Donor designation: How does informed consent fit in?

Experiences from LifeNet’s OPO
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Discussion Points

• The conflict between settings for consent
  – Hospital-based (traditional, clinical)
  – Community-based (non-traditional, public)
• Pillars of “informed consent”
• Do registries meet the tests?
• Challenges from an OPO perspective
• Considerations as a tissue processor
Disclaimers

• I am not a lawyer
• You do not need to remember your high school Latin (quid pro quo, etc.)
• All legal material is referenced / researched
• Consult your legal counsel for practice change / review of state law and/or quasi-governmental agency code
Stewards of a Public Trust?

- “Stewardship entails honoring the wishes of the donor, which I take to include the very desire to donate, perhaps even more than the end-point of allocation.”

- “There is no moral merit to encouraging people to ‘Share Your Life, Share Your Decision’ and then to not honor that decision.”

- “When one has made a decision, there is no justification for pursuing even the pretense of an approval or the possibility of an override from the next-of-kin.”

Setting for Consent

• Hospital
  – Clinical in nature
  – Goals for informed consent handed down through “clinical” culture
  – As OPOs formed, leadership inherited same concepts & transferred to the OPO structure
  – How is an OPO like an ICU?

• Community
  – Non-clinical
  – Public domain
  – Goals are new news to OPOs but clearly legislated since UAGA, and old news to the public
  – OPO leadership (not health care providers) are resisting transition to the new “community” culture
Three Conditions of Informed Consent

An effective informed consent is traditionally said to depend upon three essential conditions:

1) The decision-maker must possess appropriate capacity or competence to make the choice at hand.

2) Information must be provided about the choice or subject being considered.

3) The consent should be given voluntarily, without coercion or duress.
How Does This Connect?

Individual signing up or registering as a donor has met the existing standards for “informed consent”:

• Information has been provided about donation (brochures, mailings, access to information on the web, etc)

• Decision-making meets reasonable person standard

• Context is coercion free and totally voluntary, especially if opt-in system only
State Legal Consistencies

• Donor document signifying donor designation provides sufficient legal authority for proceeding with donation

• Designation is irrevocable

• Protection from civil liability is provided
Some Challenges

• Quality of donation information and education provided:
  • Can older adults comprehend?
    – Aging society
  • Can underserved populations comprehend?
    – Diverse population
    – Cultural expectations / fears

• Review your information….
  • Was it written by OPO staff for OPO staff to understand?
  • Who is actually going to read *and understand* the material?
Donor Designation in Virginia

• Legislative revision included specific language
• Rights of individual paramount
• Defines anatomical gift
• Includes research and education

Approximately 50% of tissue donors are found on donor registry!
Practical Considerations

Donation decision made by NOK, on behalf of the decedent:

- Requesting authorization
- Must disclose elements of informed consent
- Witnessed or recorded line for authorization discussion, or signature required
- Separate request for education research or medical therapy

Donation decision by decedent:

- Disclosing decedent’s wish to donate
- Must attempt to disclose elements of informed consent
- Donor document serves as document of gift- no need for signature or witness
- Transplantation included with research, education & medical therapy
Authorization for donation by the NOK
• Decision made by NOK
• Specific requests for education research and medical therapy

Disclosure form for donor designation
• Decision made by decedent
• Uses for tissue include education, research & medical therapy

Regardless of who authorizes donation, the process supports the model elements of “informed consent.”
Organ vs. Tissue

- Life-saving
- Organ utilization possible without med/soc history
- Larger opportunity to dialogue with family/decision maker
- National public awareness regarding organ shortage

- Life enhancing
- Tissue utilization NOT possible without med/soc history
- Telephone approach: limited dialogue with decision maker
- Lack of public information of need for allografts
Circumstances to Consider…

What if:

- The NOK knows of the decedent’s desire to donate and refuses to cooperate?
- The NOK supports the donor’s designation but does not want to know the details of donation?
- The decedent is listed in another state’s donor registry?
- The family members do not all agree to honor the designation?
Established Protocols with Recovery Partners

Due diligence when establishing a new contract:

• Industry knowledge of the principles in the recovery organization
• Review organization’s mission and vision
• Complete Recovery Agency Pre-selection Questionnaire
• Require proof of registration with the FDA and/or state and local agencies
• Review findings and corrective actions from AATB, FDA or state board
Due Diligence

• Conduct on-site audit
• Review of all pertinent forms, including consent, medical behavior risk form and recovery forms
  – Ensure all required elements of “informed consent” are included
• Adequate document control practices
  – Ensures that current form is used
• Review of SOPs
Recovery Partners

• Existing partners
  – Annual audit
  – Establishes expectations for deficient audit findings
  – Training records
  – Routine on-site training
Discussion?