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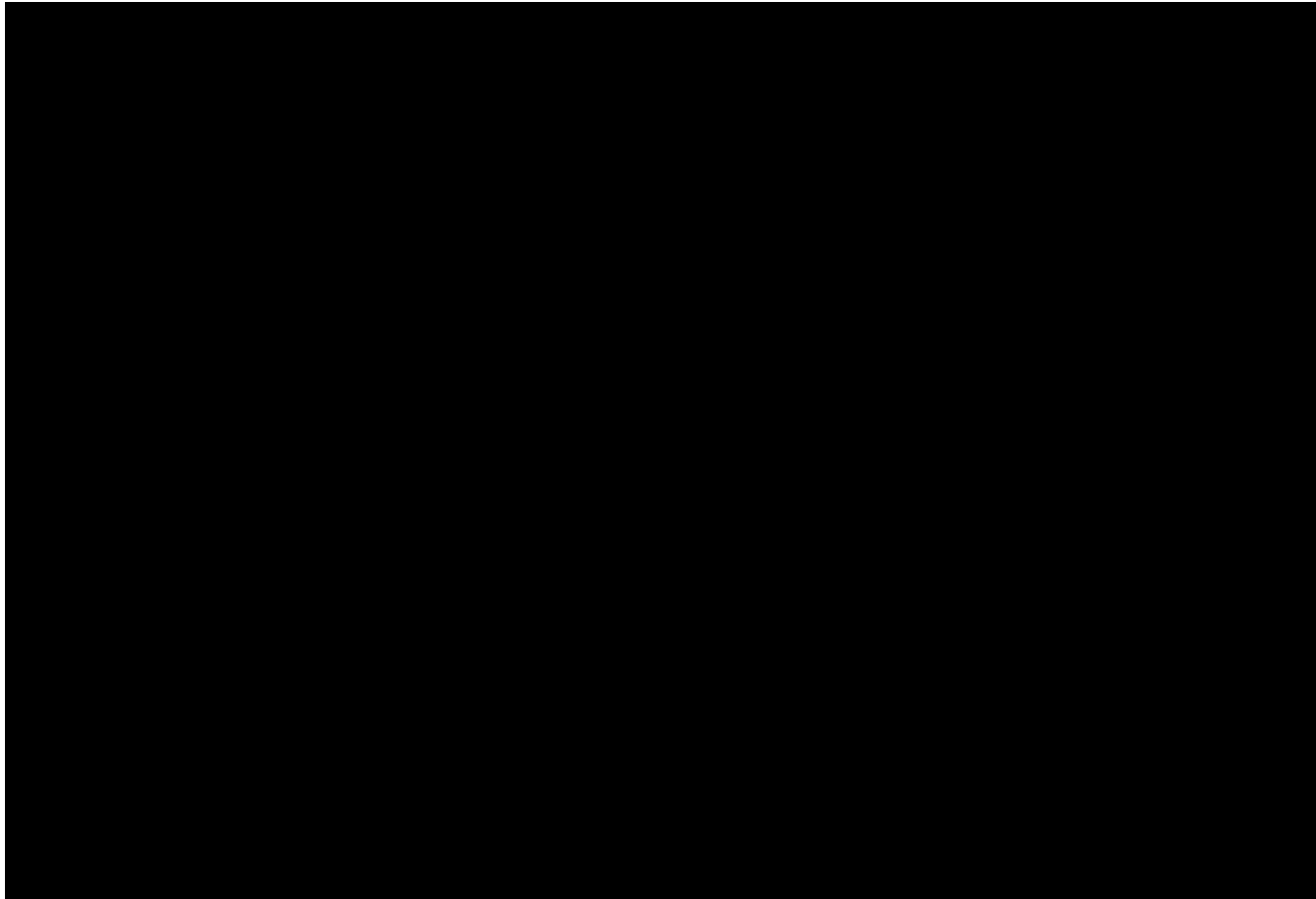
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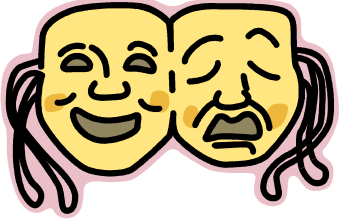
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**CLINICAL ETHICISTS AS
LIVING DONOR ADVOCATES:
CHALLENGES, CONTROVERSIES &
REFLECTIONS**

