Achieving Consensus on Increased Risk Donors to Improve Access to Organ Transplantation

Group Consensus Recommendations

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Work Group 1: Definitions

- Survey Monkey to come soon

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Work Group 2: Live Donor

- Perform testing consistently for all donors
  - Screen all live donors for risk behavior for HIV, HBV, and HCV as defined by this conference (to be determined)
  - Screening pre-transplant (any time point): HIV, HBV, and HCV serology
  - Testing within XX days prior to surgery: HIV NAT, HCV NAT, HBsAg
    - Vote for recommending for testing 29 For, 10 Against (reasons to vote against: not worth it, risk/benefit – loss of donors/pairs; heightened fear)
    - Votes on XX days (First round with 3 options in ())
      - (30 Days: For 7)
      - 14 Days: For 18 (Without 30 days option = 18)
      - Within 30 days but preferably within 14 days For 13 (Without 30 days option = 21)

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Psychosocial Issues

- Provide all donors education on how to avoid contracting HIV, HBV, and HCV at any point
- Place in context of total risk (not to add to text)
Work Group 3: Consent

- Live donors should consent for disclosure of their relevant medical and social information to recipients
  - 5 individuals voted no against this recommendation
- Risk is a continuum – donor issues should be placed within the full context of risk
- Recipient consent process should be the same for deceased and live donors
- Consent should be obtained by knowledgeable, trained personnel
- Consent should be comprehensible to recipient, utilizing format and language appropriate to recipient
- Encourage involvement of recipient social support (family, significant other, etc) in the consent process

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Work Group 3: Consent

- At least 2 discrete times for education
  - Prior to listing and at time of offer
  - Reinforcement of education throughout the waiting period
- Risk described in comprehensible terms (same as before)
- Explain post transplant testing
- Protect patient (donor and recipient) confidentiality
- Documentation of process
- There is a need for an educational tool for training professionals delivering consent discussions with talking points

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• Diagnostic tests should be used
• Nucleic acid tests (NAT) are preferred for HIV and HCV (HBsAg adequate for HBV)
• Recommended testing paradigm would include testing of recipients of organs from “donors at increased risk for transmission of infection”
  o Pre-transplantation (baseline) and
  o 1 and 3 months after transplantation
  o HBV testing at a later time point (between 6 and 12 months)
• All data on these tests should be collected centrally
Knowledge Gaps

- **Pilot Study**: all potential living donors for one year from all or some centers; how many are positive by antibody and/or NAT testing, pick different time periods of testing and comparing results to donor screening to assess relative yield of screening
- Assessment of cost of implementation of testing all living donors
- Study potential factors related to false positive results
- Study the number and impact of false positive tests on number of transplants, recipient transmissions, wait listing time and on potential donor psychological, medical and financial outcome (cost and other sequellae including turn downs).
- Consider the feasibility of using FDA approved NAT testing for off label use as donor screening
- Prospective study of transmission of infection with organ transplantation
Knowledge Gaps

- The impact of informed consent process on transplantation especially with regard to use of “increased risk” donors has not been studied in depth
- No standardized tools to assess comprehension of consent process
- How best to tailor contents (depth) and level of detail of consent from the patients point of view (tailored, patient-centered consent)
- Patient preferences regarding risk taking in transplantation relative to waiting are poorly understood
- This field would benefit tremendously from a decision analysis which quantitatively weighs the magnitude of harm associated with window period infection against the magnitude of unused organs
  - What happens if donor identified as increased risk? Will this vary by type of organ? Will it vary by which risk factor led to this identification?
- Need data specifically addressing the strength of risk for unsuspected window period infection for many of potential Risks to inform net value of including them
Knowledge Gaps

- Can we identify more precisely the “times” associated with proposed risks to enhance their specificity to identify window period infections?
- Incidence studies of people in various putative risk groups, particularly those where high-quality incidence studies do not currently exist.
- Expanded national data collection on the specific risk factors underlying "CDC high risk" designation.
- Studies of patient attitudes, concerns, and priorities regarding infectious risk and the specific categories used to define higher infectious risk.
- Improvements in efficiency, accuracy, and availability of nucleic acid testing.
- Better quantification of false-positive rates of nucleic acid tests.
- National consensus and homogeneity among OPO's regarding nucleic acid testing methods.
- Comparative Risk analysis: between risk of infection and risks of turning down an organ or donor withdrawing (i.e. no transplant)