly found donor conditions at the discretion of the center