INTERVIEW VIGNETTE #1



**CONCLUSION OF ADVOCACY INTERVIEW WITH
POTENTIAL KIDNEY DONOR**



TODAY'S PROGRAM

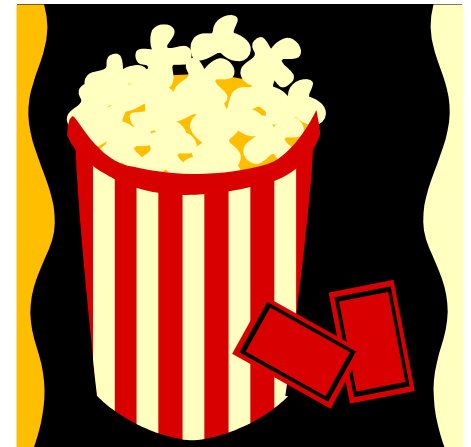
Insider's View of Living Donor Advocacy

Setting the Stage: Demand for/benefits of living donor kidney transplants

Act One: Practical considerations

Act Two: Uncertainties and controversies

Act Three: Experiences and opportunities



Warning for Program Audience

Today's program has a "G" rating however viewers may find themselves leaving with as many questions* as answers.

**(Ethicists like to refer to this as "food for thought")*

Comprehensive Requirements for Approval & Re-approval of Organ Transplant Centers

- Department of Health & Human Services and Centers for Medicare & Medicaid
- Vol 72, No 60 Federal Register—March 30, 2007
- **Independent advocates or advocacy teams for living organ donors**



Goal of Living Donor Advocacy

“Ensure the protection of the rights of living donors and prospective living donors.”



“I’m afraid the shark got your arms and legs. It’s probably not a good time, but your brother’s here. He needs a kidney.”

Advocacy Qualifications and Process

- No specification of required credentials.



- No specifics regarding advocacy process.

Advocate Qualifications

- Knowledge of living organ donation, transplantation, medical ethics and informed consent
- Understanding of potential impact of family and other external pressures on the prospective donor's decision and ability to discuss these issues with the donor

Responsibilities of the Donor Advocate or Advocacy Team per Federal Register

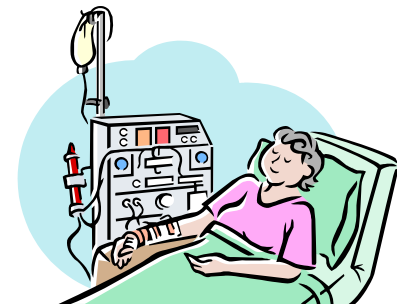
- Representing and advising the donor
- Protecting and promoting the interests of the donor
- Respecting the donor's decision and ensuring that the donor's decision is informed and free from coercion.

Why Are Potential Living Donors In Need of Protection?

- Contrary to almost everything they stand for, health care providers intentionally inflict medical harm with no prospect of medical benefit to the patient being harmed.
- Pressure to procure more organs
- Vulnerabilities of select individuals/populations to bribes, threats, family/societal pressures or abuses

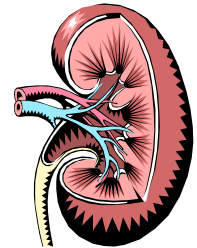
HARSH REALITY

- End stage kidney disease affects nearly half a million people in the US
- Of those that start dialysis, only 20% will be considered healthy enough to be listed for a transplant
- Of those listed, just over 50% will receive a kidney transplant
- The need for organs for transplant increases each year
- The wait lengthens



