“Traditional” Organ Transplant

- Deceased donation
- Living donation
- Many ethical issues
  - largely driven by lack of other good therapies, and scarcity
  - definitions of death
  - donation decision
  - allocation of scarce resources
Deceased Donation

- Deceased donation
  - “Dead donor rule”
    - death by brain criteria
      - irreversible cessation of brain function
    - donation after cardiac death
      - lack of spontaneous circulatory function after withdrawal of support
  - Donation and transplant of organ must be separate
    - Clear donation decision by donor
      - Role of family
  - Extremely scarce
    - allocated by public process (UNOS)
Living Donation

- Living donation
  - Rule of informed consent
    - understanding of risks and benefits
    - voluntary, unpressured donation
  - Splitting apart of risk and benefit
    - risk to donor, benefit to recipient
  - “Allocation” by donor
    - individual resource
    - still usually to family or emotionally connected recipient but changing . . .
    - increasing discussion about paying for organs as a way to relieve existing shortage
Xenotransplantation

- Solves shortages, in theory
- Allocation issues will focus on affordability
- Consent issues will focus on typical clinical trials issues
- Public health
- Public perception
- Risk
- Use of animals
Informed Consent

- Informed consent in research
  - difficult to do well
    - overpromising of benefit/underestimating risk
      - esp. difficult in novel therapies with limited understanding of risk in humans; are there risks to others?
    - consent forms often difficult to understand
      - reading level, technical language, overwhelming detail
  - standard commitments regarding withdrawal from studies may be difficult to carry out

- Informed consent for therapy
  - also difficult, but at least incentives are parallel
  - accepting risk to others?
Public Health

- **Risks**
  - infection?
  - what level of uncertainty is acceptable?

- **Potential benefits**
  - reducing the burden of disease

- **Costs**
  - of illness
  - of treating illness
Public Perception

- Do we need to use animals for organs in humans?

- Animal parts in human bodies

- Risk of infection

- However, xenogeneic transplantation carries risks, in particular of transmission of known or yet unrecognized xenogeneic infectious agents from animals to human beings and from recipients of xenogeneic transplants to their contacts and the public at large.
Looking Forward

- Stages of acceptance of new medical technologies
  - Ex: organ transplant
  - “yuck factor”
    - rejection as ‘against nature’
  - amazement
  - slow acceptance
  - societal embrace
  - struggle to provide sufficient supply and access