Work Group 3: Consent
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Basic Assumptions

• Requirements (CMS and OPTN)
  – Transplant candidates should be informed of donor risk factors that may affect recipient health and allograft function
    • Documents outline general areas to be covered – not specific in guidance

• Although this conference is focused on disease transmission, the concept of consent for transplant risk is much broader than just disease transmission from “increased risk donors”
  – Transplant related risks, including those related to donors, are much more complex
    • Transmission risks – infection (not just HIV, HBV, HCV), malignancy
    • Other donor risk issues – ECD, DCD
    • Risks of procedure and medications
    • Risks of not being transplanted

• Focusing on deceased donor but will make some comments about live donor

• Informed consent process in each institution will reflect institutional individual needs
  – Any recommendations and policies should be flexible enough to allow for institutional variation
General Concerns about Informed Consent

• Evidence is very limited in this area
• Risk can never be totally predicted
  – Unknown, unpredictable for many events
  – Even with known entities (e.g., CMV), risk is not always quantifiable
  – Individual circumstances may alter risk
    • Prophylaxis, compliance, individual variation all may play a role
General Concerns, Continued....

- Incomplete information at the time of consent discussion with candidate
  - Donor histories not necessarily complete/accurate
    - May be better with live donors but even those may be incomplete due to donor comprehension or willingness to share
  - Objective data have limitations
    - Physical exam
    - Laboratory tests

- Patient comprehension variable
  - Different consent procedures may help but still may have issues with patient understanding
Basic Principles for Consent

• Process of consent for deceased and live donation should be similar
  – Should include alternates to transplantation (both with/without “increased risk organs)
  – Risk benefit discussion

• Informed consent discussions should be conducted during more than 1 session
  – Reinforcement throughout the pre-transplant process
    • First discussion should be prior to registration on the wait list
    • Second discussion at time of offer
  – Personnel obtaining consent should be knowledgeable
  – Discussions should be comprehensible at diverse levels of understanding
  – Patients should include others in their discussion
Basic Principles, Continued

• Documentation of informed consent required by CMS and OPTN
  – Content of consent not stipulated
  – CMS and OPTN can audit documentation and process (even interviewing patients)
Elements of Consent

• Definition of “increased risk” as part of a continuum of risk
• Issues of testing limitations for estimating transmission risks should be noted !!
  – Available tests for pathogens and use in organ donation
  – Timing of tests with window periods
  – False positive and false negative test potential
  – Identifying at risk populations does not necessarily equate to transmission risk
    • Additionally experience of blood and tissue donation may not be the same as organ donation
• Risk discussion should include risk of choosing to pass on organ
Conveying Information

• Address comprehension level of candidate
• Convey risk statistics in comprehensible terms
  – Use same denominators or understandable scenarios (every day comparisons)
  – Use alternate aids as appropriate to the level of comprehension/education of the candidate
• Avoid the term “high risk” as misleading
First Discussion

• Should occur prior to registration on list
• Should include
  – Concept that all transplantation carries risk and not being transplanted also carries risk
  – General donor risk behaviors associated with specific blood borne pathogens should be included in discussion
    • Term “increased risk” should be explained
    • Specific donor information will be shared at time of offer
  – Notification that when organ becomes available there will be another more specific discussion
• Encourage presence of family member/friend/advocate during discussion
• Documentation of consent discussion/process
Discussion at the Time of Organ Offer

- Candidate should be encouraged to remember the initial discussion of risk to place it in context
- Disclosure of relevant specific information that defines the risk as well as other donor specific characteristics that may affect outcome (e.g., donor age, etc)
  - Protection of donor identity as per NOTA
- Discussion of testing with its limitations
- Follow up testing plan for recipient to evaluate for disease transmission
- Documentation as per OPTN policy 4.2
Live Donor Issues

• No data to define live donor transmission issues
  – Anecdotal reports
• Live donors must be notified prior to obtaining health history that:
  – Their own risk behaviors may be conveyed to recipient
    • Need to address concerns related to prior relationship of donor and recipient
  – Medical excuse to opt out if this is not acceptable
• Donors should be educated in risk behavior avoidance
• Recipient consent should be analogous to deceased donation
Gaps

• The impact of informed consent process on transplantation especially with regard to use of “increased risk” donors has not been studied in depth
• Unknown
  – Whether using this designation as a separate category improves patient understanding
  – Increases donor utilization
  – Improves recipient outcomes
• No standardized tools to assess comprehension of this
• Unclear if recipients want this information
• Patient preferences regarding risk taking in transplantation relative to waiting are poorly understood
• Unknown if providing specific details for consent form (“skeleton consent”) would be useful
• Unclear whether 1994 PHS exclusionary criteria apply 2012