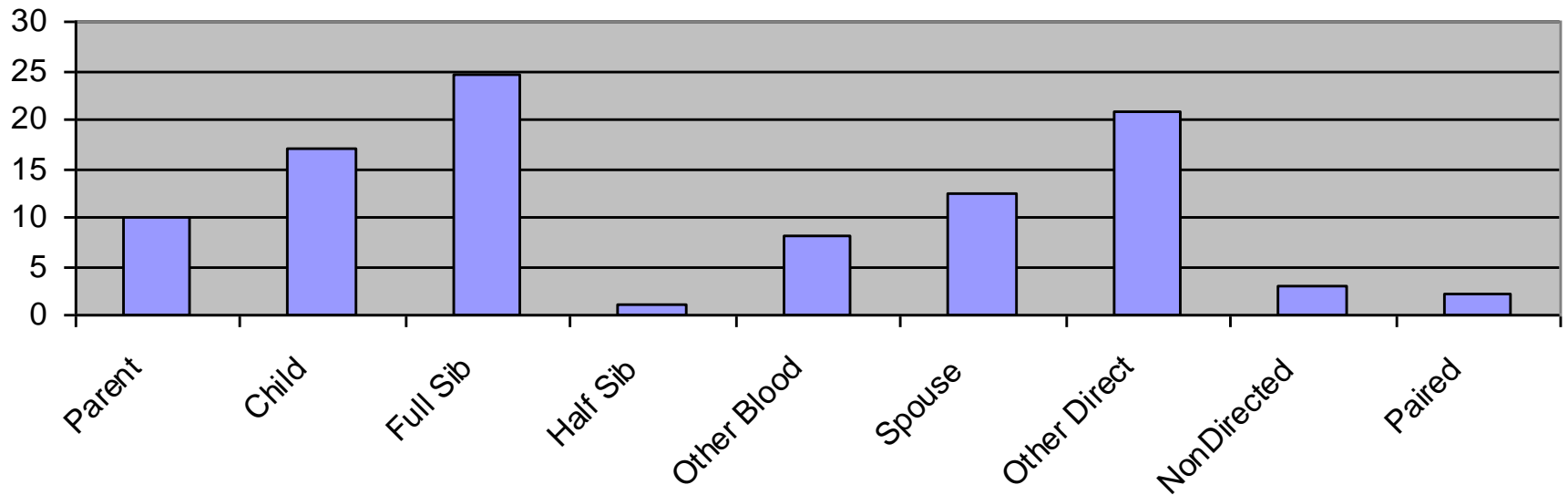
ADVANTAGES OF RECEIVING A LIVING DONOR KIDNEY

- Avoids or shortens time on dialysis
 - Physiologic/tissue consequences
 - Lifestyle restrictions
 - Family or support stress
- Provides a inherently healthier organ
 - Virtually no cold ischemic time
 - Immediate function
 - Lessened incidence of acute rejection
 - Allows for more clinically compromised potential recipients to be transplanted – age, health status
- Associated with increased short and long term patient and graft survival



WHO ARE THE LIVING DONORS?

Living Donor by Donor Type - 2007 - Percent



TRANSPLANT CENTER PHILOSOPHY



- To prevent any conflict of interest, the evaluation of the donor should be performed by a different team from that taking care of the donor
- Must take into account that the donor is often under tremendous familial, community and/or personal coercion to proceed with the donor operation
- **“Nothing can go wrong with the donor”**

TRANSPLANT CENTER'S EXPECTATIONS FOR THE RELATIONSHIP

- Donor advocates require a strong commitment to their role in the transplant process
- **The program allows the advocate the full freedom to speak on the donor's behalf**
- There is a professional relationship between the members of the transplant program and the donor advocacy team which exemplifies mutual understanding, confidence and trust

THE EDUCATION PROCESS FOR ADVOCATES

Meeting with transplant team

**Review of educational materials
provided to donors**

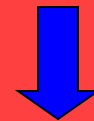
**Review of literature & some of the more
popular internet materials/web sites**

WHAT IS OUR CHARGE?

**Assuring Informed and
Voluntary Consent**

**Providing Potential Donor
With a Way Out**

**Should there be
an advocacy role
post donation?**





"...And seven years ago I donated one of my kidneys to him. I want it back."

IF CONCERNS ARISE

What is our role?

What can we disclose to the transplant team?

**Do we need specific consent to disclose
to the transplant team?**

**What should appear in the potential
donor's medical record?**

PRACTICAL AND LOGISTICAL ASPECTS

“Dissociating” ourselves from the Transplant Center
When to see the donor
Multiple meetings?
Phone meetings?

HOW DID WE STRUCTURE THE SERVICE?

