Informed Consent & Donor Authorization: Lessons Learned

American Association of Tissue Banks
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- Impact of Donor Registries on donation
- Donor Authorization vs. NOK Consent – lessons learned
- Challenges in the consent/authorization process
- Update on Case Western Reserve University (CWRU) Consent Project
Donor Registries

- 40 Statewide Donor Registries
  - 32 1st person Consent Registries
- 1st Person Consent Allowed
  - 37 States
- Applicable to Tissue and Organ
  - 35 States
- Applicable to Research and Tissue
  - 20 States

Source: AOPO February 2006
LOOP Data

2006 through 9/7/06
Donor Alliance Data

- **2005** –
  - 23.2/23.7% registered referrals (CO/WY)
  - 21% family uncooperative (Colorado)
  - 26% family uncooperative (Wyoming)

- **2006**
  - 24.6/23.7% registered referrals (CO/WY)
  - 27% family uncooperative (Colorado)
  - 38% family uncooperative (Wyoming)
Registered Donors

- GLDP
  - 2005: 35% YES 65% NO
  - 42% are registered in PA, 52% in DE
  - no significant difference from 2003 - 2005

- Gift of Hope
  - New Registry (January 2006)
  - 5% organ and tissue donors were registered
NOK Consent vs. Donor Authorization
Lessons Learned

- NOK Consent Form and Donor Authorization Form should look VERY different
- Be prepared to PROVE to a family that their loved one is a registered donor (e.g., fax to the hospital)
- Introduce the topic of end of life decisions/discussions BEFORE notifying the family of the donor registration
Lessons Learned

- Families may decline to participate in the Med/Soc History Interview – public education opportunity
- TRAINING is key, especially with language used to describe registration status
Sample Conversation

Introduction

- My name is Martha Anderson. I’m a Family Services Coordinator with the Give Life Foundation. We work with St. Mary’s Hospital. I received a call from them about your son Larry’s death. I’m very sorry for your loss.
Reason for the Call

- The reason for my call is to let you know that we have checked the Illinois Organ and Tissue Donor Registry, and verified that Larry had joined the registry.
- This means that Larry had expressed his desire to be a donor.
- Do you have any reason to believe that he had changed his mind about being an organ and tissue donor?
What is Needed

- In order for Larry’s wishes to be carried out, I need to ask you information about Larry’s medical and social history to help ensure that his donated tissues can be transplanted safely and that Larry’s desire to give this gift can be fulfilled.
Challenges

- Consent given by family despite previous REFUSAL of gift by deceased
- Non-profit requests with no option for non-profit processing (e.g., overage donors, skin)
- International Distribution exclusions
  - Requires separate inventory locations, donor chart identification, interdepartmental communication
- Special requests
  - Clothing, funeral plans
- Positive Serology Notification
Case Study
Unrevoked Refusal

- 78 y.o. male

- Power of Attorney for Health Care Decisions signed in 1995
  - NO Organ Eye or Tissue Donation
  - Constitutes a REFUSAL under the state Anatomic Gift Act

- Donor record: “Wife and sons knew in their heart he had changed his mind”
Legal conclusions

- The decedent made an unrevoked refusal. Our legal interpretation of this could change if the wife signs an affidavit stating that her husband verbally amended his POA in the presence of two individuals.

- Cannot accept the gift without an affidavit because:
  - Wife was not entitled to make the gift, knowing of the refusal.
  - Tissue bank cannot be donee, knowing of the prior refusal.
Then,

- Contradictory information from tissue recovery agency
- Wife had been told by husband he had changed his mind
- Improper documentation by tissue coordinator re: “I know in my heart”
- Affidavit still requested
Case Study
Special Request for Burial

- Authorization for donation including upper extremities given by family
- Request for short sleeved shirt made later in conversation
- Documented on consent form (but not in the list of tissues)
- Radius & Ulna recovered
- UNHAPPY Family
- Consent Form being changed
Notification of Donor Rejection

- Consent Form – do you want to be informed?
- Initial Notification by Donor Family Coordinator (certified mail)
- Medical Records Release Form signed by NOK/personal representative
- Letter sent by Medical Director (certified mail)
- Follow-up coordinated by Donor Family Coordinator
Consent Protocol Study: CWRU

- Evaluation of Consent/Authorization Forms & Policies
- Common Practices
- Non-profit, International, Cosmetic
- Language comparison
- Participation: 44 OPOs
  - 15 Eye Banks
  - 9 Tissue Banks
Conclusions

- Donor Authorization and 1st Person Consent is increasingly common
- Registered donors will increase over time, and hopefully will result in more donors
- Requires additional training, new systems, forms and protocols
- Challenges abound regardless of NOK Consent or DA
- Please participate in the CWRU study!