Research in Deceased Organ Donors: Ethical and Practical Challenges

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Fields
Recipient consent, no donor consent

Ischemic Preconditioning in Deceased Donor Liver Transplantation: A Prospective Randomized Clinical Trial of Safety and Efficacy

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No recipient or donor consent
Donor consent, no recipient consent

Effects of Donor Pretreatment With Dopamine on Graft Function After Kidney Transplantation
A Randomized Controlled Trial

Context: Kidney graft function after transplantation can be improved through pharmacological donor pretreatment to limit organ injury from cold preservation.

A Randomized Trial of the Effects of Nebulized Albuterol on Pulmonary Edema in Brain-Dead Organ Donors

American Journal of Transplantation 2014; 14: 621–628

Therapeutic Hypothermia in Deceased Organ Donors and Kidney-Graft Function


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Some framing points about donors

“Who would want to bequeath a jalopy when they could instead bequeath a Porsche?”

Halpern SD, Truog RD. Crit Care Med 2010

Dying ends your coverage under the Common Rule, but not necessarily your personhood
Why obtain donor consent

1. Accommodate pluralistic views of personhood

2. Alignment with respect commonly accorded to deceased over what becomes of their body/estate

3. Evidence that people value the procedural fairness of surrogate consent in states of incapacity
How to obtain donor consent

1. In rare cases in which donor specified preference for research, honor it.

2. Otherwise, separate surrogate consent from donation authorization.

3. General consent to research or study-specific.
Some framing points about recipients

1. Transplantation invariably carries donor-derived risks

2. Helping recipients is what drives the increasing use of donors harboring non-standard risk (and benefit!) profiles

3. Because organs are *scarce public goods*, rather than *plentiful private goods*, individuals have no innate right to choose among them exclusively for their own benefit (positive vs. negative liberty)

Are recipients “human research subjects?”

“those in whom investigators obtain identifiable private information or data through an interaction”

(46 CFR 45)

THE EFFECTS OF LEUKOREDUCTED BLOOD TRANSFUSION ON INFECTION RISK FOLLOWING INJURY: A RANDOMIZED CONTROLLED TRIAL

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Are recipients “human research subjects?”

- Studies that collect data on recipient outcomes (e.g., delayed graft function) vs. only data upstream to recipients (e.g., # of organs utilized)

- A distinction without a (normative) difference
Some notes about bystander organs

1. In vivo interventions:
   - bystander effects *always* possible
   - differences of degree not kind
   - drugs that optimize some organs at expense of others routinely used without regulation (e.g., lasix)

2. Ex vivo interventions: bystander effects rarely if ever possible
What’s the “right” rate of risk to recipients from donor research?

‘Behind a veil of ignorance’ no rational, informed recipient could possibly want risks from donor research to be 0%

(think: unnecessary appendectomies, hospital readmission rates, re-intubation rates, etc.)
3 options

1. Organ-specific consent at time of organ offer

2. General consent at time of listing

3. Waiver from requirement for informed consent
Organ-specific consent at time of offer

1. Time pressure is the hobgoblin of speaking our minds

2. Creates false trust that all risks are well defined

3. Sometimes impracticable, always inefficient (and unfair)

Consent to non-standard organs at listing

1. Shared decision making about goals at time of listing

2. Patients make a choice to accept or reject “non-standard” organs (could be subdivided into a few broad risk categories)

3. Patients declare whether decision would change if clinical status deteriorated and they lost decisional capacity

4. Patients encouraged to revisit decision frequently, but not required to do so

5. Transplant physicians retain discretion to use judgment on offers

Waiver of consent

1. In many cases, minimal risk (e.g., interventions that donors may receive with or without the research)

2. In many other cases, recipients could not reasonably opt out, so no point to consent (i.e., would not preclude transplant eligibility)

3. When not minimal risk, and reasonable to opt out, include donor-research organs (including bystander) in prospective recipient consent

4. Notify afterwards that research was conducted on their organs, and recipient outcomes will be collected as part of that research
Summary suggestions

1. Require donor (surrogate) consent

2. Consider recipients to be human research subjects

3. Generally, waive requirement for recipient consent

4. In certain circumstances, allow potential recipients to opt out from organs (including bystander) from experimented-upon donors