Decided on the following:

- Quickie meeting following first education session (prior to most of medical workup) to introduce the concept of advocacy and provide contact information**
- Semi-structured interview following completion of all education and most of the workup
- Three advocates---each on-call one month at a time—3-6 interviews per month average
- Extensive notes kept on internal file
- Simple form for transplant institute indicating concerns or no concerns
- IRB approved post survey via telephone to assess perceptions about entire process and in particular to examine advocacy needs/avenues for QI

DESIGNING THE INTERVIEW

- Goals:
 - Verify informed consent
 - Note unacceptable coercion
 - Provide assistance with deliberation
 - Watch for other “red flags”
- What needs to be documented?
 - ***Is this interview totally confidential?***
- Challenge: redundancy, burden to donor

INTERVIEW



- Semi-structured; aim to be conversational
- 3 different interviewers, variable styles
- Interview donor alone
- Done after full course of education (group and surgeon)

Our General Experience with Interviews

- Most donors are very polite, cooperative, but don't express need for advocate
- All donors have made their decision prior to interview, no one acknowledged questioning it**
- Seems like they would do this no matter what the consequences
- Wide range of “informed consent”
- No “rejections,” but recommended 1 receive more education (*Does this reflect good screening and educational efforts on part of Transplant Institute or are we failing to pick up concerning circumstances?*)

The following slides document:

SAMPLING OF PRELIMINARY FINDINGS
FROM LIMITED NUMBER OF INTERVIEWS
EARLY IN THE HISTORY OF THE
ADVOCACY TEAM





DEMOGRAPHICS (N=29)



- 59% female, 41% male
- Age range: 24-58**
 - 20s 20%
 - 30s 28%
 - 40s 36%
 - 50s 16%
- Ethnicity: 65% Cauc, 28% AA, 7% Hisp.

RELATIONSHIP TO RECIPIENT



- 31% Sibling
- 27% Child
- 17% Cousin, nephew, other relative
- 3% Mother
- 7% Known, but unrelated

MOTIVATION

- Saw need, suffering (9)
- Poor quality of life with dialysis (8)
- Closeness with recipient (3)
- Duty, “it’s what you do” (3)
- Recipient has young child (3)
- Donor doesn’t have children (3)
- Inevitability, intuition (3)

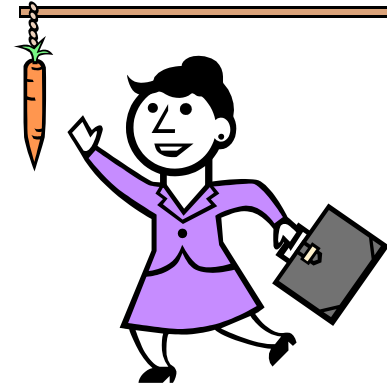
MOTIVATION

- No one else, others eliminated (2)
- God's will, Christian thing to do (2)
- Impact recipient's behavior (2)
- Existential, purpose in life
- Making up for past wrongs
- Encourage others to donate
- Male should donate, "take care of things"
- None stated (spouse/child, expected?) (3)

MOTIVATION

- *“This shows how much you love your brother”* (Mom to donor)
- *“I don’t want the girls (sisters) to be the donor...I want to be the one to take care of things”*
- *“Of course I am going to do this. She’s my auntie...I’d do it for anybody. I’d do it for you if you asked me! It’s like if you saw me on the street and asked me for a quarter—this ain’t so different.”*

DOES MOTIVATION MATTER?



- Wide range, complex issue
- Must donor “prove” has “right” motivation?
- Are there unacceptable motivations?
- Some merit further probing
- Dropped question about “receiving anything in return”

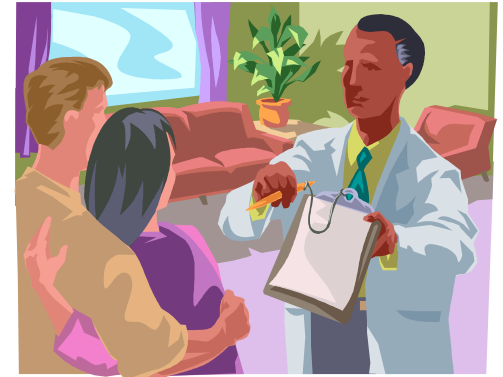
WHO INITIATED?

- 60% donor's idea
- 12% family decided together
- 4% recipient asked
- 4% MD suggested (?)

Does it matter?

VERIFYING INFORMED CONSENT

- Elements of informed consent
 - Competent individual
 - Informed adequately
 - Condition and prognosis
 - Treatment and alternatives, with risks/benefits of each
 - Rational (reasoned) choice, consistent with values, goals
 - Voluntary
- ***Should standard be higher for organ donation?***
- Are we simply verifying, or trying to encourage deeper consideration, and personalization?



WHAT CONSTITUTES “INFORMED CONSENT” FOR DONORS?

- *Understand medical condition of recipient, prognosis, options for treatment? In how much detail?*
 - Most of donors knew basics of recipient’s disease
 - Most knew other options were available
 - Some had little or no detail about recipient’s condition and did not wish to have that information

INFORMED CONSENT

- *Understand surgical procedure, risks (immediate and long term) to self?*
 - Most donors knew basics about procedure
 - 45% could name only 1-3 risks, but 48% named 5+
- *Psychological Risks?*
- *We decided our role was to remind them of major risks and encourage to speculate how they/loved ones would handle*

INFORMED CONSENT

- *Should donor be able to express understanding of the likelihood of complications?*
 - *Guidelines say donors should be informed of national statistics, and transplant center's statistics*
 - *But does it matter?*
 - “I would donate even if there were a 95% chance that it would fail”
 - “I would do it even if it took 30 years off my life”

INFORMED CONSENT

- *Post surgical course, restrictions*
 - All donors could recite what restrictions they would experience, and for how long
- *Long term risks*
 - 2 donors concerned about lack of data
- *Risk to future eligibility for insurance*
 - 26% had some knowledge
 - Only 1 person expressed concern

INFORMED CONSENT

- *Risk of complications/ risk for recipient?*
 - *Does donor need to know statistics?*
 - We didn't review this
 - Did query what their reaction would be if kidney failed or was quickly rejected; no one seemed vulnerable to dangerous reaction
 - ***“at least I know I did all I could” (14)***
 - ***“out of my control” “can't do anything about it” (7)***
 - ***1 said she'd be angry***
 - ***1 said “I'd be disappointed, maybe enough to ask myself ‘why did I do this?’”***
 - ***3 said “I don't/can't think about that”***
 - Should we be focusing more on coping?

LOOKING FOR COERCION

- What constitutes coercion?
 - *“It’s family...it’s what you do”*
 - *“I am the one who doesn’t have kids, so I was the logical one to donate”*
 - *“No one else was a match”*
- Internal v. external pressure
 - *Is there a different societal expectation (or internal expectation) of mothers than of fathers or of others?*



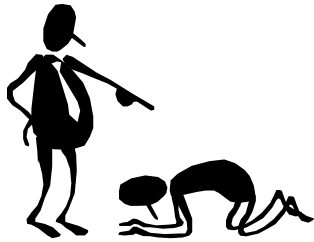
Lauren's Experiment

- Discussed opposition to living kidney donation with family and indicated that if beloved niece needed a kidney Lauren would not get tested or if tested and found to be a match, would not donate.
- Strong family reactions of disbelief and then anger.
- Two years later, they rehash this scenario with friends at dinner party and the reactions a pretty universally the same.
- Now a family joke---okay, I'll do "X" for you but only if you'll give me a kidney.

LOOKING FOR COERCION



- *Who have you talked to about donating?*
 - Almost all donors talked to MANY family members, friends, even employers
 - 2 specified that they did NOT talk to recipient
 - One exception wouldn't tell anyone, planned to give fictitious story about his absence
- *How does your family feel about you donating?*
 - 70% “totally supportive”; rest mixed
- **Should probably ask more about how influential family/friends are**



LOOKING FOR COERCION

- *Where have you been getting information?*
 - 48% searching internet
 - 41% have talked to other donors
 - 2 consulted own MD
- *Is balance of information the issue?*
 - Our own center's literature: is it biased?
 - Several mentioned positive bias of internet
 - Is it important to talk to “non-missionaries?”
- *Again, if decision is already made, does it matter?*

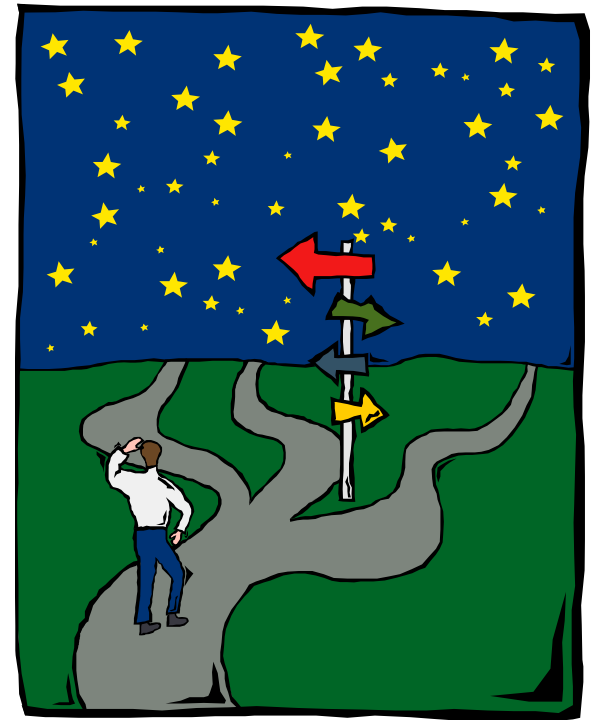
PROVIDING ASSISTANCE WITH DELIBERATION PROVIDING EXIT STRATEGY

- Only one donor has requested assistance with exit strategy but has since reconsidered. Should we advocate against using him as a donor?
- One donor reported need for “neutral” person earlier in process, when family was deciding who of siblings should be donor



LOOKING FOR DOUBT

- *Do you have any second thoughts?*
 - 92%: No!
 - ***“I didn’t have any first thoughts”***
 - ***“It’s a slam dunk”***
 - ***“It’s a no-brainer”***
 - ***“God wouldn’t have made me a perfect match if He did not want me to give my kidney to my brother”***
- ***Did we ask in right way?***



“RED FLAGS”



Unrealistic expectations?

Donor who was “mourning” her kidney?

18-year-old who “can’t wait until all my friends
find out what I am doing?”

Employee wishing to donate to boss?

FINANCIAL CONSIDERATIONS & LIFE DISRUPTIONS

- *What arrangements have you made for period of recovery?*
 - All donors had family to assist them during recovery
 - 1 was between tours in Iraq and Afghanistan
 - However, many donors were unemployed, uninsured, and financially stressed
 - *6 had no health insurance*
 - *One planned to use his tax refund to support himself during recovery*
 - *Single mother on Aid to Dependent Children*
 - *“why does the government pay for all of the recipient’s health care, and we are dropped after the donation?”*
- *What is the Advocate’s role (beyond asking)?*

INTRODUCING ADVANCE DIRECTIVES



Purpose

Response

Reporting to Transplant Team



- Simple form: *Approved, or Concerns*
- Only 1 “concern”
 - Major misunderstandings (*“they take out my kidney, and if they can’t put it in her, they’ll put it back in me”*)
 - Had been educated 1 year prior, but transplant delayed
 - Recommended careful re-education with “talk back”

QUESTIONS

- Should we be asking different questions?
- Should we meet earlier, more often with donor?
- Should we be interviewing all potentials?
- Should we be doing more for donor?
- Are there post surgery donor advocacy actions we should consider?

How Informed Is Informed?

- How much does one have to dwell on risks?
- What if the potential donor (PD) doesn't want to focus on risks?
- If PD can list potential risks but can't personalize the information, is he informed?



- How much rational thinking must be evidenced in the face of strong altruistic and/or religious motivation?
- Should there be a higher standard for informed consent in a situation where the health care team is causing medical harm to an individual for no medical benefit to that person?

HOW VOLUNTARY IS VOLUNTARY?

- Is there such a thing as “voluntary” for a parent when it comes to donating to his or her child?
- Some say a greater degree of risk is tolerable when immediate family is involved but others suggest there is also more pressure to donate. Is either distinction valid? What implications does either have for advocates?
- How can we effectively assess pressures to donate and at what point is this best undertaken?



THE DONOR'S INTERESTS



- Are we talking about the donor's well-being or his objectives?
- When objectives seem to put well-being in jeopardy, where does the advocate's duty lie?
- What about potential donor's confidentiality interests?

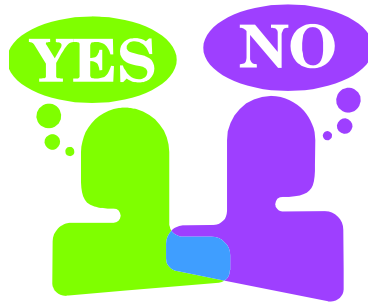


Advocate's Allegiance



Primary duty is to the potential donor. There is also a duty to the recipient and the Transplant Center. How do we determine when those duties override the duty to the PD?

WHEN SHOULD WE SAY “NO”?



Once advocates share concerns/recommendations with the Transplant Center, do they have rights/obligations beyond that?

Should advocates ask for/are they entitled to information regarding the Center’s response?

If advocates and the Transplant Center fundamentally disagree as to a potential donor’s level of informed and voluntary decision making, what recourse should there be?